

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

**FORM 10-Q**

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the quarterly period ended March 31, 2019

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: 001-38470

**Unity Biotechnology, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**3280 Bayshore Blvd. Suite 100**  
**Brisbane, CA**

(Address of principal executive offices)

**26-4726035**  
(I.R.S. Employer  
Identification No.)

**94005**  
(Zip Code)

**Registrant's telephone number, including area code: (650) 416-1192**

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

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

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

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

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001	UBX	The Nasdaq Global Select Market

As of May 1, 2019, the registrant had 42,907,149 shares of common stock outstanding.

**UNITY BIOTECHNOLOGY, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
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**PART I. FINANCIAL INFORMATION**

**Item 1. Condensed Financial Statements**

**Unity Biotechnology, Inc.**  
**Condensed Balance Sheets**  
(In thousands, except share and per share amounts)

	<u>March 31, 2019</u>	<u>December 31, 2018</u>
	<u>(Unaudited)</u>	
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 34,249	\$ 15,399
Short-term marketable securities	115,949	155,736
Prepaid expenses and other current assets	1,642	1,830
<b>Total current assets</b>	<b>151,840</b>	<b>172,965</b>
Property and equipment, net	5,880	6,238
Restricted cash	1,446	550
Other long-term assets	1,631	1,622
<b>Total assets</b>	<b>\$ 160,797</b>	<b>\$ 181,375</b>
<b>Liabilities, convertible preferred stock, and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 4,071	\$ 4,847
Accrued compensation	1,674	3,791
Accrued and other current liabilities	4,920	4,990
Settlement liability	—	2,059
Contingent consideration liability	446	895
<b>Total current liabilities</b>	<b>11,111</b>	<b>16,582</b>
Deferred rent, net of current portion	2,265	2,467
Contingent consideration liability, net of current portion	792	1,588
Other non-current liabilities	26	45
<b>Total liabilities</b>	<b>14,194</b>	<b>20,682</b>
<b>Commitments and contingencies (Note 6)</b>		
Convertible preferred stock, \$0.0001 par value; 10,000,000 shares authorized as of March 31, 2019 and December 31, 2018; no shares issued and outstanding as of March 31, 2019 and December 31, 2018	—	—
<b>Stockholders' equity:</b>		
Common stock, \$0.0001 par value; 300,000,000 shares authorized as of March 31, 2019 and December 31, 2018; 42,888,359 and 42,414,294 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	4	4
Additional paid-in capital	329,226	324,663
Related party promissory notes for purchase of common stock	(201)	(201)
Employee promissory notes for purchase of common stock	(400)	(400)
Accumulated other comprehensive loss	19	(95)
Accumulated deficit	(182,045)	(163,278)
<b>Total stockholders' equity</b>	<b>146,603</b>	<b>160,693</b>
<b>Total liabilities, convertible preferred stock, and stockholders' equity</b>	<b>\$ 160,797</b>	<b>\$ 181,375</b>

See accompanying notes to the condensed financial statements.

**Unity Biotechnology, Inc.**  
**Condensed Statements of Operations and Comprehensive Loss**  
(In thousands, except share and per share amounts)  
(Unaudited)

	Three Months Ended March 31,	
	2019	2018
Operating expenses:		
Research and development	\$ 16,505	\$ 13,025
General and administrative	4,477	3,457
Change in fair value of contingent consideration	(1,245)	—
Total operating expenses	<u>19,737</u>	<u>16,482</u>
Loss from operations	(19,737)	(16,482)
Interest income (expense), net	1,006	352
Other expense, net	(36)	(3)
Net loss	<u>(18,767)</u>	<u>(16,133)</u>
Other comprehensive loss		
Unrealized gain (loss) on marketable securities, net of tax	114	(34)
Comprehensive loss	<u>\$ (18,653)</u>	<u>\$ (16,167)</u>
Net loss per share, basic and diluted	<u>\$ (0.44)</u>	<u>\$ (4.69)</u>
Weighted-average number of shares used in computing net loss per share, basic and diluted	<u>42,190,457</u>	<u>3,437,345</u>

See accompanying notes to the condensed financial statements.

**Unity Biotechnology, Inc.**  
**Statements of Stockholders' Equity**  
(In thousands, except share and per share amounts)  
(Unaudited)

**For the Three Months Ended March 31, 2019**

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Related Party Promissory Notes for Purchase of Common Stock	Employee Promissory Notes for Purchase of Common Stock	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount						
<b>Balances at December 31, 2018</b>	—	\$ —	42,414,294	\$ 4	\$ 324,663	\$ (201)	\$ (400)	\$ (95)	\$ (163,278)	\$ 160,693
Issuance of common stock upon exercise of stock options	—	—	340,731	—	300	—	—	—	—	300
Vesting of early exercised stock options	—	—	—	—	207	—	—	—	—	207
Stock-based compensation	—	—	—	—	1,997	—	—	—	—	1,997
Common stock issued to third parties	—	—	133,334	—	2,059	—	—	—	—	2,059
Unrealized gain on available-for-sale marketable securities, net of tax	—	—	—	—	—	—	—	114	—	114
Net loss	—	—	—	—	—	—	—	—	(18,767)	(18,767)
<b>Balances at March 31, 2019</b>	—	\$ —	<u>42,888,359</u>	<u>4</u>	<u>329,226</u>	<u>(201)</u>	<u>(400)</u>	<u>19</u>	<u>(182,045)</u>	<u>146,603</u>

**For the Three Months Ended March 31, 2018**

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Related Party Promissory Notes for Purchase of Common Stock	Employee Promissory Notes for Purchase of Common Stock	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount						
<b>Balances at December 31, 2017</b>	28,159,724	\$ 173,956	4,830,389	\$ 1	\$ 4,072	\$ (202)	\$ —	\$ (104)	\$ (86,880)	\$ (83,113)
Issuance of Series C convertible preferred stock at \$15.3317 per share for cash, net of issuance costs of \$100	3,590,573	54,950	—	—	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	400,587	—	31	—	—	—	—	31
Vesting of early exercised stock options	—	—	—	—	38	—	—	—	—	38
Stock-based compensation	—	—	—	—	1,370	—	—	—	—	1,370
Unrealized gain on available-for-sale marketable securities, net of tax	—	—	—	—	—	—	—	(34)	—	(34)
Receipt of promissory note from related party for purchase of common stock	—	—	—	—	—	(390)	—	—	—	(390)
Receipt of promissory note from employee for purchase of common stock	—	—	—	—	—	—	(400)	—	—	(400)
Net loss	—	—	—	—	—	—	—	—	(16,133)	(16,133)
<b>Balances at March 31, 2018</b>	<u>31,750,297</u>	<u>\$ 228,906</u>	<u>5,230,976</u>	<u>1</u>	<u>5,511</u>	<u>(592)</u>	<u>(400)</u>	<u>(138)</u>	<u>(103,013)</u>	<u>(98,631)</u>

See accompanying notes to the condensed financial statements.

**Unity Biotechnology, Inc.**  
**Condensed Statements of Cash Flows**  
(In thousands)  
(Unaudited)

	Three Months Ended March 31,	
	2019	2018
<b>Operating activities</b>		
Net loss	\$ (18,767)	\$ (16,133)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	637	502
Amortization of premium and discounts on marketable securities	(366)	(33)
Stock-based compensation	1,997	1,370
Accretion of tenant improvement allowance	(152)	(152)
Change in fair value of contingent consideration for license agreements	(1,245)	—
Changes in operating assets and liabilities:		
Contribution receivable	—	1,382
Prepaid expenses and other current assets	188	291
Other long-term assets	(9)	(4)
Accounts payable	(776)	1,830
Accrued compensation	(2,117)	(1,223)
Accrued liabilities and other current liabilities	65	239
Deferred rent, net of current portion	(51)	48
Net cash used in operating activities	<u>(20,596)</u>	<u>(11,883)</u>
<b>Investing activities</b>		
Purchase of marketable securities	(18,054)	(6,225)
Maturities of marketable securities	58,321	19,273
Purchase of property and equipment	(207)	(101)
Net cash provided by investing activities	<u>40,060</u>	<u>12,947</u>
<b>Financing activities</b>		
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	54,951
Proceeds from issuance of common stock upon exercise of stock options, net of repurchases	300	27
Payments of deferred offering costs	—	(569)
Payments made on capital lease obligations	(18)	(17)
Net cash provided by financing activities	<u>282</u>	<u>54,392</u>
Net increase in cash, cash equivalents and restricted cash	19,746	55,456
Cash, cash equivalents and restricted cash at beginning of the period	15,949	7,848
Cash, cash equivalents and restricted cash at end of the period	<u>\$ 35,695</u>	<u>\$ 63,304</u>
<b>Supplemental Disclosures of Non-Cash Investing and Financing Information</b>		
Issuance of common stock to settle contingent consideration liability	<u>\$ 2,059</u>	<u>\$ —</u>
Property and equipment included in accounts payable and accrued liabilities	<u>\$ 71</u>	<u>\$ 34</u>
Deferred offering costs included in accounts payable and accrued liabilities	<u>\$ —</u>	<u>\$ 1,138</u>
Receipt of promissory note from related party for purchase of common stock	<u>\$ —</u>	<u>\$ 390</u>
Receipt of promissory note from employees for purchase of common stock	<u>\$ —</u>	<u>\$ 400</u>

See accompanying notes to the condensed financial statements.

**Unity Biotechnology, Inc.**  
**Notes to Condensed Financial Statements**  
**(Unaudited)**

**1. Organization**

**Description of Business**

Unity Biotechnology, Inc. (the “Company”) is a biotechnology company engaged in the research and development of therapeutics to extend human healthspan. The Company devotes substantially all of its time and efforts to performing research and development, raising capital and recruiting personnel. The Company is located in Brisbane, California, was incorporated in the State of Delaware in 2009 and operates in one segment.

**Need for Additional Capital**

The Company has incurred operating losses and has an accumulated deficit as a result of ongoing efforts to develop drug product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. The Company had an accumulated deficit of \$182.0 million and \$163.3 million as of March 31, 2019 and December 31, 2018, respectively. The Company had net losses of \$18.8 million and \$16.1 million for the three months ended March 31, 2019 and 2018, respectively, and net cash used in operating activities of \$20.6 million and \$11.9 million for the three months ended March 31, 2019 and 2018, respectively. To date, none of the Company’s drug candidates have been approved for sale. The Company has not generated any revenue from contracts with customers and does not expect positive cash flows from operations in the foreseeable future. The Company has historically financed its operations primarily through the issuance and sale of convertible preferred stock and convertible promissory notes. The Company has evaluated and concluded there are no conditions or events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern for a period of one year following the date that these financial statements are issued. Management expects operating losses to continue for the foreseeable future. As a result, the Company will need to raise additional capital. If sufficient funds on acceptable terms are not available when needed, the Company could be required to significantly reduce its operating expenses and delay, reduce the scope of, or eliminate one or more of its development programs. Failure to manage discretionary spending or raise additional financing, as needed, may adversely impact the Company’s ability to achieve its intended business objectives.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

These financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) and the rules and regulations of United States Securities and Exchange Commission (“SEC”) for interim reporting.

The condensed financial statements are unaudited and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary for the fair presentation for interim reporting. The results of operations for any interim period are not necessarily indicative of results of operations for any future period. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted. Accordingly, the unaudited condensed financial statements should be read in conjunction with the audited financial statements and the related notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC.

**Reverse Stock Split**

On April 19, 2018, the Company’s board of directors approved an amendment to the Company’s amended and restated certificate of incorporation to effect a 1-for-2.95 reverse split (“Reverse Split”) of shares of the Company’s common and convertible preferred stock, which was effected on April 20, 2018. The par value and authorized shares of common stock and convertible preferred stock were not adjusted as a result of the Reverse Split. All of the share

and per share information included in the accompanying financial statements have been adjusted to reflect the Reverse Split. Accordingly, all share and per share information presented in the condensed financial statements herein, and notes thereto, have been retroactively adjusted to reflect the Reverse Split.

### **Initial Public Offering**

On May 7, 2018, the Company closed its initial public offering (“IPO”), of 5,000,000 shares of common stock, at an offering price to the public of \$17.00 per share. The Company received net proceeds of approximately \$75.9 million, after deducting underwriting discounts, commissions and offering related transaction costs of approximately \$9.1 million. In connection with the IPO, all of the Company’s outstanding shares of convertible preferred stock were automatically converted into 32,073,149 shares of common stock. In addition, all of our convertible preferred stock warrants were converted into warrants to purchase shares of common stock.

In connection with the completion of its IPO, on May 7, 2018, the Company’s certificate of incorporation was amended and restated to provide for 300,000,000 authorized shares of common stock with a par value of \$0.0001 per share and 10,000,000 authorized shares of preferred stock with a par value of \$0.0001 per share.

### **Use of Estimates**

The condensed financial statements have been prepared in accordance with GAAP, which requires management to make estimates and assumptions that affect the amounts and disclosures reported in the condensed financial statements and accompanying notes. The Company bases its estimates on historical experience and market-specific or other relevant assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company’s condensed balance sheets and the amount of expenses and income reported for each of the periods presented are affected by estimates and assumptions, which are used for, but are not limited to, determining the fair value of assets and liabilities, common stock valuation, contingent consideration liability and stock-based compensation. Actual results could differ from such estimates or assumptions.

### **Contingent Consideration Liability**

The Company has entered into, and may continue to enter into, license agreements to access and utilize certain technology. In each case, the Company evaluates if the license agreement results in the acquisition of an asset or a business. To date none of the Company’s license agreements have been considered an acquisition of a business. For asset acquisitions, the upfront payments to acquire such licenses, as well as any future milestone payments made before product approval, are immediately recognized as research and development expense when due, provided there is no alternative future use of the rights in other research and development projects. These license agreements also include contingent consideration in the form of additional issuances of the Company’s common stock based on the achievement of certain milestones. For asset acquisitions, the Company assesses on a continuous basis whether such contingent consideration meets the definition of a derivative and can or cannot be classified within stockholders’ equity, until such time that equity classification criteria are met or the milestones expire. The derivative related to this contingent consideration is measured at fair value as of each balance sheet date with the related change in fair value being reflected in operating expenses. Upon a reassessment event that results in the contingent consideration no longer meeting the definition of a derivative and/or meeting equity classification criteria, the final change in fair value of the instrument is recorded within operating expenses and the liability is reclassified into stockholders’ equity. As of March 31, 2019, the Company has recorded a liability related to contingent consideration as the net settlement criteria of the definition of a derivative had been met.

### **Deferred Offering Costs**

Deferred offering costs, consisting of direct incremental legal, accounting, filing and other fees incurred related to the preparation of the IPO, have been capitalized and were offset against proceeds upon completion of the offering in May 2018. As of March 31, 2018, \$1.7 million of deferred offering costs were capitalized and included in current assets on the balance sheet. There were no capitalized deferred offering costs at March 31, 2019.



## Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with original maturities of 90 days or less from the date of purchase to be cash equivalents. Cash equivalents primarily include money market funds that invest in U.S. Treasury obligations which are stated at fair value.

The Company has issued a letter of credit under a lease agreement which has been collateralized. This cash is classified as noncurrent restricted cash on the balance sheet based on the term of the underlying lease.

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

	March 31, 2019	December 31, 2018
Cash and cash equivalents	\$ 34,249	\$ 15,399
Restricted cash	1,446	550
Total cash, cash equivalents and restricted cash	<u>\$ 35,695</u>	<u>\$ 15,949</u>

## Variable Interest Entities

The Company reviews agreements it enters into with third-party entities, pursuant to which the Company may have a variable interest in the entity, in order to determine if the entity is a variable interest entity ("VIE"). If the entity is a VIE, the Company assesses whether or not it is the primary beneficiary of that entity. In determining whether the Company is the primary beneficiary of an entity, the Company applies a qualitative approach that determines whether it has both (i) the power to direct the economically significant activities of the entity and (ii) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. If the Company determines it is the primary beneficiary of a VIE, it consolidates that VIE into the Company's financial statements. The Company's determination about whether it should consolidate such VIEs is made continuously as changes to existing relationships or future transactions may result in a consolidation or deconsolidation event.

## Concentrations of Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, restricted cash and marketable securities. Substantially all of the Company's cash and cash equivalents and restricted cash is deposited in accounts with financial institutions that management believes are of high credit quality. Such deposits have and will continue to exceed federally insured limits. The Company maintains its cash with accredited financial institutions, and accordingly, such funds are subject to minimal credit risk. The Company has not experienced any losses on its cash deposits.

The Company's investment policy limits investments to certain types of securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents, restricted cash and marketable securities and issuers of marketable securities to the extent recorded on the balance sheets. As of March 31, 2019, the Company had no off-balance sheet concentrations of credit risk.

The Company depends on third-party suppliers for key raw materials used in its manufacturing processes and is subject to certain risks related to the loss of these third-party suppliers or their inability to supply the Company with adequate raw materials.

## Recently Adopted Accounting Pronouncements

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, Disclosure Update and Simplification. The Company adopted the amendments during the first quarter of fiscal year 2019, and as a result, disclosed in its statements of stockholders' equity the quarterly activity of each

caption of stockholders' equity for the three months ended March 31, 2019 and 2018. The adoption of the amendments did not have a material impact on the Company's condensed financial statements.

In January 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-01, *Financial Instruments Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*. This guidance makes amendments to the classification and measurement of financial instruments and revises the accounting related to: (1) the classification and measurement of investments in equity securities (except for investments accounted for under the equity method of accounting); and (2) the presentation of certain fair value changes for financial liabilities measured at fair value. In addition, the update also amends certain disclosure requirements associated with the fair value of financial instruments. The guidance is effective for the Company for annual periods beginning in 2019 and interim periods beginning in 2020. Early adoptions of certain amendments within the update are permitted. The Company adopted this guidance during the first quarter of fiscal year 2019. The adoption of this guidance did not have a material impact on the Company's condensed financial statements.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*. This ASU clarifies the definition of a business when evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The guidance is effective for the Company for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company adopted this ASU during the first quarter of fiscal year 2019. The adoption of this ASU did not have a significant impact on its condensed financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230: Classification of Certain Cash Receipts and Cash Payments)*. This guidance addresses specific cash flow issues with the objective of reducing the diversity in practice for the treatment of these issues. The areas identified include: debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies; distributions received from equity method investees; beneficial interests in securitization transactions; and application of the predominance principle with respect to separately identifiable cash flows. The guidance will generally be applied retrospectively and is effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company adopted this ASU during the first quarter of fiscal year 2019. The adoption of this ASU did not have a significant impact on its condensed financial statements and related disclosures.

#### **Recently Issued Accounting Pronouncements Not Yet Adopted**

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles (Topic 350): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. This new standard also requires customers to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. This standard is effective for the Company for annual reporting periods beginning after December 15, 2020, and interim periods within annual periods beginning after December 15, 2021. This new standard can be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company is currently evaluating the impact of adoption on its condensed financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*. This ASU eliminates, modifies and adds disclosure requirements for fair value measurements. The amendments in this ASU are effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the effects of this ASU on its condensed financial statements and related disclosures.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. The amendments in this ASU expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. This new guidance is effective for the Company in fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted. The Company is currently evaluating the effects of this ASU on its condensed financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses, or Topic 326, Measurement of Credit Losses on Financial Instruments* which changes the accounting for recognizing impairments of financial assets. The ASU changes the impairment model for certain financial instruments. The new model is a forward-looking expected loss model and will apply to financial assets subject to credit losses and measured at amortized cost and certain off-balance sheet credit exposures. This includes loans, held-to-maturity debt securities, loan commitments, financial guarantees and net investments in leases, as well as trade receivables. For available-for-sale debt securities with unrealized losses, credit losses will be measured in a manner similar to today, except that the losses will be recognized as allowances rather than reductions in the amortized cost of the securities. The standard will be effective for fiscal years beginning after December 15, 2019, including interim periods within such fiscal years. Early adoption is permitted. The Company is currently assessing the effect that this ASU will have on its financial position, results of operations, and disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, and related amendments which supersedes the guidance in former ASC 840, *Leases*. The new standard, as amended by subsequent ASUs on the Topic, requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases today. For the Company, this standard is effective for annual reporting periods beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2020. Early adoption is permitted. The ASU is expected to impact the Company's financial statements as the Company has certain operating lease arrangements for which the Company is the lessee. While the Company is currently evaluating the impact of the adoption of this standard on its financial statements, the Company anticipates the recognition of additional assets and corresponding liabilities on its balance sheet related to these leases. The adoption of this accounting standard update is also expected to impact the Company's condensed financial statement disclosures.

### **3. Fair Value Measurements**

The Company determines the fair value of financial and non-financial assets and liabilities based on the assumptions that market participants would use in pricing the asset or liability in an orderly transaction between market participants at the measurement date. The identification of market participant assumptions provides a basis for determining what inputs are to be used for pricing each asset or liability. A fair value hierarchy has been established which gives precedence to fair value measurements calculated using observable inputs over those using unobservable inputs. This hierarchy prioritized the inputs into three broad levels as follows:

- Level 1: Quoted prices in active markets for identical instruments

- Level 2: Other significant observable inputs (including quoted prices in active markets for similar instruments)
- Level 3: Significant unobservable inputs (including assumptions in determining the fair value of certain investments)

The carrying amounts of financial instruments such as cash and cash equivalents, restricted cash, prepaid expenses and other current assets, accounts payable, accrued compensation, accrued and other current liabilities approximate the related fair values due to the short maturities of these instruments.

The fair value of the Company's cost method investment is measured when it is deemed to be other-than-temporarily impaired.

The Company's financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements were as follows (in thousands):

	March 31, 2019			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Cash equivalents:				
Money market funds	\$ 29,239	\$ 29,239	\$ —	\$ —
Receivable from maturity of U.S. treasury security	4,000	4,000	—	—
Total cash equivalents	<u>33,239</u>	<u>33,239</u>	<u>—</u>	<u>—</u>
Short-term marketable securities:				
U.S. treasuries	17,204	—	17,204	—
U.S. and foreign commercial paper	16,616	—	16,616	—
U.S. and foreign corporate debt securities	16,408	—	16,408	—
U.S. government debt securities	65,721	—	65,721	—
Total short-term marketable securities	<u>115,949</u>	<u>—</u>	<u>115,949</u>	<u>—</u>
Total assets subject to fair value measurements on a recurring basis	<u>\$ 149,188</u>	<u>\$ 33,239</u>	<u>\$ 115,949</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Contingent consideration liability	\$ 1,238	\$ —	\$ —	\$ 1,238
Total liabilities subject to fair value measurements on a recurring basis	<u>\$ 1,238</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,238</u>

	December 31, 2018			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Cash equivalents:				
Money market funds	\$ 14,131	\$ 14,131	\$ —	\$ —
Total cash equivalents	<u>14,131</u>	<u>14,131</u>	<u>—</u>	<u>—</u>
Short-term marketable securities:				
U.S. treasuries	34,121	—	34,121	—
U.S. and foreign commercial paper	10,635	—	10,635	—
U.S. and foreign corporate debt securities	26,533	—	26,533	—
Asset-backed securities	2,748	—	2,748	—
U.S. government debt securities	81,699	—	81,699	—
Total short-term marketable securities	<u>155,736</u>	<u>—</u>	<u>155,736</u>	<u>—</u>
Total assets subject to fair value measurements on a recurring basis	<u>\$ 169,867</u>	<u>\$ 14,131</u>	<u>\$ 155,736</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Contingent consideration liability	\$ 2,483	\$ —	\$ —	\$ 2,483
Total liabilities subject to fair value measurements on a recurring basis	<u>\$ 2,483</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,483</u>

The Company estimates the fair value of its money market funds, U.S. and foreign commercial paper, U.S. and foreign corporate debt securities, asset-backed securities, U.S. treasuries and U.S. government debt securities by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs.

The fair value of the contingent consideration liability includes inputs not observable in the market and thus represents a Level 3 measurement. The Company has recorded a contingent consideration liability related to three agreements with a privately held clinical-stage biopharmaceutical company (see Note 5). As of March 31, 2019, these Commercial Agreements included contingent consideration of up to an aggregate of 533,336 additional shares of common stock to be issued in specified portions to the Licensor and an academic institution from which the Licensor had previously in-licensed the underlying technology based on achievement of certain specified preclinical and clinical development and sales milestone events. The probability of achieving the defined milestone events under the Commercial Agreements is estimated on a quarterly basis by the Company's management using a probability-weighted valuation approach model which reflects the probability and timing of future issuances of shares. Total contingent consideration may change significantly as preclinical and clinical development related to the compounds covered by the Commercial Agreements progresses and additional data is obtained, impacting the Company's assumptions regarding probabilities of and timing for successful achievement of the related milestone events. For example, significant increases in the estimated probability of achieving a milestone would result in a significantly higher fair value measurement while significant decreases in the estimated probability of achieving a milestone would result in a significantly lower fair value measurement. The potential outstanding contingent consideration value results in shares to be issued ranging from zero, if none of the milestones are achieved, to a maximum of \$4.9 million (using the Company's stock price as of March 31, 2019). As of March 31, 2019, and December 31, 2018, none of the commercial milestones had been achieved and no royalties were due from the sales of licensed products.

As of December 31, 2018, the Company determined that the net settlement criteria of the definition of a derivative had been met for 133,334 shares of common stock to the third parties. The Company issued 106,667 of these shares to the Licensor in January 2019 and the remaining 26,667 shares to the academic institution in March 2019. The settlement liability of \$2.0 million recorded at December 31, 2018 was reclassified into stockholders' equity upon the issuance of these shares. The Company recorded a contingent consideration liability of \$1.2 million at March 31, 2019 related to additional potential shares subject to the achievement of certain specified clinical development and sales milestone events under the agreements. The following table provides a reconciliation of assets and liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) (in thousands):

	<u>Amount</u>
Balance at December 31, 2018	\$ 2,483
Additions	—
Settlements	—
Change in fair value	(1,245)
Balance at March 31, 2019	<u>\$ 1,238</u>

There were no transfers between the hierarchies during the three months ended March 31, 2019 and the year ended December 31, 2018.

#### 4. Marketable Securities

Marketable securities, which are classified as available-for-sale, consisted of the following as of March 31, 2019 (in thousands):

	<u>Amortized Cost Basis</u>	<u>Unrealized Gains</u>	<u>Unrealized Losses</u>	<u>Fair Value</u>
Money market funds	\$ 29,239	\$ —	\$ —	\$ 29,239
Short-term marketable securities:				
U.S. and foreign commercial paper	\$ 16,607	\$ 10	\$ (1)	\$ 16,616
U.S. and foreign corporate debt securities	16,404	5	(1)	16,408
U.S. government debt securities	65,711	14	(4)	65,721
U.S. treasuries	17,208	1	(5)	17,204
Total short-term marketable securities	<u>115,930</u>	<u>30</u>	<u>(11)</u>	<u>115,949</u>
Total marketable securities	<u>\$ 145,169</u>	<u>\$ 30</u>	<u>\$ (11)</u>	<u>\$ 145,188</u>

Marketable securities, which are classified as available-for-sale, consisted of the following as of December 31, 2018 (in thousands):

	<u>Amortized Cost Basis</u>	<u>Unrealized Gains</u>	<u>Unrealized Losses</u>	<u>Fair Value</u>
Money market funds	\$ 14,131	\$ —	\$ —	\$ 14,131
Short-term marketable securities:				
U.S. and foreign commercial paper	10,638	—	(3)	10,635
U.S. and foreign corporate debt securities	26,552	2	(21)	26,533
Asset-backed securities	2,750	—	(2)	2,748
U.S. government debt securities	81,755	1	(57)	81,699
U.S. treasuries	34,136	1	(16)	34,121
Total short-term marketable securities	<u>155,831</u>	<u>4</u>	<u>(99)</u>	<u>155,736</u>
Total marketable securities	<u>\$ 169,962</u>	<u>\$ 4</u>	<u>\$ (99)</u>	<u>\$ 169,867</u>

There have been no significant realized gains or losses on available-for-sale securities for the periods presented. Available-for-sale debt securities that were in a continuous loss position but were not deemed to be other than temporarily impaired were immaterial at both March 31, 2019 and December 31, 2018.

## 5. License Agreements

### *License and Compound Library and Option Agreement*

The Company is a party to three agreements with a privately held clinical-stage biopharmaceutical company (the “Licensor”): (a) a compound library and option agreement executed in February 2016 granting the Company the right to identify and take licenses to research, develop, and seek and obtain marketing approval for library compounds for the treatment of indications outside of oncology, (b) an initial license agreement executed in February 2016 granting the Company rights to an initial licensed compound, and (c) a second license agreement executed in January 2019 granting the Company rights to a second licensed compound (collectively, the “Commercial Agreements”). As of March 31, 2019, as part of these agreements, the Company has issued 640,002 shares of common stock to the Licensor and 160,000 shares of common stock to an academic institution from whom the Licensor had previously licensed the technology.

The Commercial Agreements referenced above include cash payments of up to \$70.3 million as well as the equity payments of up to an aggregate 533,336 additional shares of common stock, in each case to be issued based on the Company’s achievement of certain preclinical and clinical development and sales milestone events. The milestones include the advancement of additional compounds into investigational drug application, or IND, enabling studies, the filing of an IND, the commencement of clinical studies, Food and Drug Administration and/or European Medicines Agency approval, and a net sales threshold. The license agreement also includes tiered royalties in the low-single digits based on sales of licensed products.

In December 2018, the Company elected to advance a second compound into formal preclinical development which gave rise to an obligation under the compound library and option agreement to issue an additional 133,334 shares of common stock to the Licensor and the academic institution. These shares were issued to the Licensor in January 2019 and the academic institution in March 2019. In connection with the additional shares of common stock that the Company may be obligated to issue under the Commercial Agreements upon achievement of the specified milestones events, the Company recorded a contingent consideration liability of \$1.2 million at March 31, 2019 and \$2.5 million at December 31, 2018. To date, no royalties were due from the sales of licensed products.

The Company agreed to provide funding to the Licensor for research and development work performed at a cost of up to \$2.0 million through February 2020. The research and development expense under the research services agreement was not material for the three months ended March 31, 2019 and March 31, 2018.

Under the consolidation guidance, the Company determined that the Licensor is a VIE. The Company does not have the power to direct the activities that most significantly affect the economic performance of this entity and as such the Company is not the primary beneficiary and consolidation is not required. As of March 31, 2019 and December 31, 2018, the Company has not provided financial, or other, support to the Licensor that was not contractually required.

### *Other License Agreements with Research Institutions*

The Company has entered into license agreements with various research institutions which have provided the Company with rights to patents, and in certain cases, research “know-how” and proprietary research tools to research, develop and commercialize drug candidates. In addition to upfront consideration paid to these various research institutions in either cash or shares of the Company’s common stock, the Company may be obligated to pay milestone payments in cash or the issuance of the Company’s common stock upon achievement of certain specified clinical development and/or sales events. The contingent consideration liability considered to be a derivative associated with the potential issuance of common stock related to these license agreements was not significant at March 31, 2019 or December 31, 2018. To date, none of these events has occurred and no contingent consideration, milestone or royalty payments have been recognized.

## 6. Commitments and Contingencies

### Operating Leases

In February 2019, the Company entered into a lease agreement for new office and laboratory space in South San Francisco, California. The term of the lease agreement is expected to commence in May 2019. The lease has an initial term of ten years from the commencement date, and the Company has an option to extend the initial term for an additional eight years at the then market rental rates as determined pursuant to the lease agreement. The total base rent payment escalates annually based on a fixed percentage beginning from the 13th month of the lease agreement. The Company will also be responsible for the operating expenses and tax expenses allocated to the building, and the operating expenses and tax expenses attributable to the common areas. Pursuant to the lease agreement, the landlord will provide the Company with a tenant improvement allowance of up to \$7.8 million. The Company also has the ability to have the landlord finance up to \$2.8 million for additional tenant improvements subject to repayment provisions as described in the lease agreement. In connection with the execution of the lease agreement, the Company delivered a letter of credit of approximately \$0.9 million to the landlord.

The Company has a non-cancelable operating lease consisting of administrative and research and development office space for its current Brisbane, California headquarters that expires in October 2022.

Future minimum lease payments under the Company's non-cancellable operating leases at March 31, 2019 were as follows (in thousands):

	Amount
2019	1,517
2020	5,373
2021	6,230
2022	5,859
2023 and later	33,658
Total future minimum lease payments	<u>\$ 52,637</u>

Rent expense for the three months ended March 31, 2019 and 2018 was \$0.4 million and \$0.5 million, respectively.

### Indemnifications

The Company indemnifies each of its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with the Company's amended and restated certificate of incorporation and bylaws. The term of the indemnification period lasts as long as an officer or director may be subject to any proceeding arising out of acts or omissions of such officer or director in such capacity.

The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance allows the transfer of risk associated with the Company's exposure and may enable the Company to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations for any period presented.

## 7. Related-Party Transactions

### Recourse Notes

In December 2015, April 2016, and July 2016, the Company issued three full-recourse promissory notes to two executive officers for an aggregate principal amount of \$0.2 million with an interest rate of 2.5% per annum. All of the principal was used to early exercise options for 667,253 shares of the Company's common stock, in aggregate.



All of these related party full-recourse notes were repaid on April 4, 2018 in accordance with the terms of such notes.

In October 2017, the Company issued two promissory notes to an executive officer for \$1.6 million and \$0.5 million, each with an interest rate of 1.85% per annum. The aggregate principal amount of \$2.1 million was used to purchase 625,084 shares of restricted stock. The promissory notes were considered to be non-recourse in substance and accordingly, the shares sold subject to such promissory notes are considered to be an option for accounting purposes. In April 2018, the Company's board of directors approved the forgiveness of all outstanding principal and accrued interest of the \$1.6 million non-recourse promissory note. The non-recourse promissory note outstanding of \$0.5 million was repaid on April 4, 2018 in accordance with the terms of the note. The forgiveness of the promissory note was accounted for as a modification of a share-based payment and \$1.5 million of stock-based compensation from the modification was recorded in 2018.

In January 2018, the Company issued full-recourse promissory notes to an executive and an executive officer of the Company for an aggregate principal amount of \$0.4 million with an interest rate of 2.5% per annum. All of the principal was used to early exercise options for 114,406 shares of the Company's common stock. The full recourse note of \$0.2 million for the executive officer was repaid on April 4, 2018 in accordance with the terms of the note.

## Financing Activities

During the three months ended March 31, 2018, the Company issued convertible preferred stock for total proceeds of \$3.0 million to shareholders who are considered to be related parties.

## 8. Stock-Based Compensation

### Stock Option Activity

A summary of the Company's stock option activity under the 2013 Equity Incentive Plan and 2018 Incentive Award Plan for the three months ended March 31, 2019 is as follows:

	Number of Shares	Weighted- Average Exercise Price
Balances at December 31, 2018	5,500,531	\$ 6.75
Granted	76,500	\$ 12.38
Exercised	(340,731)	\$ 0.88
Canceled	(30,623)	\$ 7.49
Balances at March 31, 2019	<u>5,205,677</u>	<u>\$ 7.21</u>

### Stock Based Compensation Expense

The following table sets forth the total stock-based compensation expense for all options granted to employees and nonemployees, including shares sold through the issuance of non-recourse promissory notes which are considered to be options for accounting purposes, as well as expense related to the Company's 2018 Employee Stock Purchase Plan (in thousands):

	Three Months Ended March 31,	
	2019	2018
Research and development	\$ 995	\$ 974
General and administrative	1,002	396
Total	<u>\$ 1,997</u>	<u>\$ 1,370</u>

## 9. Net Loss per Common Share

Basic net loss per share is calculated by dividing net loss by the weighted average number of shares outstanding for the period. Diluted net loss per share is calculated by dividing net loss by the weighted average number of shares of common stock and potential dilutive common stock equivalents outstanding during the period if the effect is dilutive.

The calculation of diluted earnings (loss) per share also requires that, to the extent contingences are satisfied during the period and the presumed issuance of such additional shares as contingent consideration is dilutive to earnings (loss) per share for the period, adjustments to net income or net loss used in the calculation are required to remove the change in fair value of the contingent consideration liability for the period. Likewise, adjustments to the denominator are required to reflect the related dilutive shares. In all periods presented, the Company's outstanding stock options, convertible preferred stock, early exercised common stock subject to future vesting, restricted stock accounted for as options common and preferred stock warrants and presumed issuance of additional shares as contingent consideration were excluded from the calculation of diluted net loss per share because their effects were antidilutive.

A reconciliation of the numerators and denominators used in computing net loss from continuing operations per share is as follows (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2019	2018
Numerator:		
Net loss	\$ (18,767)	\$ (16,133)
Denominator:		
Weighted-average number of shares outstanding—basic and diluted	42,190,457	3,437,345
Net loss per share—basic and diluted	\$ (0.44)	\$ (4.69)

Since the Company was in a net loss position for all periods presented, basic net loss per common share is the same as diluted net loss per common share as the inclusion of all potential common shares outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	March 31,	
	2019	2018
Convertible preferred stock	—	31,750,297
Options to purchase common stock	5,375,168	4,433,459
Early exercised common stock subject to future vesting	591,219	1,058,270
Restricted stock accounted for as options		625,084
Warrants to purchase convertible preferred stock		763,501
Warrants to purchase common stock		96,610
Shares subject to ESPP	27,622	—
Total	5,994,009	38,727,221

Up to 606,218 shares may be contingently issued, if certain performance conditions are met under the Company's in-licensing agreements.

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

*You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and notes thereto for the year ended December 31, 2018.*

### Overview

We are a biotechnology company engaged in researching and developing therapeutics to extend healthspan by slowing, halting or reversing diseases of aging. Our initial focus is on creating senolytic medicines to selectively eliminate senescent cells and thereby treat age-related diseases, such as musculoskeletal, ophthalmologic and pulmonary diseases.

Since the commencement of our operations, we have invested a significant portion of our efforts and financial resources in research and development activities, and we have incurred net losses each year since inception. Our net losses were \$18.8 million and \$16.1 million for the three months ended March 31, 2019 and 2018, respectively. We do not have any products approved for sale, and we have never generated any revenue from contracts with customers. As of March 31, 2019, we had an accumulated deficit of \$182.0 million, and we do not expect positive cash flows from operations in the foreseeable future. We expect to continue to incur net operating losses for at least the next several years as we continue our research and development efforts, advance our drug candidates through preclinical and clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization.

Prior to our initial public offering, or IPO, we had funded our operations primarily from the issuance and sale of convertible preferred stock and convertible promissory notes. In May 2018, we completed our IPO pursuant to which we issued 5,000,000 shares of our common stock at a price of \$17.00 per share. We received proceeds of approximately \$75.9 million, after deducting underwriting discounts, commissions, and offering-related transaction costs from the IPO.

We do not expect to generate revenue from any drug candidates that we develop until we obtain regulatory approval for one or more of such drug candidates and commercialize our products or enter into collaborative agreements with third parties. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. As a result, we will need to raise additional capital. If sufficient funds on acceptable terms are not available when needed, we could be required to significantly reduce our operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs.

We rely on third parties in the conduct of our preclinical studies and clinical trials and for manufacturing and supply of our drug candidates. We have no internal manufacturing capabilities, and we will continue to rely on third parties, many of whom are single-source suppliers, for our preclinical and clinical trial materials, as well as the commercial supply of our products. In addition, we do not yet have a marketing or sales organization or commercial infrastructure. Accordingly, we will incur significant expenses to develop a marketing and sales organization and commercial infrastructure in advance of generating any product sales.

## Components of Our Results of Operations

### *Research and Development Expenses*

Research and development expenses consist primarily of costs incurred for the development of our drug candidates, which include:

- personnel-related expenses, including salaries, benefits and stock-based compensation for personnel contributing to research and development activities;
- laboratory expenses including supplies and services;
- expenses incurred under agreements with third-party contract manufacturing organizations, contract research organizations, research and development service providers, academic research institutions, and consultants;
- expenses related to license and sponsored research agreements;
- clinical trial expenses; and
- facilities and other allocated expenses, including expenses for rent and facilities maintenance, and depreciation and amortization.

We expect our research and development expenses to increase as we advance our drug candidates into and through preclinical and clinical trials and pursue regulatory approval of our drug candidates. The process of conducting the clinical trials required to obtain regulatory approval is costly and time-consuming. Clinical trials generally become larger and more costly to conduct as they advance into later stages and we are required to make estimates for expense accruals related to clinical trial expenses. The actual probability of success for our drug candidates may be affected by a variety of factors including: the safety and efficacy of our drug candidates, early clinical data, investment in our clinical program, the ability of collaborators, if any, to successfully develop any drug candidates we license to them, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our drug candidates. Program costs that are direct external expenses are tracked on a program-by-program basis once they enter clinical studies. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our drug candidates.

### *General and Administrative Expenses*

Our general and administrative expenses consist primarily of personnel costs, allocated facilities costs and other expenses for outside professional services, including legal, audit and accounting services, and depreciation and amortization expense related to property and equipment. Personnel costs consist of salaries, benefits, insurance and stock-based compensation. We expect to continue to incur additional expenses associated with operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission and standards applicable to companies listed on a national securities exchange, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect to continue to increase the size of our administrative headcount to support the growth of our business and operate as a public company.

### ***Fair Value of Contingent Consideration***

Certain of our license agreements include contingent consideration in the form of additional issuances of our common stock based on the achievement of certain milestones. For asset acquisitions, we assess whether such contingent consideration meets the definition of a derivative, until such time that the contingency is met or expires. As of March 31, 2019, we have recorded a liability related to contingent consideration as the net settlement criteria of the definition of a derivative had been met. The derivative related to this contingent consideration is measured at fair value as of each balance sheet date with the related change in fair value being reflected in operating expenses. The contingent consideration expense is driven by the change in the estimated fair value of the liability, which is determined using a probability-weighted valuation approach model that reflects the probability and timing of future issuances of our common shares.

### ***Interest Income***

Interest income is primarily related to interest earned on our marketable securities for the three months ended March 31, 2019 and 2018.

### **Results of Operations**

#### ***Comparison of the Three Months Ended March 31, 2019 and 2018***

The following table sets forth the significant components of our results of operations (in thousands):

	<b>Three Months Ended March 31,</b>		<b>Increase/ (Decrease)</b>
	<b>2019</b>	<b>2018</b>	
Summary of Operations Data:			
Operating expenses:			
Research and development	\$ 16,505	\$ 13,025	\$ 3,480
General and administrative	4,477	3,457	1,020
Fair value of contingent consideration	(1,245)	—	(1,245)
Total operating expenses	<u>19,737</u>	<u>16,482</u>	<u>3,255</u>
Loss from operations	(19,737)	(16,482)	3,255
Interest income	1,006	352	654
Other expense, net	(36)	(3)	33
Net loss	<u>\$ (18,767)</u>	<u>\$ (16,133)</u>	<u>\$ 2,634</u>

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

Research and development expenses increased by \$3.5 million, to \$16.5 million for the three months ended March 31, 2019 from \$13.0 million for the three months ended March 31, 2018. The increase was primarily due to increases of \$1.5 million for personnel-related expenses, \$2.1 million for direct research and development activities, and \$0.1 million for facilities-related costs. The increases were partially offset by \$0.2 million decrease in consultant expenses.

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

General and administrative expenses increased by \$1.0 million, to \$4.5 million for the three months ended March 31, 2019 from \$3.5 million for the three months ended March 31, 2018. The increase was primarily due to increases of \$1.5 million for personnel related expenses, of which \$0.6 million was related to non-cash stock-based compensation, and \$0.2 million for insurance expense. This was partially offset by a decrease of \$0.4 million in professional services.

### ***Change in fair value of contingent consideration***

The change in fair value of contingent consideration was \$1.2 million for the three months ended March 31, 2019. The decrease in contingent consideration expense was due to a change in the estimated fair value of the liability under our license agreements, driven by the decrease in our stock price. The fair value is determined using a probability-weighted valuation approach model which considers our stock price and the probability and timing of the achievement of certain milestones at the balance sheet date.

### ***Interest Income***

Our interest income was \$1.0 million for the three months ended March 31, 2019, as compared to \$0.3 million for the three months ended March 31, 2018, as we invested our cash and proceeds from our Series C financing and IPO in marketable securities.

### **Liquidity, Capital Resources and Capital Requirements**

#### ***Sources of Liquidity***

We have incurred net losses each year since inception. We do not have any products approved for sale and have never generated any revenue from product sales. Historically, we have incurred operating losses as a result of ongoing efforts to develop our drug candidates, including conducting ongoing research and development, preclinical studies and providing general and administrative support for these operations. As of March 31, 2019, we had an accumulated deficit of \$182.0 million, and we do not expect positive cash flows from operations in the foreseeable future. We expect our operating losses and net cash used in operating activities will increase over at least the next several years as we continue our research and development activities, advance our drug candidates through preclinical and clinical testing and move into later and more costly stages of drug development, hire personnel and prepare for regulatory submissions and the commercialization of our drug candidates.

Prior to our IPO in May 2018, we financed our operations primarily through issuance and sale of convertible preferred stock and convertible promissory notes and will continue to be dependent upon equity and/or debt financing until we are able to generate positive cash flows from our operations. In March 2018, we sold 3,590,573 shares of Series C convertible preferred stock at \$15.3317 per share for proceeds of \$54.9 million. In April 2018, we sold 322,852 shares of Series C convertible preferred stock at \$15.3317 per share for additional proceeds of \$5.0 million. In May 2018, we consummated our initial public offering and received net proceeds of \$75.9 million, after deducting underwriting discounts, commissions and offering expenses payable by us. As of March 31, 2019, we had \$150.2 million in cash, cash equivalents and marketable securities.

## *Future Funding Requirements*

To date we have not generated any revenue for contracts with customers and have only received a contribution from a third-party organization for certain research and development activities to support their philanthropic mission. We expect to continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our drug candidates, and begin to commercialize any approved products. We are subject to all of the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Moreover, following the completion of our IPO, we have begun to incur additional ongoing costs associated with operating as a public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Until we can generate a sufficient amount of revenue from the commercialization of our drug candidates or from collaborative agreements with third parties, if ever, we expect to finance our future cash needs through public or private equity or debt financings. Additional capital may be raised through the sale of our equity securities, incurring debt, entering into licensing or collaboration agreements with partners, receiving research contributions, grants or other sources of financing to fund our operations. There can be no assurance that sufficient funds will be available to us on attractive terms or at all. If we are unable to obtain additional funding from these or other sources, it may be necessary to significantly reduce our rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs. Insufficient liquidity may also require us to relinquish rights to drug candidates at an earlier stage of development or on less favorable terms than we would otherwise choose.

Since our inception, we have incurred significant losses and negative cash flows from operations. We have an accumulated deficit of \$182.0 million through March 31, 2019. We expect to incur substantial additional losses in the future as we conduct and expand our research and development activities. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to enable us to fund our projected operations through at least the next 12 months. Based on our current operating plans, we expect our existing capital resources will fund our planned operating expenses into 2021, including through clinical data readout from our Phase 1 clinical study of UBX0101 and data readouts from additional Phase 1 clinical studies of our lead program for ophthalmologic diseases.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of biotechnology 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 scope, progress, results and costs of researching and developing UBX0101, UBX1967 or any other drug candidates, and conducting preclinical studies and clinical trials, including our Phase 1 clinical study of UBX0101, which was initiated in the second quarter of 2018;
- the timing of, and the costs involved in, obtaining regulatory approvals for our lead drug candidates or any future drug candidates;
- the number and characteristics of any additional drug candidates we develop or acquire;
- the timing and amount of any milestone payments we are required to make pursuant to our license agreements;
- the cost of manufacturing our lead drug candidates or any future drug candidates and any products we successfully commercialize;

- the cost of building a sales force in anticipation of product commercialization;
- the cost of commercialization activities if our lead drug candidates or any future drug candidates are approved for sale, including marketing, sales and distribution costs;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and
- the timing, receipt and amount of sales of any future approved or cleared products, if any.

## Cash Flows

The following table sets forth a summary of the primary sources and uses of cash and restricted cash for each of the periods presented below (in thousands):

	Three Months Ended	
	March 31,	
	2019	2018
Cash used in operating activities	\$ (20,596)	\$ (11,883)
Cash provided by investing activities	40,060	12,947
Cash provided by financing activities	282	54,392
Net increase in cash and restricted cash	<u>\$ 19,746</u>	<u>\$ 55,456</u>

## Operating Activities

Cash used in operating activities of \$20.6 million for the three months ended March 31, 2019 consisted primarily of a net loss of \$18.8 million adjusted for net non-cash charges of \$0.9 million and decrease of \$2.7 million in net operating assets and liabilities. Our non-cash charges consisted primarily of \$2.0 million in stock-based compensation and \$0.6 million in depreciation and amortization, partially offset by a \$1.2 million change in fair value of contingent consideration liability associated with our two license agreements and our compound library and option agreement, \$0.4 million in amortization of premium and discounts on marketable securities and \$0.1 million in accretion of our tenant improvement allowance. The net decrease in our operating assets and liabilities consisted primarily of decreases of \$2.1 million in accrued compensation, \$0.8 million in accounts payable, partially offset by an increase of \$0.2 million in prepaid expenses and other current assets.

Cash used in operating activities of \$11.9 million for the three months ended March 31, 2018 consisted primarily of a net loss of \$16.0 million, which was offset by net non-cash charges of \$1.5 million and increase of \$2.6 million in net operating assets and liabilities. Our non-cash charges primarily consisted of \$1.4 million in stock-based compensation. The change in our net operating assets and liabilities was primarily due to an increase in contribution receivable of \$1.4 million related to contribution revenue received, increase in accounts payable of \$1.9 million due to the increase in overall research and development activities, increase in prepaid expenses and other current assets of \$0.03 million due to ongoing amortization of prepaid expenses and a decrease in accrued compensation of \$1.2 million due to the payment of annual bonuses.



### ***Investing Activities***

Cash provided by investing activities of \$40.0 million for the three months ended March 31, 2019 was related to maturities of marketable securities of \$58.3 million, offset by purchases of marketable securities of \$18.1 million and purchases of property and equipment of \$0.2 million.

Cash provided by investing activities of \$12.9 million for the three months ended March 31, 2018 was related to purchases of marketable securities of \$6.2 million and purchases of property and equipment of \$0.1 million, which were partially offset by maturities of marketable securities of \$19.3 million.

### ***Financing Activities***

Cash provided by financing activities of \$0.3 million for the three months ended March 31, 2019 was primarily related to proceeds from issuance of common stock upon exercise of stock options, net of repurchases.

Cash provided by financing activities of \$54.4 million for the three months ended March 31, 2018 was primarily related to net proceeds from the issuance of Series C convertible preferred stock of \$54.9 million offset by payments of deferred offering costs in relation to our planned IPO of \$0.6 million.

### **Contractual Obligations and Other Commitments**

Our contractual obligations and commitments and commitments relate primarily to our operating leases and non-cancelable purchase obligations under agreements with various research and development organizations and suppliers in the ordinary course of business. In February 2019, we entered into a lease agreement for new office and laboratory space in South San Francisco, California. See Note 6, Commitments and Contingencies, to our condensed financial statements for further information.

### **Off-Balance Sheet Arrangements**

We have not entered into any off-balance sheet arrangements. While we have an investment in a variable interest entity, its purpose is not to provide off-balance sheet financing.

### **Critical Accounting Policies and Estimates**

There have been no material changes to our critical accounting policies and estimates during the three months ended March 31, 2019 as compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018, other than as provided in Note 2 to our Financial Statements "Summary of Significant Accounting Policies."

### **Recent Accounting Pronouncements**

See Note 2 to our Financial Statements "Summary of Significant Accounting Policies" for information.

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

There have been no material changes to our market risks from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018.

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

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

Our management, with the participation of our chief executive and financial officers, evaluated the effectiveness of our disclosures controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of March 31, 2019. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2019, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

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

Management determined that, as of March 31, 2019, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

We are not currently a party to any material litigation or other material legal proceedings.

### Item 1A. Risk Factors

This Quarterly Report on Form 10-Q contains forward-looking information based on our current expectations. Because our business is subject to many risks and our actual results may differ materially from any forward-looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our business, operating results, financial condition and the trading price of our common stock. This discussion should be read in conjunction with our condensed financial statements as of March 31, 2019 and December 31, 2018 and the notes accompanying those financial statements.

#### Risks Related to Our Limited Operating History, Financial Condition, and Capital Requirements

*We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception, and we anticipate that we will continue to incur losses for the foreseeable future, which, together with our limited operating history, make it difficult to assess our future viability.*

We are a clinical-stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have not yet sought approval for commercial sale of any products and therefore have no products approved for commercial sale and have not generated any revenue from contracts with customers and have incurred losses in each year since our inception in March 2009. We have only a limited operating history upon which you can evaluate our business and prospects. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. We initiated a Phase 1 clinical study of UBX0101, a potent senolytic small molecule inhibitor of the MDM2/p53 interaction, in osteoarthritic patients in the second quarter of 2018. We have not yet submitted an Investigational New Drug, or IND, application or initiated a clinical study for any other drug candidates.

We have had significant operating losses since our inception. Our net loss for the three months ended March 31, 2019 and 2018 was approximately \$18.8 million and \$16.1 million, respectively. As of March 31, 2019, we had an accumulated deficit of \$182.0 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to develop our drug candidates, conduct clinical studies and pursue research and development activities. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities. Preclinical studies and clinical studies for our drug candidates and additional research and development activities to discover and develop new drug candidates will require substantial funds to complete. As of March 31, 2019, we had capital resources consisting of cash, cash equivalents, and marketable securities of

\$150.2 million. In March and April 2018, we sold and issued an aggregate of 3,913,425 shares of our Series C convertible preferred stock at \$15.3317 per share for net cash proceeds to us of approximately \$59.9 million. In May 2018, we completed our initial public offering, or IPO, and received net proceeds of \$75.9 million, after deducting underwriting discounts, commissions and offering expenses payable by us. We believe that we will continue to expend substantial resources for the foreseeable future in connection with the preclinical and clinical development of our lead drug candidates, UBX0101 and UBX1967, and the discovery and/or development of any other drug candidates we may choose to pursue. These expenditures will include costs associated with conducting preclinical studies and clinical studies, obtaining regulatory approvals, and manufacturing and supply, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any preclinical study or clinical study is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our lead drug candidates or any future drug candidates.

Based on our current operating plans, we expect our existing capital resources will fund our planned operating expenses into 2021. However, our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, the imposition of burdensome debt covenants and repayment obligations, or other restrictions that may affect our business. 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.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing UBX0101, UBX1967 or any other drug candidates, and conducting preclinical studies and clinical studies, including our ongoing Phase 1 clinical study of UBX0101, which was initiated in the second quarter of 2018;
- the timing of, and the costs involved in, obtaining regulatory approvals for our lead drug candidates or any future drug candidates;
- the number and characteristics of any additional drug candidates we develop or acquire;
- the timing and amount of any milestone payments we are required to make pursuant to our license agreements;
- the cost of manufacturing our lead drug candidates or any future drug candidates and any products we successfully commercialize;
- the cost of building a sales force in anticipation of product commercialization;
- the cost of commercialization activities if our lead drug candidates or any future drug candidates are approved for sale, including marketing, sales and distribution costs;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and

- the timing, receipt and amount of sales of any future approved products, if any.

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 studies or other development activities for our lead drug candidates or any future drug candidate;
- delay, limit, reduce or terminate our research and development activities; or
- delay, limit, reduce or terminate our efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize our lead drug candidates or any future drug candidate, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

We also could choose or be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies or drug candidates that we would otherwise pursue on our own. We do not expect to realize revenue from sales of products or royalties from licensed products in the foreseeable future, if at all, and unless and until our drug candidates are clinically tested, approved for commercialization and successfully marketed. To date, we have primarily financed our operations through the sale of debt and equity securities. We will be required to seek additional funding in the future and currently intend to do so through collaborations, public or private equity offerings or debt financings, credit or loan facilities or a combination of one or more of these funding sources. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. Additional funds may not be available to us on acceptable terms or at all. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

***Due to the significant resources required for the development of our drug candidates, we must prioritize development of certain drug candidates and/or certain disease indications. We may expend our limited resources on candidates or indications that do not yield a successful product and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

We plan to continue to develop a pipeline of drug candidates to treat age-related diseases and extend human healthspan. Our clinical development strategy is initially focused on the development of senolytic medicines designed to be administered locally into diseased tissue and we are currently advancing programs in musculoskeletal, ophthalmologic, and pulmonary disorders. We are also in the early stages of developing senolytic medicines that could be administered systemically to treat additional age-related diseases, such as kidney disease, liver disease, and neurodegenerative disease. In addition to our efforts to eliminate senescent cells, we are also advancing other programs with the potential to extend human healthspan, including the administration of circulating youth factors.

We seek to maintain a process of prioritization and resource allocation among our programs to maintain a balance between aggressively advancing lead programs in identified indications and exploring additional indications and/or mechanisms related to diseases of aging. However, due to the significant resources required for the development of our drug candidates, we must focus on specific diseases and disease pathways and decide which drug candidates to pursue and the amount of resources to allocate to each. Our near-term objective is to demonstrate in our clinical studies that local treatment with senolytic molecules can alter the course of an age-related disease. To accomplish this goal, we initiated a Phase 1 clinical study of UBX0101 in patients with osteoarthritis of the knee in the second quarter of 2018. In addition, we plan to submit an IND application for UBX1967 for ophthalmologic disease in early 2020 that, if accepted, would enable us to pursue multiple indications in age-related eye diseases.

Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular drug candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or drug candidates or misread trends in the biopharmaceutical industry, particularly those segments focused on aging and healthspan, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other drug candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such drug candidates through collaboration, licensing or other royalty arrangements in cases where it may have been more advantageous for us to invest additional resources to retain development and commercialization rights.

***Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.***

Our quarterly and annual operating results may fluctuate significantly, making it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing, cost and level of investment in research, development and, if approved, commercialization activities relating to our drug candidates, which may change from time to time;
- the timing and status of enrollment for our clinical studies;
- the cost of manufacturing our drug candidates, as well as building out our supply chain, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures we may incur to acquire, develop or commercialize additional drug candidates and technologies;
- timing and amount of any milestone, royalty or other payments due under any collaboration or license agreement;
- future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of preclinical studies and clinical studies for our drug candidates or competing drug candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the timing of receipt of approvals for our drug candidates from regulatory authorities in the United States, or U.S., and internationally;
- coverage and reimbursement policies with respect to our drug candidates, if approved, and potential future drugs that compete with our products; and
- the level of demand for our products, if approved, which may vary significantly over time.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or

investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

## **Risks Related to Our Business**

***Our core therapeutic approach to extending human healthspan is based on our understanding of cellular senescence. Utilizing senolytic molecules to treat age-related diseases is a novel therapeutic approach, which exposes us to unforeseen risks and makes it difficult to predict the time and cost of drug development and potential for regulatory approval.***

We are developing a pipeline of drug candidates to treat age-related diseases and extend human healthspan. Our foundational science and lead drug candidates are based on senescence biology. We believe that we can develop drug candidates capable of eliminating accumulated senescent cells and their associated Senescence Associated Secretory Phenotype, or SASP, when administered locally. We are also in the early stages of developing senolytic medicines that could be administered systemically to treat additional other age-related diseases such as kidney disease, liver disease, and neurodegenerative disease. In our development efforts we intend to explore senolytic medicines that use multiple modalities. However, this approach to treating age-related diseases is novel and the scientific research that forms the basis of our efforts to develop senolytic medicines is ongoing. We currently have only limited data, and no conclusive evidence in humans, that the accumulation of senescent cells and resulting exposure to SASP factors is the underlying cause of tissue damage and dysfunction associated with many age-related diseases. The indications we are currently pursuing, including osteoarthritis, or OA, of the knee, and several age-related eye diseases, are believed to be heterogeneous and multifactorial diseases that are driven by multiple SASP factors. While evidence suggests that, in each case, individual SASP factors contribute to the disease, it is our belief that modulation of multiple factors is likely needed for a meaningful clinical benefit to be observed and we do not yet know which of the SASP factors will be most important in each disease or whether we can measure them. We have only just begun testing our senolytic molecules in humans and our current data is largely limited to animal models and preclinical cell lines, the results of which may not translate into humans. As such, there can be no assurances that even if we are able to develop senolytic medicines capable of eliminating senescent cells and their associated SASP, that such medicines would safely and effectively treat age-related diseases.

Further, while cellular senescence is a natural occurring biological process, the administration of senolytic medicines to eliminate accumulated senescent cells and their associated SASP in humans is untested and may potentially harm healthy tissue or result in unforeseen safety events. We may also ultimately discover that our senolytic molecules do not possess certain properties required for therapeutic effectiveness, or that even if found to be effective in one type of tissue, that such molecules will be effective in other tissues. In addition, given the novel nature of this therapeutic approach, designing preclinical and clinical studies to demonstrate the effect of senolytic medicines is complex and exposes us to unforeseen risks. For example, our attempts to replicate early *in vivo* findings in different animal models proved to be challenging, particularly with respect to our efforts to mimic a disease like OA, which develops over a long period of time in humans. In addition, the scientific evidence to support the feasibility of developing systemic senolytic medicines is both preliminary and limited. We may spend substantial funds attempting to develop these drug candidates and never succeed in doing so.

No regulatory authority has granted approval for a senolytic medicine. As such, we believe the U.S. Food and Drug Administration, or the FDA, has limited experience with biological senescence, which may increase the complexity, uncertainty and length of the clinical development and regulatory approval process for our drug candidates. We may never receive approval to market and commercialize any drug candidate. Even if we obtain regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may be required to perform additional or unanticipated clinical studies to obtain approval or be subject to post-marketing testing requirements to maintain regulatory approval. If our senolytic molecules prove to be ineffective, unsafe or commercially unviable, our entire senolytic platform and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Our business is dependent on the successful development, regulatory approval, and commercialization of our drug candidates, all of which are in early stages of development and none of which have been tested in a human subject.***

We have no products approved for sale and all of our drug candidates are in early stages of development. Our first lead drug candidate, UBX0101, is currently being evaluated in a Phase 1 clinical study and we commenced IND-enabling studies with our other lead drug candidate, UBX1967 in the first quarter of 2019. UBX0101 is the only drug candidate that we have administered to humans, and as such, we face significant translational risk with our drug candidates. We may also be required by the FDA or similar foreign regulatory agencies to conduct additional preclinical studies beyond those planned to support the commencement of clinical trials. For example, one of the properties of UBX1967 is a sustained exposure in ocular tissues of interest after intravitreal injection. After engaging the FDA regarding the design of IND-enabling studies for UBX1967, we determined that the duration of these nonclinical studies will be longer than originally anticipated due to the pharmacokinetic profile, which will delay the filing of our IND until early 2020.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of drug candidates from our senolytic medicine pipeline. However, given our early stage of development, it may be many years, if we succeed at all, before we have demonstrated the safety and efficacy of a drug candidate sufficient to warrant approval for commercialization.

In the future, we may also become dependent on other drug candidates that we may develop or acquire. The clinical and commercial success of our drug candidates and future drug candidates will depend on a number of factors, including the following:

- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete IND-enabling studies and successfully submit IND or comparable applications;
- timely completion of our preclinical studies and clinical studies, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical studies or other studies beyond those planned to support the approval and commercialization of our drug candidates or any future drug candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our drug candidates by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk-to-benefit profile of our lead drug candidates or any future drug candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our drug candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain compliance with our contractual obligations and with all regulatory requirements applicable to our lead drug candidates or any future drug candidates or approved products, if any;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our future drug candidates to treat age-related diseases;



- the ability of third parties with whom we contract to manufacture adequate clinical study and commercial supplies of our lead drug candidates or any future drug candidates, to remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our drug candidates or any future drug candidates in the U.S., and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- the convenience of our treatment or dosing regimen;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our drug candidates or any future drug candidates, if approved, including relative to alternative and competing treatments;
- patient demand for our drug candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our drug candidates or any future drug candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or be unable to obtain regulatory approvals or commercialize our drug candidates. Even if regulatory approvals are obtained, we may never achieve success in commercializing any of our drug candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our drug candidates or any future drug candidates to continue our business or achieve profitability.

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

To gain approval to market our drug candidates, we must provide the FDA and foreign regulatory authorities with clinical data that adequately demonstrate the safety and efficacy of the drug candidate for the intended indication applied for in the applicable regulatory filing. For our senolytic medicines, we must also demonstrate that eliminating senescent cells and the associated SASP will lead to the improvement of well-defined and measurable endpoints.

We have not previously submitted a new drug application, or NDA, or biologics license application, or BLA, to the FDA, or similar approval filings to comparable foreign regulatory authorities. An NDA, BLA or other relevant regulatory filing must include extensive preclinical and clinical data and supporting information to establish that the drug candidate is safe, pure and potent for each desired indication. The NDA, BLA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product.

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

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our drug candidates for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that any of our drug candidates is safe and effective for the requested indication;
- the FDA's or the applicable foreign regulatory agency's disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical studies;
- our inability to demonstrate that the clinical and other benefits of any of our drug candidates outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory agency's requirement for additional preclinical studies or clinical studies;
- the FDA's or the applicable foreign regulatory agency's failure to approve the formulation, labeling or specifications of UBX0101, UBX1967, or any of our future drug candidates;
- the FDA's or the applicable foreign regulatory agency's failure to approve the manufacturing processes or facilities of third-party manufacturers upon which we rely; or
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner that renders our clinical data insufficient for approval.

Of the large number of biopharmaceutical and pharmaceutical products in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized.

In addition, disruptions at the FDA and other regulatory agencies that are unrelated to our company or our products could also cause delays to the regulatory approval process for our products. For example, over the last several years, including in December 2018 and January 2019, the U.S. government has shut down several times and certain regulatory agencies, including the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions.

Even if we eventually complete clinical testing and receive approval from the FDA or applicable foreign agencies for any of our drug candidates, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical studies which may be required after approval. The FDA or the applicable foreign regulatory agency also may approve our lead drug candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA, or applicable foreign regulatory agency, may not approve our drug candidates with the labeling that we believe is necessary or desirable for the successful commercialization of such drug candidates.

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

***Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.***

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the clinical study process. Success in preclinical studies and early clinical studies does not ensure that later clinical studies will be successful. A number of companies in the biotechnology, and pharmaceutical industries have suffered significant setbacks in clinical studies, even after positive results in earlier preclinical studies or clinical studies. These setbacks have been caused by, among other things, preclinical findings made while clinical studies were underway and safety or efficacy observations made in clinical studies,

including previously unreported adverse events. The results of our preclinical animal studies or studies in *ex vivo* human tissues may not be predictive of the results of outcomes in human clinical studies. For example, our senolytic molecules may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Additionally, with respect to our initial clinical trials for our senolytic drug candidates, we may be unable to accurately predict whether or in what manner we will be able to measure the impact of a drug candidate on relevant SASP factors and disease biomarkers. The indications we are currently pursuing, including OA of the knee and several age-related eye diseases, are believed to be heterogeneous and multifactorial diseases that are driven by multiple SASP factors. While evidence suggests that, in each case, individual SASP factors contribute to the disease, it is our belief that modulation of multiple factors is likely needed for a meaningful clinical benefit to be observed and we do not yet know which of the SASP factors or disease biomarkers will be most important in each disease or whether we can measure them. For example, in the initial phase, or Part A, of our Phase 1 clinical of UBX0101 in patients with OA of the knees, we sought to collect synovial fluid via simple aspiration; however, a number of patients had an insufficient amount of fluid for sampling. This led us to expand the study to include a second phase, or Part B, with an additional cohort of patients to provide an increased sample size for SASP and OA biomarkers assessment by allowing saline lavage in those patients who do not have adequate fluid to collect via simple aspiration.

Drug candidates in later stages of clinical studies may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies and initial clinical studies. Notwithstanding any promising results in earlier studies, we cannot be certain that we will not face similar setbacks. Even if we are able to initiate and complete clinical studies, the results may not be sufficient to obtain regulatory approval for our drug candidates.

Although we initiated our Phase 1 clinical study of UBX0101 in OA in the second quarter of 2018, we may experience delays in obtaining the FDA's authorization to initiate further clinical studies under the IND for UBX0101, completing ongoing studies of our other drug candidates and initiating our planned studies and trials. Additionally, we cannot be certain that studies or trials for our drug candidates will begin on time, not require redesign, enroll an adequate number of subjects on time or be completed on schedule, if at all. Clinical studies can be prolonged, delayed or terminated for a variety of reasons, including:

- the FDA or comparable foreign regulatory authorities disagreeing with or requiring changes to the design or implementation of our clinical studies;
- delays in obtaining regulatory approval to commence or continue a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval at each trial site;
- recruiting an adequate number of suitable patients to participate in a trial;
- having subjects complete a trial or return for post-treatment follow-up;
- encountering difficulties in gathering the range of biological data from patients needed to fully assess the impact of our drug candidates, such as the challenges we encountered in collecting synovial fluid from OA patients in Part A of our Phase 1 clinical study;
- clinical sites deviating from trial protocol or dropping out of a trial;
- addressing subject safety concerns that arise during the course of a trial;
- adding a sufficient number of clinical study sites; or

- obtaining sufficient product supply of drug candidate for use in preclinical studies or clinical studies from third-party suppliers.

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

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

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

- incur unplanned costs;
- be delayed in obtaining marketing approval for our drug candidates or fail to obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or

- have the treatment removed from the market after obtaining marketing approval.

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

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

Principal investigators for our clinical studies may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or a regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical study site may be questioned and the utility of the clinical study itself may be jeopardized, which could result in the delay or rejection of the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future drug candidates.

If we experience termination or delays in the completion of any preclinical study or clinical study of our drug candidates, the commercial prospects of our drug candidates may be harmed, and our ability to generate revenues from any of these drug candidates will be delayed or unrealized. In addition, any delays in completing our clinical studies may increase our costs, slow down our drug candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our drug candidates. If one or more of our drug candidates or our senescence technology generally prove to be ineffective, unsafe or commercially unviable, our platform and pipeline would have significantly diminished value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

***We may not be successful in our efforts to continue to create a pipeline of drug candidates or to develop commercially successful products. If we fail to successfully identify and develop additional drug candidates, our commercial opportunity may be limited.***

We are committed to developing senolytic medicines that slow, halt or reverse age-related diseases and we are currently advancing multiple senolytic molecules to address a variety of age-related diseases, including musculoskeletal, ophthalmologic and pulmonary disorders. As senolytic medicines are not limited to intervention by a single mode of action or molecular target, we believe that we can modulate a number of biologic pathways in order to trigger the beneficial elimination of senescent cells. However, our core therapeutic approach is based on our belief that the elimination of the accumulation of senescent cells and their accompanying SASP can treat a root cause of many diseases of aging, which may never be successfully validated in a human. The indications we are currently pursuing, including OA of the knee and several age-related eye diseases, are believed to be heterogeneous and multifactorial diseases that are driven by multiple SASP factors. While evidence suggests that, in each case, individual SASP factors contribute to the disease, it is our belief that modulation of multiple factors is likely needed for a meaningful clinical benefit to be observed and we do not yet know which of the SASP factors will be most important or whether we can measure them.

In addition, identifying, developing, obtaining regulatory approval and commercializing drug candidates for the treatment of age-related diseases will require substantial additional funding and is prone to the risks of failure inherent in drug development. Research programs to identify drug candidates also require substantial technical, financial and human resources, regardless of whether or not any drug candidates are ultimately identified, and even if our preclinical research programs initially show promise in identifying potential drug candidates, they may fail to yield drug candidates for clinical development.

In addition, we believe that many age-related diseases will require the development of senolytic medicines that can be administered systemically and that our ability to realize the full potential of extending human healthspan will require additional non-senescence based therapeutic approaches. As a result, we intend to continue to dedicate resources and effort to better understand fundamental aging mechanisms, such as loss of circulating youth factors and mitochondrial dysfunction and translate these insights into human medicines. However, the scientific evidence to support the feasibility of developing systemic senolytic medicines is both preliminary and limited and our non-senolytic programs are based on emerging science. We therefore cannot provide any assurance that we will be able to successfully identify or acquire additional drug candidates, advance any of these additional drug candidates through the development process, successfully commercialize any such additional drug candidates, if approved, or assemble sufficient resources to identify, acquire, develop or, if approved, commercialize additional drug candidates. If we are unable to successfully identify, acquire, develop and commercialize additional drug candidates, our commercial opportunity may be limited.

***It may be many years, if ever, before we develop senolytic medicines capable of systemic administration to treat systemic diseases of aging.***

We are focusing initially on the development of senolytic molecules for age-related diseases that can be treated by means of local treatment and intend to continue our research into the development of systemic senolytic medicines. However, we are still at a very early stage of developing locally administered senolytic medicines, and we must establish proof-of-concept in humans for local treatment before developing a systemically administered senolytic medicine. We still face significant risks in the development of localized treatments. As a result, it may be many years before we have sufficient human data and scientific understanding to effectively pursue a systemically administered senolytic medicine, if ever.

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

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

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical study investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating; and
- our ability to obtain and maintain patient consents.

In addition, our clinical studies may compete with other clinical studies for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical studies at the same clinical study sites that some of our competitors use, which will reduce the number of patients who are available for our clinical studies in such clinical study site.

Further, the administration of senolytic medicines designed to eliminate senescent cells and associated SASP may result in unforeseen events, including by harming healthy tissues. As a result, it is possible that safety concerns could negatively affect patient enrollment among the patient populations that we intend to treat, including among those in indications with a low risk of mortality. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical studies, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

***Our drug candidates 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 marketing approval, if any.***

Undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Other than in our Phase I clinical study of UBX0101, which was initiated in the second quarter of 2018, senolytic medicines designed to eliminate senescent cells and associated SASP have never been tested in humans. As a result, any clinical studies we initiate could reveal a high and unacceptable severity and prevalence of side effects, and it is possible that patients enrolled in such clinical studies could respond in unexpected ways. For instance, in preclinical *in vivo* animal and *ex vivo* human tissue studies, our senolytic molecules have exhibited clearance of senescent cells, however the elimination of accumulated senescent cells may result in unforeseen events, including by harming healthy cells or tissues. In addition, the entry by cells into a senescent state is a natural biological process that we believe may have protective effects, such as halting the proliferation of damaged cells. The treatment of tissues with senolytic molecules could interfere with such protective processes.

If unacceptable side effects arise in the development of our drug candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted, or the DSMB could suspend or terminate our clinical studies or the FDA or comparable foreign regulatory authorities could order us to cease clinical studies or deny approval of our drug candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical studies or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our drug candidates to understand the side effect profiles for our clinical studies and upon any commercialization of any of our drug candidates. Inadequate training in recognizing or managing the potential side effects of our drug candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, even if we successfully advance any of our drug candidates into and through clinical studies, such trials will likely only include a limited number of subjects and limited duration of exposure to our drug candidates. As a result, we cannot be assured that adverse effects of our drug candidates will not be uncovered when a significantly larger number of patients are exposed to the drug candidate. Further, clinical studies may not be sufficient to determine the effect and safety consequences of taking our drug candidates over a multi-year period.

If any of our drug candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;

- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, if approved, and result in the loss of significant revenues to us, which would materially and adversely affect our results of operations and business. In addition, if one or more of our drug candidates or our senescence approach generally prove to be unsafe, our entire platform and pipeline could be affected, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Even if our lead drug candidates or any future drug candidates obtain regulatory approval, they may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.***

Even if one or more of our drug candidates receive FDA or other regulatory approvals, the commercial success of any of our current or future drug candidates will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. Our drug candidates may not be commercially successful for a variety of reasons, including: competitive factors, pricing or physician preference, reimbursement by insurers, the degree and rate of physician and patient adoption of our current or future drug candidates. If approved, the commercial success of our drug candidates will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the safety and efficacy of our product as compared to other available therapies;
- the availability of coverage and adequate reimbursement from managed care plans, insurers and other healthcare payors for any of our drug candidates that may be approved;
- acceptance by physicians, operators of clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- proper training and administration of our drug candidates by physicians and medical staff;
- public misperception regarding the use of our therapies, or public bias against “anti-aging” companies;
- patient satisfaction with the results and administration of our drug candidates and overall treatment experience, including, for example, the convenience of any dosing regimen;



- the cost of treatment with our drug candidates in relation to alternative treatments and reimbursement levels, if any, and willingness to pay for the product, if approved, on the part of insurance companies and other third-party payers, physicians and patients;
- the willingness of patients to pay for certain of our products, if approved;
- the revenue and profitability that our products may offer a physician as compared to alternative therapies;
- the prevalence and severity of side effects;
- limitations or warnings contained in the FDA-approved labeling for our products;
- the willingness of physicians, operators of clinics and patients to utilize or adopt our products as a solution;
- any FDA requirement to undertake a REMS;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our products or favorable publicity about competitive products; and
- potential product liability claims.

We cannot assure you that our current or future drug candidates, if approved, will achieve broad market acceptance among physicians and patients. Any failure by our drug candidates that obtain regulatory approval to achieve market acceptance or commercial success would adversely affect our results of operations.

***We rely on third-party suppliers to manufacture preclinical supplies of our drug candidates and we intend to rely on third parties to produce clinical supplies as well as commercial supplies of any approved product. The loss of these suppliers, or their failure to comply with applicable regulatory requirements or to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.***

We do not have the infrastructure or capability internally to manufacture supplies of our drug candidates or the materials necessary to produce our drug candidates for use in the conduct of our preclinical studies or clinical studies, and we lack the internal resources and the capability to manufacture any of our drug candidates on a preclinical, clinical or commercial scale. The facilities used by our contract manufacturers to manufacture our drug candidates are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable regulatory authorities in foreign jurisdictions, we may not be able to rely on their manufacturing facilities for the manufacture of our drug candidates. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds these facilities inadequate for the manufacture of our drug candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates.

We currently intend to supply all of our drug candidates in all territories for our clinical development programs. We currently rely on third parties at key stages in our supply chain. For instance, the supply chains for our lead drug candidates involve several manufacturers that specialize in specific operations of the manufacturing process, specifically, raw materials manufacturing, drug substance manufacturing, and drug product manufacturing. As a result, the supply chain for the manufacturing of our drug candidates is complicated and we expect the logistical challenges associated with our supply chain to grow more complex as our drug candidates such as UBX0101 and UBX1967, progress through the clinical trial process.

We do not have any control over the process or timing of the acquisition or manufacture of materials by our manufacturers. We generally do not begin a preclinical study and we do not intend to initiate any clinical studies unless we believe we have access to a sufficient supply of a drug candidate to complete such study or trial. In addition, any significant delay in, or quality control problems with respect to, the supply of a drug candidate, or the raw material components thereof, for an ongoing study or trial could considerably delay completion of our preclinical studies or future clinical studies, product testing and potential regulatory approval of our drug candidates.

We have not yet engaged any manufacturers for the commercial supply of our drug candidates. Although we intend to enter into such agreements prior to commercial launch of any of our drug candidates, we may be unable to enter into any such agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. Moreover, if there is a disruption to one or more of our third-party manufacturers' or suppliers' relevant operations, or if we are unable to enter into arrangements for the commercial supply of our drug candidates, we will have no other means of producing our lead drug candidates until they restore the affected facilities or we or they procure alternative manufacturing facilities or sources of supply. Our ability to progress our preclinical and clinical programs could be materially and adversely impacted if any of the third-party suppliers upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory or reputational issues.

Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to manufacture our drug candidates on a timely basis.

In addition, to manufacture our lead drug candidates in the quantities that we believe would be required to meet anticipated market demand, our third-party manufacturers would likely need to increase manufacturing capacity and, in some cases, we would need to secure alternative sources of commercial supply, which could involve significant challenges and may require additional regulatory approvals. In addition, the development of commercial-scale manufacturing capabilities may require us and our third-party manufacturers to invest substantial additional funds and hire and retain the technical personnel who have the necessary manufacturing experience. Neither we nor our third-party manufacturers may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all. If our manufacturers or we are unable to purchase the raw materials necessary for the manufacture of our drug candidates on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, the commercial launch of our lead drug candidates or any future drug candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of such drug candidates, if approved.

***We depend on third-party suppliers for key raw materials used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business.***

We rely on third-party suppliers for the raw materials required for the production of our drug candidates. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including limited control over pricing, availability, and quality and delivery schedules. As a small company, our negotiation leverage is limited and we are likely to get lower priority than our competitors who are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our drug candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our drug candidates, including limiting supplies necessary for clinical studies and regulatory approvals, which would have a material adverse effect on our business.

We rely on third parties in the conduct of critical portions of our preclinical studies and intend to rely on third parties in the conduct of critical portions of our future clinical studies. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or meet expected deadlines, we may be unable to obtain regulatory approval for our drug candidates.

We currently do not have the ability to independently conduct preclinical studies that comply with the regulatory requirements known as good laboratory practice, or GLP, requirements. We also do not currently have the ability to independently conduct any clinical studies. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, commonly referred to as good clinical practice, or GCP, requirements for conducting, monitoring, recording and reporting the results of clinical studies, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical studies. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant preclinical studies and GCP-compliant clinical studies on our drug candidates properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP-compliant preclinical studies and our GCP-compliant clinical studies play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our GLP-compliant preclinical studies and GCP-compliant clinical studies, we remain responsible for ensuring that each of our GLP preclinical studies and clinical studies is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

Many of the third parties with whom we contract may also have relationships with other commercial entities, potentially including our competitors, for whom they may also be conducting clinical studies or other drug development activities that could harm our competitive position. If the third parties conducting our preclinical studies or our clinical studies do not adequately perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical studies may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable drug candidate, our financial results and the commercial prospects for our drug candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

***We face significant competition in an environment of rapid technological and scientific change, and our drug candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do and we may not be able to successfully compete.***

The biotechnology and pharmaceutical industries in particular are characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that we are developing. We face competition from a number of sources, such as pharmaceutical companies, generic drug companies, biotechnology companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical study expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for drug candidates and other resources than we do. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. Mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, certain of our drug candidates, if approved, may compete with other products that treat age-related diseases, including over-the-counter, or OTC, treatments, for a share of some patients' discretionary budgets and for physicians' attention within their clinical practices.

We are aware of other companies seeking to develop treatments to prevent or treat aging-related diseases through various biological pathways, including Calico and resTORbio. Within our three leading senolytic programs, our drug candidates would compete against current therapies from a wide range of companies and technologies, including:

- Musculoskeletal diseases, including osteoarthritis: current standard of care treatments (though not disease-modifying and focused on symptom management) include anti-inflammatory drugs (Ibuprofen, Diclofenac, Celecoxib), analgesic pain relief (Acetaminophen), or narcotic pain relief (Tramadol).
- Ophthalmology diseases, including diabetic retinopathy: potentially disease-modifying therapeutics are being sold and developed by several pharmaceutical and biotechnology companies, including Roche/Genentech and Regeneron.
- Pulmonary disease, including idiopathic pulmonary fibrosis: therapeutics are being sold and developed by several pharmaceutical and biotechnology companies and academic institutions, including Genentech, Boehringer-Ingelheim, Cytokinetics and Mallinckrodt, and are in various stages of clinical studies.

Further, we believe that potential competitors may be able to develop senolytic medicines utilizing well-established molecules and pathways, which could enable the development of competitive drug candidates utilizing the same cellular senescence biological theories.

Certain alternative treatments offered by competitors may be available at lower prices and may offer greater efficacy or better safety profiles. Furthermore, currently approved products could be discovered to have application for treatment of age-related diseases generally, which could give such products significant regulatory and market timing advantages over any of our drug candidates. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications our drug candidates are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Newly developed systemic or non-systemic treatments that replace existing therapies that currently are only utilized in patients suffering from severe disease may also have lessened side effects or reduced prices compared to current therapies, which make them more attractive for patients suffering from mild to moderate disease. Even if a generic or OTC product is less effective than our drug candidates, it may be more quickly adopted by physicians and patients than our competing drug candidates based upon cost or convenience.

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

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our drug candidates, assuming FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our drug candidates. Assuming we obtain coverage for our drug candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the U.S., the EU or elsewhere will be available for our drug candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our drug candidates as substitutable and only offer to reimburse patients for the cost of the less expensive product. Even if we show improved efficacy or improved convenience of administration with our drug candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our drug

candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our drug candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our drug candidates, and may not be able to obtain a satisfactory financial return on our investment in the development of drug candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly- approved products. In the U.S., third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the U.S. for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our drug candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the U.S. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our drug candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Outside the U.S., international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries have and will continue to put pressure on the pricing and usage of our drug candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits.

Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our drug candidates. Accordingly, in markets outside the U.S., the reimbursement for our drug candidates may be reduced compared with the U.S. and may be insufficient to generate commercially-reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the U.S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our drug candidates. We expect to experience pricing pressures in connection with the sale of our drug candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

***We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell our drug candidates effectively in the U.S. and foreign jurisdictions, if approved, or generate product revenue.***

We currently do not have a marketing or sales organization. In order to commercialize our drug candidates in the U.S. and foreign jurisdictions, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If any of our drug candidates receive regulatory approval, we expect to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize each such drug candidate, which will be expensive and time consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide

adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with

third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our drug candidates. If we are not successful in commercializing our drug candidates or any future drug candidates, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

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

As of March 31, 2019, we had 106 full-time employees. We will need to continue to expand our managerial, operational, finance and other resources in order to manage our operations and clinical studies, continue our development activities and commercialize our lead drug candidates or any future drug candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- manage our clinical studies effectively;
- identify, recruit, retain, incentivize and integrate additional employees, including sales personnel;
- manage our internal research, development and operational efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reports systems and procedures.

***If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully develop our lead drug candidates or any future drug candidates, conduct our clinical studies and commercialize our current or any future drug candidates.***

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, particularly our President, Nathaniel E. David, and our Chief Executive Officer, Keith R. Leonard, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our planned clinical studies or the commercialization of our lead drug candidates or any future drug candidates.

Competition for qualified personnel in the biotechnology and pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and if we initiate commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

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

We face an inherent risk of product liability as a result of the clinical testing of our drug candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, and a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranty. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates.

Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our current or future drug candidates;
- injury to our reputation;
- withdrawal of clinical study participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize our current or any future drug candidates.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of our current or any future drug candidates we develop. We currently carry product liability insurance covering our clinical studies. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient funds to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing any of our drug candidates, we intend to expand our insurance coverage to include the sale of such drug candidate; however, we may be unable to obtain this liability insurance on commercially reasonable terms or at all.

***Our existing collaborations as well as additional collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our drug candidates.***

We utilize external collaborations and currently maintain approximately ten active early-stage research and discovery focused collaborations. In the future, we may seek additional collaboration arrangements for the commercialization, or potentially for the development, of certain of our drug candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. To the extent that we decide to enter into additional collaboration agreements in the future, we may face significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain and challenging to manage. We may not be successful in our efforts to prudently manage our existing collaborations or to enter new ones should we chose to do so. The terms of new collaborations, or other arrangements that we may establish may not be favorable to us.

The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators and partners. Collaborations are subject to numerous risks, which may include risks that:

- collaborators and partners have significant discretion in determining the efforts and resources that they will apply to collaborations and they may not devote the level of effort or resources we expect;

- collaborators may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical study results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical studies, provide insufficient funding for a clinical study program, stop a clinical study, abandon a drug candidate, repeat or conduct new clinical studies or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or drug candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our current or future drug candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, resulting in a need for additional capital to pursue further development or commercialization of the applicable current or future drug candidates;
- collaborators may own or co-own intellectual property covering products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

***Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.***

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Furthermore, the market for products with the potential to treat age-related diseases, particularly those affecting large populations in a wide range of geographic locations, may be particularly vulnerable to unfavorable economic conditions. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including weakened demand for our lead drug candidates or any future drug candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.



***We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which in the past has experienced both severe earthquakes and wildfires. Although we carry earthquake insurance, it is limited in scope. Earthquakes, wildfires or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

***Significant disruptions of information technology systems or breaches of data security could materially adversely affect our business, results of operations and financial condition.***

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical study data from completed or ongoing or planned clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require

notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Clinical Health Act of 2009, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

***Our employees and independent contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.***

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

***Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.***

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product and drug candidates and other hazardous compounds. We and any third-party manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products.

Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or

past facilities and at third-party facilities. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical studies or regulatory approvals could be suspended, which could have a material adverse effect on our business, results of operations and financial condition.

#### **Risks Related to Intellectual Property**

*Our senolytic medicine platform and any future products that we commercialize could be alleged to infringe patent rights and other proprietary rights of third parties, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages and/ or limit our ability to commercialize our products.*

Our commercial success depends on our ability to develop, manufacture and market our senolytic medicines and future drug candidates and use our proprietary technology without infringing the patents and other proprietary rights of third parties. Intellectual property disputes can be costly to defend and may cause our business, operating results and financial condition to suffer. We operate in an industry with extensive intellectual property litigation. As the biopharmaceutical and pharmaceutical industries expand and more patents are issued, the risk increases that there may be patents issued to third parties that relate to our products and technology of which we are not aware or that we may need to challenge to continue our operations as currently contemplated.

Whether merited or not, we may face allegations that we have infringed the trademarks, copyrights, patents and other intellectual property rights of third parties, including patents held by our competitors or by non-practicing entities. We may also face allegations that our employees have misappropriated the intellectual property rights of their former employers or other third parties.

Litigation may make it necessary to defend ourselves by determining the scope, enforceability and validity of third-party proprietary rights, or to establish our proprietary rights. Regardless of whether claims that we are infringing patents or other intellectual property rights have merit, the claims can be time consuming, divert management attention and financial resources and are costly to evaluate and defend. Results of any such litigation are difficult to predict and may require us to stop treating certain conditions, obtain licenses or modify our products and features while we develop non-infringing substitutes, or may result in significant settlement costs. For example, litigation can involve substantial damages for infringement (and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees), and the court could prohibit us from selling or licensing our products unless the third party licenses rights to us, which it is not required to do at a commercially reasonable price or at all. If a license is available from a third party, we may have to pay substantial royalties, upfront fees or grant cross-licenses to intellectual property rights for our products. We may also have to redesign our products so they do not infringe third-party intellectual property rights, which may not be possible at all or may require substantial monetary expenditures and time, during which our products may not be available for manufacture, use, or sale.

In addition, patent applications in the U.S. and many international jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and publications in the scientific literature often lag behind actual discoveries. Thus, we cannot be certain that others have not filed patent applications or made public disclosures relating to our technology or our contemplated

technology. A third party may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, depending on whether the timing of the filing date falls under certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the U.S. Patent and Trademark Office, to determine priority of invention in the U.S. The costs of patent and other proceedings could be substantial, and it is possible that such efforts would be unsuccessful if it is determined that the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business with respect to intellectual property. Although we are not currently subject to any claims from third parties asserting infringement of their intellectual property rights, in the future, we may receive claims from third parties asserting infringement of their intellectual property rights. Future litigation may be necessary to establish our intellectual property rights or to defend ourselves by determining the scope, enforceability and validity of third-party intellectual property rights. There can be no assurance with respect to the outcome of any current or future litigation brought by or against us, and the outcome of any such litigation could have a material adverse impact on our business, operating results and financial condition. Litigation is inherently unpredictable and outcomes are uncertain. Further, as the costs and outcome of these types of claims and proceedings can vary significantly, it is difficult to estimate potential losses that may occur. Accordingly, we are unable at this time to estimate the effects of these potential future lawsuits on our financial condition, operations or cash flows.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Finally, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

***If we are unable to obtain, maintain and enforce intellectual property protection directed to our senolytic medicine platform and any future technologies that we develop, others may be able to make, use, or sell products substantially the same as ours, which could adversely affect our ability to compete in the market.***

As of May 1, 2019, we own, co-own, or have an exclusive license or option in certain fields of use to more than 100 patents and pending applications in the United States and foreign jurisdictions. This portfolio includes 25 issued U.S. patents and allowed U.S. patent applications, 27 pending U.S. applications (including 5 provisional applications), 12 granted foreign patents and over 46 pending applications in foreign jurisdictions.

We have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our products in every country or territory in which we may sell our products. In addition, we cannot be sure that any of our pending patent applications or pending trademark applications will issue or that, if issued, they will issue in a form that will be advantageous to us. The U.S. Patent and Trademark Office, or the USPTO, international patent offices or judicial bodies may deny or significantly narrow claims made under our patent applications and our issued patents may be successfully challenged, may be designed around, or may otherwise be of insufficient scope to provide us with protection for our commercial products. Further, the USPTO, international trademark offices or judicial bodies may deny our trademark applications and, even if published or registered, these trademarks may not effectively protect our brand and goodwill. Like patents, trademarks also may be successfully opposed or challenged.

We cannot be certain that the steps we have taken will prevent unauthorized use or unauthorized reverse engineering of our technology. Moreover, third parties may independently develop technologies that are competitive with ours and such competitive technologies may or may not infringe our intellectual property. The enforcement of our intellectual property rights also depends on the success of our legal actions against these infringers in the respective country or forum, but these actions may not be successful. As with all granted intellectual property, such intellectual

property may be challenged, invalidated or circumvented, may not provide specific protection and/or may not prove to be enforceable in actions against specific alleged infringers.

The market for biopharmaceuticals, pharmaceuticals and treatments for age-related diseases is highly competitive and subject to rapid technological change. Our success depends, in part, upon our ability to maintain a competitive position in the development and protection of technologies and products for use in these fields and upon our ability to obtain, maintain and enforce our intellectual property rights in connection therewith. We seek to obtain and maintain patents and other intellectual property rights to restrict the ability of others to market products that misappropriate our technology and/or infringe our intellectual property to unfairly and illegally compete with our products. If we are unable to protect our intellectual property and proprietary rights, our competitive position and our business could be harmed, as third parties may be able to make, use, or sell products that are substantially the same as ours without incurring the sizeable development and licensing costs that we have incurred, which would adversely affect our ability to compete in the market.

We use a combination of patents, trademarks, know-how, confidentiality procedures and contractual provisions to protect our proprietary technology. However, these protections may not be adequate and may not provide us with any competitive advantage. For example, patents may not issue from any of our currently pending or any future patent applications, and our issued patents and any future patents that may issue may not survive legal challenges to their scope, validity or enforceability, or provide significant protection for us.

If we or one of our current or future collaborators were to initiate legal proceedings against a third party to enforce a patent covering one of our lead drug candidates or future drug candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace.

Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates. Such a loss of patent protection would have a material adverse impact on our business.

Even if our patents are determined by a court to be valid and enforceable, they may not be interpreted sufficiently broadly to prevent others from marketing products similar to ours or designing around our patents. For example, third parties may be able to make products that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our issued patents or patent applications when issued may not cover our proposed commercial technologies or the future products that we develop. We may not have freedom to commercialize unimpeded by the patent rights of others. Third parties may have dominating, blocking, or other patents relevant to our technology of which we are not aware. There may be prior public disclosures or art that could be deemed to invalidate one or more of our patent claims. Further, we may not develop additional proprietary technologies in the future, and, if we do, they may not be patentable.

Patent law can be highly uncertain and involve complex legal and factual questions for which important principles remain unresolved. In the U.S. and in many international jurisdictions, policy regarding the breadth of claims allowed in patents can be inconsistent. The U.S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the U.S. are interpreted. Similarly, international courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to

patent laws that might be enacted into law by U.S. and international legislative bodies. Those changes may materially affect our patents, our ability to obtain patents or the patents and patent applications of our licensors.

Patent reform legislation in the U.S. could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switch the U.S. patent system from a “first-to-invent” system to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The U.S. Patent and Trademark Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-to-file provisions, only became effective on March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, which could have a material adverse effect on our business and financial condition.

In addition, we have a number of international patents and patent applications, and expect to continue to pursue patent protection in many of the significant markets in which we intend to do business. The laws of some international jurisdictions may not protect intellectual property rights to the same extent as laws in the U.S., and many companies have encountered significant difficulties in obtaining, protecting, and defending such rights in international jurisdictions. If we encounter such difficulties or we are otherwise precluded from effectively protecting our intellectual property rights in international jurisdictions, our business prospects could be substantially harmed.

Varying filing dates in international countries may also permit intervening third parties to allege priority to certain technology.

Patent terms may be shortened or lengthened by, for example, terminal disclaimers, patent term adjustments, supplemental protection certificates, and patent term extensions. Patent term extensions and supplemental protection certificates, and the like, may be impacted by the regulatory process and may not significantly lengthen patent term. Non-payment or delay in payment of patent fees or annuities, delay in patent filings or delay in extension filing (including any patent term extension or adjustment filing), whether intentional or unintentional, may also result in the loss of patent rights important to our business. Certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. In addition, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of any patents.

In addition to the protection afforded by patents, we rely on confidentiality agreements to protect confidential information and proprietary knowhow that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our drug candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. We may in the future rely on trade secret protection, which would be subject to the risks identified above with respect to confidential information.

Monitoring unauthorized use of our intellectual property is difficult and costly. From time to time, we review our competitors' products, and may in the future seek to enforce our patents or other rights against potential infringement. However, the steps we have taken to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Our competitors may also independently develop similar technology. Any inability to meaningfully protect our intellectual property could result in competitors offering products that incorporate our product or service features, which could reduce demand for our products. In addition, we may need to defend our patents from third-party challenges, such as (but not limited to) interferences, derivation proceedings, reexamination proceedings, post-grant review, inter partes review, third-party submissions, oppositions, nullity actions or other patent proceedings. We may need to initiate infringement claims or litigation.

Adverse proceedings such as litigation can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm our business, whether or not we receive a determination favorable to us. In addition, in an infringement proceeding, a court or other judicial body may decide that the patent we seek to enforce is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question. An adverse result in any litigation could put one or more of our patents at risk of being invalidated or interpreted narrowly. Some of our competitors may be able to devote significantly more resources to intellectual property litigation, and may have significantly broader patent portfolios to assert against us if we assert our rights against them. Further, because of the substantial discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be disclosed or otherwise compromised during litigation.

We may not be able to correctly estimate or control our future operating expenses in relation to obtaining intellectual property, enforcing intellectual property and/or defending intellectual property, which could affect operating expenses. Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, including the costs of preparing, filing, prosecuting, defending, and enforcing patent and trademark claims and other intellectual property-related costs, including adverse proceedings (such as litigation) costs.

***Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.***

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

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

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

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

Filing, prosecuting and defending patents on drug candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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 to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or conflict with third-party rights. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. In addition, third parties may file first for our trademarks in certain countries. If they succeeded in registering such trademarks, and if we were not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. In such cases, over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then our marketing abilities may be impacted.

***If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.***

We may not be able to protect our proprietary information and technology adequately. Although we use reasonable efforts to protect our proprietary information, technology, and know-how, our employees, consultants, contractors and outside scientific advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our proprietary information, technology or know-how is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect proprietary information, technology, and know-how. We rely, in part, on non-disclosure and confidentiality agreements with our employees, consultants and other parties to protect our proprietary information, technology, and know-how. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop similar or equivalent proprietary information, and third parties may otherwise gain access to our proprietary knowledge.

#### **Risks Related to Government Regulation**

***Even if we obtain regulatory approval for a drug candidate, our products will remain subject to regulatory scrutiny.***



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

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

We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval. The holder of an approved application must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers 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, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our clinical studies;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products, or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the U.S. or abroad. For example, certain policies of the Trump administration may impact our business and industry.

Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to

engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

***If any of our small molecule drug candidates obtain regulatory approval, additional competitors could enter the market with generic versions of such drugs, which may result in a material decline in sales of affected products.***

Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic version of an approved, small molecule innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit a new drug application, or NDA, under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that references the FDA's prior approval of the small molecule innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and review) of an ANDA or 505(b)(2) NDA. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the Orange Book. If there are patents listed in the Orange Book for a product, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in their applications what is known as a "Paragraph IV" certification, challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the patent owner and NDA holder and if, within 45 days of receiving notice, either the patent owner or NDA holder sues for patent infringement, approval of the ANDA or 505(b)(2) NDA is stayed for up to 30 months.

Accordingly, if any of our small molecule drug candidates, such as UBX0101 or UBX1967, are approved, competitors could file ANDAs for generic versions of our small molecule drug products or 505(b)(2) NDAs that reference our small molecule drug products. If there are patents listed for our small molecule drug products in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any of our owned or in-licensed patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially.

***Any biologic, or large molecule, drug candidates for which we intend to seek approval may face competition sooner than anticipated.***

If we are successful in achieving regulatory approval to commercialize any biologic drug candidate faster than our competitors, such drug candidates may face competition from biosimilar products. In the U.S., large molecule drug candidates are regulated by the FDA as biologic products subject to approval under the biologics license application, or BLA, pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, creates an abbreviated pathway for the approval of biosimilar and interchangeable biologic products following the approval of an original BLA. The abbreviated 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 existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the

FDA until 12 years after the original branded 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.

Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego the biosimilar approval path and submit a full BLA after completing its own preclinical studies and clinical studies. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

If competitors are able to obtain marketing approval for biosimilars referencing our large molecule drug candidates, if approved, such products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our drug candidates may have received approval.

***We may seek orphan drug designation for certain future drug candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.***

We may pursue orphan drug designation for certain of our future drug candidates. Under the Orphan Drug Act, the FDA may designate a drug or biologic product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the European Union, the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the U.S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and application fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a drug candidate, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA or EMA can subsequently approve the same drug with the same active moiety for the same condition if the FDA or EMA concludes that the later drug is clinically superior in that it is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process.

*Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and may affect the prices we may set.*

In the U.S., the EU and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the Affordable Care Act, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the Affordable Care Act, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board, which, once empaneled, will have the authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law unless overruled by a supermajority vote of Congress; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. The current presidential administration and Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. It is uncertain the extent to which any such changes

may impact our business or financial condition.

In addition, other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Individual states in the U.S. have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drug candidates or put pressure on our product pricing. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our drug candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to commercialize our drug candidates, if approved. In markets outside of the U.S. and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the U.S., the EU or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our drug candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

***Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.***

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our drug candidates, if approved.

Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), 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, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, which, among other things, 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 U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as
- health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts

and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future 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, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

***Recent U.S. tax legislation and future changes to applicable U.S. tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations.***

Changes in laws and policy relating to taxes may have an adverse effect on our business, financial condition and results of operations. For example, the U.S. government recently enacted significant tax reform, and certain provisions of the new law for tax years beginning after December 31, 2017 may adversely affect us. Changes include, but are not limited to, a federal corporate tax rate decrease to 21%, a reduction to the maximum deduction allowed for net operating losses generated in tax years after December 31, 2017, eliminating carrybacks of net operating losses, and providing for indefinite carryforwards for losses generated in tax years after December 31, 2017. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U.S. tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations.

**Risks Related to Ownership of Our Common Stock**

***Our stock price may be volatile and you may not be able to resell shares of our common stock at or above the price you paid.***

The trading price of our common stock may be highly volatile and may be subject to wide fluctuations in response to various factors, some of which are beyond our control.

These factors include those discussed in this “Risk Factors” section of this report and others such as:

- results from, and any delays in, commencing, conducting or completing our clinical studies for our lead drug candidates, or any other future clinical development programs;
- announcements by academic or other third parties challenging the fundamental premises underlying our approach to treating age-related diseases and/or drug development;
- announcements of regulatory approval or disapproval of our current or any future drug candidates;
- failure or discontinuation of any of our research and development programs;

- announcements relating to future licensing, collaboration, or development agreements;
- delays in the commercialization of our current or any future drug candidates;
- public misperception regarding the use of our therapies, or public bias of against “anti-aging” companies;
- acquisitions and sales of new products, technologies, or businesses;
- manufacturing and supply issues related to our drug candidates for clinical studies or future drug candidates for commercialization;
- quarterly variations in our results of operations or those of our future competitors;
- changes in earnings estimates or recommendations by securities analysts;
- announcements by us or our competitors of new products, significant contracts, commercial relationships, acquisitions, or capital commitments;
- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;
- changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;
- any major changes in our board of directors or management;
- new legislation in the U.S. relating to the sale or pricing of pharmaceuticals;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- product liability claims or other litigation or public concern about the safety of our drug candidates;
- market conditions in the pharmaceutical, biopharmaceutical and biotechnology sectors; and
- general economic conditions in the U.S. and abroad.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical, and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business.

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

Prior to our initial public offering in May 2018, there was no public market for shares of our common stock. Although our common stock is listed on the Nasdaq Global Select Market, an active trading market for our common stock may never be sustained on the Nasdaq Global Select or any other exchange in the future. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, applications, or technologies using our shares as consideration.



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

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. We only recently obtained research coverage by securities and industry analysts. If no additional new or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical studies and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

***We are an “emerging growth company” and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.***

We are an “emerging growth company,” as defined in the JOBS Act, and we intend to take 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, 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. In addition, as an “emerging growth company” the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use this extended transition period under the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

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. We will remain an emerging growth company until the earlier of (1) the last day of the year following the fifth anniversary of the consummation of our IPO, (2) the last day of the year in which we have total annual gross revenue of at least \$1.07 billion, (3) the last day of the year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year or (4) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

***If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.***

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

***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.***

As of March 31, 2019, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 66.1% of our voting stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of

directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

***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, holders of approximately 15.7 million shares of our common stock 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 incur increased costs as a result of operating as a public company, and our management devote substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.***

We have incurred and will continue to incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of the Nasdaq Global Select Market and the rules of the Securities and Exchange Commission, or SEC, require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel have devoted and will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costlier. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to 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. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by these rules. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports.

Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported

financial information and cause the trading price of our stock to fall. In addition, as a public company we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. In order to report our results of operations and financial statements on an accurate and timely basis, we will depend in part on CROs to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Select Market or other adverse consequences that would materially harm to our business.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset a portion of future taxable income, if any, until such unused losses expire, if ever. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research and development tax credits) to offset its post- change income or taxes may be limited. We may have experienced ownership changes prior to March 31, 2019, and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes. Additionally, the Tax Act, which was enacted on December 22, 2017, significantly reforms the Code, including changes to the rules governing net operating loss carryforwards arising in tax years ending after December 31, 2017. For net operating loss carryforwards, the Tax Act limits a taxpayer’s ability to utilize such carryforwards to 80% of taxable income. In addition, net operating loss carryforwards arising in tax years ending after December 31, 2017 can be carried forward indefinitely, but carryback is generally prohibited. Net operating loss carryforwards generated by us before January 1, 2018 will not be subject to the taxable income limitation and will continue to have a twenty- year carryforward period. However, the changes in the carryforward and carryback periods as well as the new limitation on use of net operating losses may significantly impact our ability to use net operating loss carryforwards generated after December 31, 2017, as well as the timing of any such use, and could adversely affect our results of operations.

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

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;

- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chief executive officer or the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

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

***Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.***

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification. We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

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

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

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

### a) Sales of Unregistered Securities

Other than as reported in our current report on Form 8-K filed with the SEC on January 2, 2019, there were no sales of unregistered securities during the three months ended March 31, 2019. The sale and issuance of the 133,333 shares of our common stock pursuant to the license agreement with Ascentage Pharma Group Corp. Limited (“Ascentage”) was made in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended (the “Securities Act”), and Rule 506 promulgated thereunder, and Ascentage represented to the Company that it is an “accredited investor” within the meaning of Rule 501 under the Securities Act. Accordingly, the shares have not been registered under the Securities Act, and until so registered, these securities may not be offered or sold in the United States absent registration or availability of an applicable exemption from registration. No underwriting discounts or commissions or similar fees were payable in connection with the issuance.

### b) Use of Proceeds from our Initial Public Offering of Common Stock

On May 2, 2018, the U.S. Securities and Exchange Commission declared effective our registration statement on Form S-1 (File No. 333-224163), as amended, filed in connection with our initial public offering (IPO). There has been no material change in the planned use of proceeds from our IPO from that described in the related Prospectus.

### c) Repurchase of Shares or of Company Equity Securities

None.

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

None.

## **Item 4. Mine Safety Disclosures**

Not applicable.

## **Item 5. Other Information**

None.

## Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.1#	<a href="#">Amended and Restated Non-Employee Director Compensation Program (effective as of March 14, 2019)</a>				X
10.2†	<a href="#">License Agreement for APG1197, dated as of January 2, 2019, by and between Ascentage Pharma Group Corp. Ltd. And Unity Biotechnology, Inc.</a>	10-K	3/6/2019	10.22	
10.3	<a href="#">Lease Agreement, dated as of February 28, 2019, by and between Unity Biotechnology, Inc. and Bayside Area Development, LLC</a>	10-K	3/6/2019	10.23	
31.1	<a href="#">Certification of Chief Executive Officer of Unity Biotechnology, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a).</a>				X
31.2	<a href="#">Certification of Chief Financial Officer of Unity Biotechnology, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a).</a>				X
32.1*	<a href="#">Certification by the Chief Executive Officer and Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350).</a>				X
101.INS	XBRL Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				X

# Indicates management contract or compensatory plan.

† Confidential treatment has been granted for certain information contained in this exhibit. Such information has been omitted and filed separately with the Securities and Exchange Commission.

\* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Unity Biotechnology, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

## SIGNATURES

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

Unity Biotechnology, Inc.

Date: May 8, 2019

By: /s/ Keith R. Leonard Jr.  
Keith R. Leonard Jr.  
Chairman and Chief Executive Officer  
(Principal Executive Officer)

Date: May 8, 2019

By: /s/ Robert C. Goeltz II  
Robert C. Goeltz II  
Chief Financial Officer  
(Principal Financial Officer)

**UNITY BIOTECHNOLOGY, INC.**  
**AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM**  
**(EFFECTIVE MARCH 14, 2019)**

Whereas the Unity Biotechnology, Inc. (the “Company”) Non-Employee Director Compensation Program was adopted under the Company’s 2018 Incentive Award Plan (the “Plan”) and became effective upon the closing of the Company’s initial public offering of its common stock (the “IPO”). This Amended and Restated Non-Employee Director Compensation Program (the “Amended Program”) shall be effective as of March 14, 2019. Capitalized terms not otherwise defined herein shall have the meaning ascribed in the Plan.

***Cash Compensation***

Effective on January 1, 2019, annual retainers will be paid in the following amounts to Non-Employee Directors:

Non-Employee Director:	\$35,000
Lead Independent Director	\$25,000
Chair of Audit Committee:	\$15,000
Chair of Compensation Committee:	\$10,000
Chair of Nominating and Corporate Governance Committee:	\$8,000
Chair of Science Committee:	\$10,000
Audit Committee Member (other than Chair):	\$7,500
Compensation Committee Member (other than Chair):	\$5,000
Nominating and Corporate Governance Committee Member (other than Chair):	\$4,000
Science Committee Member (other than Chair):	\$5,000

All annual retainers will be paid in cash quarterly in arrears promptly following the end of the applicable calendar quarter, but in no event more than thirty (30) days after the end of such quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described above, for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

***Equity Compensation***

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**Initial Stock Option Grant:**

Each Non-Employee Director who is initially elected or appointed to serve on the Board after the IPO shall be granted an Option under the Plan or any other applicable Company equity incentive plan then-maintained by the Company to purchase that number of shares of Common Stock such that the Option has a Grant Date Value (as defined below) equal to \$450,000 (the "Initial Option"). For the purposes of this Amended Program, "Grant Date Value" shall mean the fair value of an option determined using the Black-Scholes pricing model with the volume weighted average trading price of a share of Common Stock on the stock exchange on which the Common Stock is then listed or traded for the thirty (30) consecutive trading days ending on the trading day prior to the date of grant and the volatility, risk-free rate and life expectancy assumptions in the Company's most recent public filings disclosing those assumptions.

The Initial Option will be automatically granted on the date on which such Non-Employee Director commences service on the Board, and will vest as to 1/36<sup>th</sup> of the shares subject thereto on each monthly anniversary of the applicable date of grant such that the shares subject to the Initial Option are fully vested on the third anniversary of the grant, subject to the Non-Employee Director continuing in service on the Board through each vesting date.

**Annual Stock Option Grant:**

Each Non-Employee Director who is serving on the Board as of the date of each annual shareholder meeting of the Company (each, an "Annual Meeting") shall be granted an Option under the Plan or any other applicable Company equity incentive plan then-maintained by the Company to purchase that number of shares of Common Stock such that the Option has a Grant Date Value equal to \$225,000 (the "Annual Option"), provided that the number of shares subject to the Annual Option will be prorated for any partial year of service as a Non-Employee Director.

The Annual Option will be automatically granted on the date of the applicable Annual Meeting, and will vest in full on the earlier of (i) the first anniversary of the date of grant and (ii) immediately prior to the Annual Meeting following the date of grant, subject to the Non-Employee Director continuing in service on the Board through such vesting date.

The per share exercise price of each Option granted to a Non-Employee Director shall equal the Fair Market Value of a share of common stock on the date the Option is granted.

The term of each Option granted to a Non-Employee Director shall be ten (10) years from the date the Option is granted.

No portion of an Initial Option or Annual Option which is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board shall become vested and exercisable thereafter.

Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Option, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from service with the Company and any parent or subsidiary of the Company, Annual Options as described above.

***Change in Control***

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Upon a Change in Control of the Company, all outstanding equity awards granted under the Plan and any other equity incentive plan maintained by the Company that are held by a Non-Employee Director shall become fully vested and/or exercisable, irrespective of any other provisions of the Non-Employee Director's Award Agreement.

***Reimbursements***

The Company shall reimburse each Non-Employee Director for all reasonable, documented, out-of-pocket travel and other business expenses incurred by such Non-Employee Director in the performance of his or her duties to the Company in accordance with the Company's applicable expense reimbursement policies and procedures as in effect from time to time.

***Miscellaneous***

The other provisions of the Plan shall apply to the Options granted automatically pursuant to this Amended Program, except to the extent such other provisions are inconsistent with this Amended Program. All applicable terms of the Plan apply to this Amended Program as if fully set forth herein, and all grants of Options hereby are subject in all respect to the terms of such Plan. The grant of any Option under this Amended Program shall be made solely by and subject to the terms set forth in a written agreement in a form to be approved by the Board and duly executed by an executive officer of the Company.

***Effectiveness***

This Amended Program is effective as of March 14, 2019.

\* \* \* \* \*

I hereby certify that the foregoing Amended Program was duly adopted by the Board of Directors of Unity Biotechnology, Inc. on March 14, 2019.

Executed on this 14th day of March, 2019.

/s/ Tamara L.  
Tompkins

Secretary

Corporate

**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Keith R. Leonard Jr., certify that:

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

Date: May 8, 2019

By: \_\_\_\_\_ /s/ Keith R. Leonard Jr.  
**Keith R. Leonard Jr.**  
**Chairman and Chief Executive Officer**  
**(Principal Executive Officer)**

**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Robert C. Goeltz II, certify that:

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

Date: May 8, 2019

By: \_\_\_\_\_  
/s/ Robert C. Goeltz II  
**Robert C. Goeltz II**  
**Chief Financial Officer**  
**(Principal Financial Officer)**

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

In connection with the Quarterly Report of Unity Biotechnology, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Keith R. Leonard Jr., Chairman and Chief Executive Officer of the Company, and Robert C. Goeltz II, Chief Financial Officer of the Company, do each hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: May 8, 2019

By: \_\_\_\_\_  
**Keith R. Leonard Jr.**  
**Chairman and Chief Executive Officer**  
**(Principal Executive Officer)**

Date: May 8, 2019

By: \_\_\_\_\_  
**Robert C. Goeltz II**  
**Chief Financial Officer**  
**(Principal Financial Officer)**