

VICAL INC  
Form 10-Q  
October 29, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2018

Or

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

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

Commission File Number: 000-21088

VICAL INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware	93-0948554
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	Identification No.)
10390 Pacific Center Court	
San Diego, California	92121
(Address of principal executive offices)	(Zip Code)

(858) 646-1100

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(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

Total shares of common stock outstanding at October 25, 2018: 21,816,041

VICAL INCORPORATED

FORM 10-Q

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## PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS  
VICAL INCORPORATED

## BALANCE SHEETS

(In thousands, except par value data)

(Unaudited)

	September 30, 2018	December 31, 2017
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$12,101	\$24,841
Marketable securities, available-for-sale	38,267	35,658
Restricted cash	192	192
Deferred contract costs	—	10,502
Receivables and other assets	1,916	5,124
Total current assets	52,476	76,317
Long-term investments	2,190	2,209
Property and equipment, net	117	606
Intangible assets, net	—	703
Other assets	844	659
Total assets	\$55,627	\$80,494
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$3,522	\$5,217
Deferred revenue	10	11,700
Total current liabilities	3,532	16,917
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000 shares authorized, none issued and outstanding	—	—
Common stock, \$0.01 par value, 50,000 shares authorized, 21,816 and 21,802 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	218	218
Additional paid-in capital	490,244	489,975
Accumulated deficit	(438,458)	(426,738)
Accumulated other comprehensive income	91	122
Total stockholders' equity	52,095	63,577
Total liabilities and stockholders' equity	\$55,627	\$80,494

See accompanying notes to unaudited financial statements



## VICAL INCORPORATED

## STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
<b>Revenues:</b>				
Contract revenue	\$37	\$3,188	\$1,468	\$9,458
License and royalty revenue	10	52	30	408
Total revenues	47	3,240	1,498	9,866
<b>Operating expenses:</b>				
Research and development	2,503	3,004	9,769	9,943
Manufacturing and production	—	1,778	1,436	4,689
General and administrative	1,610	1,639	5,988	4,739
Total operating expenses	4,113	6,421	17,193	19,371
Loss from operations	(4,066 )	(3,181 )	(15,695 )	(9,505 )
<b>Other income:</b>				
Investment and other income, net	2,555	93	3,046	273
Net loss	\$(1,511 )	\$(3,088 )	\$(12,649 )	\$(9,232 )
Basic and diluted net loss per share	\$(0.07 )	\$(0.27 )	\$(0.58 )	\$(0.82 )
<b>Weighted average shares used in computing basic and diluted net</b>				
loss per share	21,841	11,458	21,838	11,237

See accompanying notes to unaudited financial statements

## VICAL INCORPORATED

## STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three Months Ended		Nine Months	
	September 30,		Ended	
	2018	2017	2018	2017
Net loss	\$ (1,511 )	\$ (3,088 )	\$ (12,649)	\$ (9,232)
Other comprehensive (loss) gain:				
Unrealized (loss) gain on available-for-sale and long-term				
marketable securities:				
Unrealized (loss) gain arising during holding period, net of tax benefit of \$(6) and \$10 for three months ended September 30, 2018 and 2017, respectively, and \$0 and \$49 for nine months ended September 30, 2018 and 2017, respectively	(39 )	34	(31 )	102
Other comprehensive (loss) gain	(39 )	34	(31 )	102
Total comprehensive loss	\$ (1,550 )	\$ (3,054 )	\$ (12,680)	\$ (9,130)

See accompanying notes to unaudited financial statements

## VICAL INCORPORATED

## STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$(12,649)	\$(9,232 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	135	722
Accretion of discount on short-term investments	(144 )	—
Write-off of abandoned patents	673	—
Gain on sale of property and equipment	(2,286 )	—
Compensation expense related to stock options and awards	268	611
Changes in operating assets and liabilities:		
Deferred contract costs	—	(4,061 )
Receivables and other assets	4,090	319
Accounts payable and accrued expenses	(1,695 )	174
Deferred revenue	(259 )	4,785
Deferred rent	—	(223 )
Net cash used in operating activities	(11,867)	(6,905 )
Cash flows from investing activities:		
Maturities of marketable securities	28,225	20,016
Purchases of marketable securities	(30,702)	(12,175)
Sale of property and equipment	1,639	—
Purchases of property and equipment	(35 )	(27 )
Net cash (used in) provided by investing activities	(873 )	7,814
Cash flows from financing activities:		
Net proceeds from issuance of common stock	1	1,116
Payment of withholding taxes for net settlement of restricted stock units	(1 )	(3 )
Net cash provided by financing activities	-	1,113
Net (decrease) increase in cash, cash equivalents and restricted cash	(12,740)	2,022
Cash, cash equivalents and restricted cash at beginning of period	25,033	8,380
Cash, cash equivalents and restricted cash at end of period	\$12,293	\$10,402
Supplemental disclosure of noncash investing and financing activities:		
Gain related to deferred rent	\$1,067	\$—

See accompanying notes to unaudited financial statements





VICAL INCORPORATED

NOTES TO FINANCIAL STATEMENTS

September 30, 2018

(Unaudited)

1. BASIS OF PRESENTATION

Vical Incorporated, or the Company, a Delaware corporation, was incorporated in April 1987 and has devoted substantially all of its resources since that time to its research and development programs. The Company develops biopharmaceutical products for the prevention and treatment of chronic or life-threatening infectious diseases, including a candidate for treating chronic hepatitis B in preclinical development and an antifungal candidate in clinical development.

All of the Company's potential products are in research and development phases. No revenues have been generated from the sale of any such products, nor are any such revenues expected for at least the next several years. The Company earns revenue from research and development agreements with pharmaceutical collaborators. The Company's product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing. All product candidates that advance to clinical testing will require regulatory approval prior to commercial sale, and will require significant costs to commercialize. There can be no assurance that the Company's research and development efforts, or those of its collaborators, will be successful. The Company expects to continue to incur substantial losses and not generate positive cash flows from operations for at least the next several years. No assurance can be given that the Company can generate sufficient product revenue to become profitable or generate positive cash flows from operations.

The unaudited financial statements at September 30, 2018, and for the three and nine months ended September 30, 2018 and 2017, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission, or SEC, and with accounting principles generally accepted in the United States applicable to interim financial statements. These unaudited financial statements have been prepared on the same basis as the audited financial statements included in the Company's Annual Report on Form 10-K and include all adjustments, consisting of only normal recurring accruals, which in the opinion of management are necessary to present fairly the Company's financial position as of the interim date and results of operations for the interim periods presented. Interim results are not necessarily indicative of results expected for a full year or future periods. The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from those estimates. These unaudited financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2017, included in its Annual Report on Form 10-K filed with the SEC.

Cash, Cash Equivalents and Marketable Securities

Cash and cash equivalents consist of cash and highly liquid securities with original maturities at the date of acquisition of ninety days or less and that can be liquidated without prior notice or penalty. Investments with an original maturity of more than ninety days are considered marketable securities and have been classified by management as available-for-sale. These investments are classified as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date which reflects management's intention to use the proceeds from

sales of these securities to fund its operations, as necessary. Such investments are carried at fair value, with unrealized gains and losses included as a separate component of stockholders' equity. Realized gains and losses from the sale of available-for-sale securities or the amounts, net of tax, reclassified out of accumulated other comprehensive income (loss), if any, are determined on a specific identification basis.

#### Restricted Cash

The Company was required to maintain a letter of credit securing an amount equal to twelve months of the then current monthly installment of base rent for the original term of the lease for its facilities, which ended on August 31, 2017. In July 2016, the term of the lease was extended for 16 months through December 2018. During the extended term, the Company is required to maintain a letter of credit securing an amount equal to \$0.2 million.

#### Revenue Recognition

The Company recognizes revenue when control of its products and services is transferred to its customers in an amount that reflects the consideration the Company expects to receive from its customers in exchange for those products and services. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the

performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. The Company considers a performance obligation satisfied once it has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. The Company recognizes revenue for satisfied performance obligations only when it determines there are no uncertainties regarding payment terms or transfer of control.

#### Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs include salaries and personnel-related costs, supplies and materials, outside services, costs of conducting preclinical and clinical trials, facilities costs and amortization of intangible assets. The Company accounts for its clinical trial costs by estimating the total cost to treat a patient in each clinical trial, and accruing this total cost for the patient over the estimated treatment period, which corresponds with the period over which the services are performed, beginning when the patient enrolls in the clinical trial. This estimated cost includes payments to the site conducting the trial, and patient-related lab and other costs related to the conduct of the trial. Cost per patient varies based on the type of clinical trial, the site of the clinical trial, the method of administration of the treatment, and the number of treatments that a patient receives. Treatment periods vary depending on the clinical trial. The Company makes revisions to the clinical trial cost estimates in the current period, as clinical trials progress.

#### Manufacturing and Production Costs

Manufacturing and production costs include expenses related to manufacturing contracts and expenses for the production of plasmid DNA for use in the Company's research and development efforts. Production expenses related to the Company's research and development efforts are expensed as incurred.

#### Net Loss Per Share

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The weighted average number of shares used to compute diluted loss per share excludes any assumed exercise of stock options and warrants and any assumed issuance of common stock under restricted stock units (RSUs) as the effect would be antidilutive. Common stock equivalents covering 7.2 million shares for the three and nine months ended September 30, 2018 were excluded from the calculation because of their antidilutive effect. There were no common stock equivalents excluded for the three and nine months ended September 30, 2017.

#### Stock-Based Compensation

The Company records its compensation expense associated with stock options and other forms of equity compensation based on their fair value at the date of grant using the Black-Scholes-Merton option pricing model. Stock-based compensation includes amortization related to stock option awards based on the estimated grant date fair value. Stock-based compensation expense related to stock options is recognized ratably over the vesting period of the option. In addition, the Company records expense related to RSUs granted based on the fair value of those awards on the grant date. The fair value related to the RSUs is amortized to expense over the vesting term of those awards. Forfeitures of stock options and RSUs are recognized as they occur.

Stock-based compensation expense for a stock-based award with a performance condition is recognized when the achievement of such performance condition is determined to be probable. If the outcome of such performance condition is not determined to be probable or is not met, no compensation expense is recognized and any previously

recognized compensation expense is reversed.

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## Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued ASU No. 2014-09, “Revenue from Contracts with Customers” which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. The Company adopted the new standard effective January 1, 2018 using the modified retrospective method applied to contracts not completed as of December 31, 2017. As it relates to process validation lots and stock piling lots completed but not delivered as of December 31, 2017 at the request of a customer, the Company concluded that, under ASC 606, the criteria for transfer of control were met prior to January 1, 2018 and as a result, the Company recorded an adjustment as of January 1, 2018 to recognize previously deferred revenue of \$11.4 million and previously deferred contract costs of \$10.5 million, with an adjustment to retained earnings of \$0.9 million. The impact of adoption on the Company’s income statement and balance sheet as of September 30, 2018 and for the nine months then ended was as follows (in thousands):

	As	Balances Without Adoption of ASC	Effect of Change
Income Statement	Reported	606	Increase/(Decrease)
<b>Revenues</b>			
Contract revenue	\$ 1,468	\$ 1,468	\$ -
<b>Operating expenses</b>			
Manufacturing and production	1,436	1,436	-
Net loss	(12,649 )	(12,649 )	-

	As	Balances Without Adoption of ASC	Effect of Change
Balance Sheet	Reported	606	Increase/(Decrease)
<b>Assets</b>			
Deferred contract costs	\$—	\$ 10,502	\$ (10,502 )
<b>Liabilities</b>			
Deferred revenue	10	11,440	(11,430 )
<b>Equity</b>			
Accumulated deficit	(438,458 )	(439,386 )	928

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842).” The new standard requires a lessee to record on the balance sheet the assets and liabilities for the rights and obligations created by leases with lease terms of more than 12 months and will require both lessees and lessors to disclose certain key information about lease transactions. The standard will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is evaluating the effect that the adoption of the new guidance will have on its financial statements and related disclosures.

## 2. STOCK-BASED COMPENSATION

Total stock-based compensation expense was allocated to research and development, manufacturing and production and general and administrative expense as follows (in thousands):

	Three Months Ended September 30, 2018		Nine Months Ended September 30, 2017	
Research and development	\$41	\$61	\$117	\$184
Manufacturing and production	—	30	(68)	95
General and administrative	18	92	219	332
Total stock-based compensation expense	\$59	\$183	\$268	\$611

During the nine months ended September 30, 2018 and September 30, 2017, the Company granted stock-based awards with a total estimated value of \$0.4 million and \$0.7 million, respectively. At September 30, 2018, total unrecognized estimated compensation expense related to unvested stock-based awards granted prior to that date was \$0.3 million, which is expected to be recognized over a weighted-average period of 1.4 years. Stock-based awards granted during the nine months ended September 30, 2018 and 2017, were equal to 2.5% and 5.1%, respectively, of the outstanding shares of common stock at the end of the applicable period.

### 3. MARKETABLE SECURITIES, AVAILABLE FOR SALE

The following is a summary of available-for-sale marketable securities (in thousands):

	Amortized	Unrealized	Unrealized	Market
September 30, 2018	Cost	Gain	Loss	Value
U.S. treasuries	\$ 38,307	\$ —	\$ 40	\$38,267
	\$ 38,307	\$ —	\$ 40	\$38,267

	Amortized	Unrealized	Unrealized	Market
December 31, 2017	Cost	Gain	Loss	Value
U.S. treasuries	\$ 34,462	\$ —	\$ 29	\$34,433
Certificates of deposit	1,225	—	—	1,225
	\$ 35,687	\$ —	\$ 29	\$35,658

At September 30, 2018, none of these securities were scheduled to mature outside of one year. The Company did not realize any gains or losses on sales of available-for-sale securities for the nine months ended September 30, 2018. As of September 30, 2018, none of the securities had been in a continuous material unrealized loss position longer than one year.

### 4. OTHER BALANCE SHEET ACCOUNTS

Accounts payable and accrued expenses consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Employee compensation	\$ 1,438	\$ 2,654
Clinical trial accruals	1,042	1,017
Accounts payable	576	1,213
Other accrued liabilities	466	333
Total accounts payable and accrued expenses	\$ 3,522	\$ 5,217

### 5. LONG-TERM INVESTMENTS



As of September 30, 2018, the Company held an auction rate security with a par value of \$2.5 million. This auction rate security has not experienced a successful auction since the liquidity issues experienced in the global credit and capital markets in 2008. As a result, the security is classified as a long-term investment as it is scheduled to mature in 2038. The security was rated BBB by Standard and Poor's as of September 30, 2018. The security continues to pay interest according to its stated terms.

The valuation of the Company's auction rate security is subject to uncertainties that are difficult to predict. The fair value of the security is estimated utilizing a discounted cash flow analysis. The key drivers of the valuation model include the expected term, collateral underlying the security investment, the creditworthiness of the counterparty, the timing of expected future cash flows, discount rates, liquidity and the expected holding period. The security was also compared, when possible, to other observable market data for securities with similar characteristics. As of September 30, 2018, the inputs used in the Company's discounted cash flow analysis assumed an interest rate of 5.70%, an estimated redemption period of five years and a discount rate of 1.00%. Based on the valuation of the security, the Company has recognized cumulative losses of \$0.4 million as of September 30, 2018, none of which were realized during the nine months ended September 30, 2018. The losses when recognized are included in investment and other income. The market value of the security has partially recovered. Included in other comprehensive income are unrealized (loss) gain of \$(20,000) and \$95,000 for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, the Company had recorded cumulative unrealized gains of \$0.4 million. The resulting carrying value of the auction rate security at September 30, 2018, was \$2.2 million. Any future decline in market value may result in additional losses being recognized.

## 6. FAIR VALUE MEASUREMENTS

The Company measures fair value as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. Fair value measurements are based on a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Cash equivalents, marketable securities and long-term investments measured at fair value are classified in the table below in one of the three categories described above (in thousands):

September 30, 2018	Fair Value Measurements			Total
	Level 1	Level 2	Level 3	
Money market funds	9,208	—	—	9,208
U.S. treasuries	38,267	—	—	38,267
Auction rate securities	—	—	2,190	2,190
	\$47,475	\$	—\$2,190	\$49,665

December 31, 2017	Fair Value Measurements			Total
	Level 1	Level 2	Level 3	
Certificates of deposit	\$1,225	\$	—\$—	\$1,225
Money market funds	21,760	—	—	21,760
U.S. treasuries	34,433	—	—	34,433
Auction rate securities	—	—	2,209	2,209
	\$57,418	\$	—\$2,209	\$59,627

The Company's investments in U.S. treasury securities, certificates of deposit and money market funds are valued based on publicly available quoted market prices for identical securities as of September 30, 2018. The Company determines the fair value of corporate bonds and other government-sponsored enterprise related securities with the aid of valuations provided by third parties using proprietary valuation models and analytical tools. These valuation models and analytical tools use market pricing or similar instruments that are both objective and publicly available, including matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids and/or offers. The Company validates the valuations received from its primary pricing vendors for its Level 2 securities by examining the inputs used in that vendor's pricing process and determines whether they are reasonable and observable. The Company also compares those valuations to recent reported trades for those securities. As of September 30, 2018 and December 31, 2017, the Company had no investments in Level 2 securities. The Company did not transfer any investments between level categories during the nine months ended September 30, 2018. The valuation of the Company's investments in auction rate securities, which includes significant unobservable inputs, is more fully described in Note 5.

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Activity for assets measured at fair value using significant unobservable inputs (Level 3) is presented in the table below (in thousands):

Balance at December 31, 2017	\$	2,209
Total unrealized gains, excluding tax impact, included in other comprehensive loss		(19 )
Balance at September 30, 2018	\$	2,190
Total gains or losses for the period included in net loss attributable to the change in		
unrealized gains or losses relating to assets still held at the reporting date	\$	—

## 7. COMMITMENTS AND CONTINGENCIES

In the ordinary course of business, the Company may become a party to additional lawsuits involving various matters. The Company is unaware of any such lawsuits presently pending against it which, individually or in the aggregate, are deemed to be material to the Company's financial condition or results of operations.

The Company prosecutes its intellectual property vigorously to obtain the broadest valid scope for its patents. Due to uncertainty of the ultimate outcome of these matters, the impact on future operating results or the Company's financial condition is not subject to reasonable estimates.

## 8. ASTELLAS OUT-LICENSE AGREEMENTS

In July 2011, the Company entered into license agreements with Astellas Pharma Inc., or Astellas, granting Astellas exclusive, worldwide, royalty-bearing licenses under certain of the Company's know-how and intellectual property to develop and commercialize certain products containing plasmids encoding certain forms of cytomegalovirus, glycoprotein B and/or phosphoprotein 65, including ASP0113 (TransVax™) but excluding CyMVectin™.

In January 2018, Astellas announced the results from a Phase 3 trial of ASP0113 in approximately 515 CMV seropositive subjects undergoing HCT procedures. Top-line results from the Phase 3 study demonstrated that the trial did not meet its primary endpoint in CMV end organ disease. Based on these results, Astellas determined to cease further clinical development of ASP0113 and terminated the license agreement.

Under the terms of the agreements, the Company was performing research and development services and manufacturing services which were being paid for by Astellas. During the three months ended September 30, 2018 and 2017, the Company recognized \$30,000 and \$3.1 million, respectively, of revenue related to these contract services. During the nine months ended September 30, 2018 and 2017, the Company recognized \$1.2 million and \$9.1 million, respectively, of revenue related to these contract services. The Company also recognized \$0.2 million in license revenue under the Astellas agreements during the nine months ended September 30, 2017.

## 9. FACILITY LEASE

The Company leases approximately 68,400 square feet of manufacturing, research laboratory and office space at a single site in San Diego, California. In July 2016, the term of the lease was extended for 16 months through December 2018. In July 2018, the Company entered into an agreement with Genopis, Inc., or Genopis, to sell the Company's idle manufacturing assets. As part of the agreement, Genopis agreed to sublease 51,400 square feet of the Company's facility through the remaining term of the Company's lease. See Note 13 for additional information.

## 10. STOCKHOLDERS' EQUITY

As of the date of this filing, the Company has on file a shelf registration statement that allows it to raise up to an additional \$40.0 million from the sale of common stock, preferred stock, debt securities and/or warrants, subject to

limitations on the amount of securities that it may sell under the registration statement in any 12-month period. Specific terms of any offering under a shelf registration statement and the securities involved would be established at the time of sale.

In November 2017, the Company sold 9,194,286 shares of its common stock in a public offering at a price of \$1.75 per share, including an overallotment of 2,142,857 shares issued at a price of \$1.75 per share, and pre-funded warrants to purchase 7,234,285 shares of common stock at a purchase price of \$1.74 per share. Net proceeds from the offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company, totaled \$26.4 million. The pre-funded warrants have an exercise price of \$0.01 per share and may be exercised at any time.

#### 11. RELATED PARTY TRANSACTION

On April 4, 2017, the Company entered into a research collaboration agreement with AnGes. As of the date of the transaction, AnGes held 18.6% of the outstanding stock of the Company. Pursuant to the collaboration agreement, AnGes agreed to make a non-refundable payment to the Company of \$750,000 and the Company agreed to conduct certain research activities related to a development program targeting chronic hepatitis B. An amendment to the agreement was executed in September 2018 that added an additional non-refundable payment from AnGes to the Company of \$145,000. In exchange for the payments, AnGes received an

option to negotiate exclusive rights in Japan related to the program. The parties also agreed to share the costs of prosecuting and maintaining intellectual property rights arising from the research program after such costs reach a specified limit. The decision to sell, license or sublicense rights is a contingent event within the Company's control. There are no guarantees for any outcomes of the research activities, no purchase obligations required by the Company and no debt or equity arrangements connected with the research activities. There are no other written or oral side agreements between the Company and AnGes that indicate that the funding of the research activities will be repaid. The Company is responsible for the conduct of the research activities. The upfront payments, when received, are deferred and recognized as contract revenue as the related research costs are incurred. As of September 30, 2018, the Company had recognized \$757,000 as contract revenue.

## 12. RESTRUCTURING COSTS

In January 2018, the Company and Astellas announced that ASP0113 did not meet its primary endpoint in a Phase 3 clinical study in CMV end organ disease, after which Astellas informed the Company that it was terminating further development. As a result, the Company restructured its operations to conserve capital, which included a staff reduction of 40 employees and the write-off of certain intangible assets. The Company recorded charges for one-time employee termination benefits of \$1.1 million and for intangible asset impairments of \$0.3 million during the nine months ended September 30, 2018. Overhead costs associated with the former manufacturing facility of 0.2 million and \$1.2 million have been recognized as general and administrative expense during the three and nine months ended September 30, 2018, respectively. The following table summarizes the components of the restructuring charges (in thousands):

	Employee Termination Benefits	Asset Impairments	Total
Research and development	\$ 272	\$ 267	\$539
Manufacturing and production	735	—	735
General and administrative	117	—	117
	\$ 1,124	\$ 267	\$1,391

The following table sets forth the accrual activity for employee termination benefits for the nine months ended September 30, 2018 (in thousands). No additional charges are expected to be incurred.

Balance at December 31, 2017	\$—
Accruals	1,124
Payments	(1,124)
Balance at September 30, 2018	\$—

## 13. SALE OF MANUFACTURING ASSETS

In July 2018, the Company entered into an agreement with Genopis to sell the Company's idle manufacturing assets for \$1.7 million. As part of the agreement, Genopis agreed to sublease 51,400 square feet of the Company's facility through the remaining term of the Company's lease, which expires on December 31, 2018. Genopis was also required to sign a long-term lease with the facility's landlord beginning on January 1, 2019. Genopis agreed to sublease 17,000 square feet of the facility (consisting of lab and office space) to the Company at no cost for the one-year period ending on December 31, 2019. A gain on the sale of assets of \$2.3 million was recorded and is included in Investment and Other Income, Net. The gain includes \$1.1 million for the fair value of rent of the lab and office space that the Company is occupying at no cost, with the offset recorded to deferred rent expense in Receivables and Other Assets.

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

This Quarterly Report on Form 10-Q, or Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding our business, our financial position, the research and development of biopharmaceutical products, the funding of our research and development efforts, and other statements describing our goals, expectations, intentions or beliefs. These statements often contain words such as “may,” “will,” “expect,” “anticipate,” “intend,” “plan,” “believe,” “estimate” or other words indicating future results, though forward-looking statements necessarily contain these identifying words. Such statements reflect our current views and assumptions and are subject to risks and uncertainties, particularly those inherent in the process of developing and commercializing biopharmaceutical products based on our patented DNA delivery and other technologies. Actual results could differ materially from those projected herein. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in our Annual Report on Form 10-K for the year ended December 31, 2017, and in our subsequent filings with the SEC, and those identified in Part II, Item 1A of this Report under the caption “Risk Factors”. As a result, you are cautioned not to rely on these forward-looking statements. We disclaim any duty to update any forward-looking statement to reflect events or circumstances that occur after the date on which such statement is made.

### Overview

We research and develop biopharmaceutical products, including those based on our patented DNA delivery technologies, for the prevention and treatment of serious or life-threatening diseases. We currently have two active development programs in the area of infectious disease comprised of:

• An ongoing Phase 2 trial of our novel antifungal candidate, VL-2397, for the treatment of patients with invasive aspergillosis. The multicenter, open label randomized clinical study, will compare the efficacy and safety of VL-2397 to standard treatment for invasive aspergillosis in acute leukemia patients and recipients of allogeneic hematopoietic cell transplant (HCT). The global Phase 2 trial will enroll approximately 200 patients and will be randomized on a 2:1 basis with approximately 134 patients treated with VL-2397 and approximately 66 patients treated with a standard treatment course of their physician's choice of voriconazole, isavuconazole, or liposomal amphotericin B. The patients in the VL-2397 arm will receive daily treatment with VL-2397 for 4 weeks, followed by a 2-week course of their physician's choice of the comparator. The primary endpoint of all-cause mortality will be measured at 4 weeks and again at 6 weeks for the key secondary endpoint. The trial will be conducted at selected sites in North America, Europe and Asia. The U.S. Food and Drug Administration (FDA) has advised that VL 2397 would be eligible for a Limited Use Indication (LUI) approval assuming a successful outcome of a single Phase 2 trial carried out in accordance with a protocol and statistical analysis plan consistent with the FDA's advice. The final determination of whether the VL-2397 is approvable will be made by the FDA after review of all relevant data. The LUI is a provision of the Limited Population Pathway established under the 21st Century Cures Act of 2016. The FDA has granted us Qualified Infectious Disease Product (QIDP), Orphan Drug and Fast Track designations for VL-2397 for the treatment of invasive aspergillosis.

• An ongoing early stage development program of a novel treatment for chronic hepatitis B virus (CHB) infection based on our DNA and lipid-delivery technologies. The initial stage of this program will be to demonstrate preclinical proof of concept for inhibiting hepatitis B virus (HBV) infection in a mouse model in the fourth quarter of 2018. The ultimate aim of this program would be to demonstrate eradication of persistent HBV infection in CHB patients. This preclinical development effort is being conducted in collaboration with our strategic partner, AnGes, Inc.





## Product Development

The table below summarizes our active development programs.

Product/Concept	Intended Use	Development Status <sup>1</sup>
VL-2397 antifungal	Treatment of invasive fungal infections	Phase 2
VR-CHB-01 chronic hepatitis B	Eradication of persistent HBV infection	Preclinical

<sup>1</sup>“Preclinical” (or “nonclinical”) indicates that a specific product candidate is undergoing in vitro testing and/or in vivo testing in animals. “Phase 1” clinical trials are typically conducted with a small number of patients or healthy subjects to evaluate safety, determine a safe dosage range, identify side effects, and, if possible, gain early evidence of effectiveness. “Phase 2” clinical trials are conducted with a larger group of patients to evaluate effectiveness of an investigational product for a defined patient population, and to determine common short-term side effects and risks associated with the product candidate. “Phase 3” clinical trials involve large scale, multi-center, comparative trials that are conducted with patients afflicted with a target disease to evaluate the overall benefit-risk relationship of the investigational product and to provide an adequate basis for product labeling.

## Research, Development and Manufacturing Programs

To date, we have not received revenues from the sale of independently developed pharmaceutical products and have received minimal revenues from the sale of commercially marketed products by our licensees. We have previously earned revenues by performing services under research and development and manufacturing contracts, from grants, and from licensing access to our proprietary technologies. Revenues by source were as follows (in millions):

Source	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Astellas supply and services contract	—	\$ 3.1	\$ 1.2	\$ 9.1
Astellas license	—	—	—	0.2
Other contracts, licenses and royalties	—	0.2	0.3	0.6
Total revenues	\$ —	\$ 3.3	\$ 1.5	\$ 9.9

In January 2018, we and Astellas announced that ASP0113 did not meet its primary endpoint in a Phase 3 clinical study in CMV end organ disease, after which Astellas informed us that it was terminating further development. As a result, we do not expect additional collaboration or license revenue absent new agreements with third parties.

Research, development, manufacturing and production costs by major program, as well as other costs, were as follows (in millions):

Program	Three Months Ended		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
CMV	\$—	\$2.6	\$1.5	\$7.1
HSV-2	0.3	0.8	1.7	4.6
VL-2397	1.7	1.1	6.4	1.9
Other research, development, manufacturing and production	0.5	0.3	1.6	1.0
Total research, development, manufacturing and production	\$2.5	\$4.8	\$11.2	\$14.6

Each of our on-going programs will require significant additional funds to advance through development to commercialization. From inception through September 30, 2018, we had spent approximately \$17.4 million on our VL-2397 program. The development of our CMV and HSV-2 vaccine programs has been terminated following negative trial results and we do not expect additional material spending on these programs going forward.

Our chronic hepatitis B product candidate is in the research stage. It can take many years to develop product candidates from the initial decision to screen product candidates, perform preclinical and safety studies, and perform clinical trials leading up to possible approval of a product by the FDA or comparable foreign agencies. The outcome of the research is unknown until each stage of the testing is completed, up through and including registration-enabling clinical trials. Accordingly, we are unable to predict which potential product candidates we may proceed with, the time and cost to complete development, and ultimately whether we will have a product approved by the FDA or comparable foreign agencies.

As a result, we expect to incur substantial operating losses for at least the next several years, due primarily to the advancement of our research and development programs, the cost of preclinical studies and clinical trials, spending for outside services, costs related to maintaining our intellectual property portfolio, costs related to our facilities, and possible advancement toward commercialization activities.

#### Critical Accounting Policies and Estimates

The preparation and presentation of financial statements in accordance with accounting principles generally accepted in the United States requires that management make a number of assumptions and informed estimates that affect the reported amounts of assets, liabilities, revenues and expenses in our financial statements and accompanying notes. Management bases its estimates on historical information and assumptions believed to be reasonable. Although these estimates are based on management's best knowledge of current events and circumstances that may impact us in the future, they are inherently uncertain and actual results may differ materially from these estimates.

Our critical accounting policies are those that affect our financial statements materially and involve a significant level of judgment by management. Our critical accounting policies regarding revenue recognition are in the following areas: license and royalty agreements, manufacturing contracts, contract services and grant revenues. Our critical accounting policies also include recognition of research and development expenses and the valuation of long-lived and intangible assets.

We describe our significant accounting policies in Note 1 of the Notes to Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2017. We discuss our critical accounting policies and estimates in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2017.

#### Recent Accounting Pronouncements

For information on the recent accounting pronouncements which may impact our business, see Note 1 of the Notes to Financial Statements included in this Report.

#### Results of Operations

##### Three Months Ended September 30, 2018, Compared with Three Months Ended September 30, 2017

**Total Revenues.** Total revenues decreased \$3.2 million, or 98.5%, to \$47,000 for the three months ended September 30, 2018, from \$3.2 million for the three months ended September 30, 2017. This decrease was primarily due to a decrease in Astellas contract revenues due to the termination of the ASP0113 program in January 2018.

**Research and Development Expenses.** Research and development expenses decreased \$0.5 million, or 16.7%, to \$2.5 million for the three months ended September 30, 2018, from \$3.0 million for the three months ended September 30, 2017. This decrease was primarily due to higher VL2397 clinical trial costs in 2017 due to start-up of the trial.

**Manufacturing and Production Expenses.** Manufacturing and production expenses decreased to \$0 for the three months ended September 30, 2018, from \$1.8 million for the three months ended September 30, 2017. This decrease was due to the termination of the ASP0113 program in January 2018. The termination resulted in a decrease in manufacturing activity and a headcount reduction. In February 2018, we discontinued all manufacturing and production activities and, as a result, we do not expect to incur any future manufacturing or production expenses.

General and Administrative Expenses. General and administrative expenses were \$1.6 million for the three months ended September 30, 2018 and September 30, 2017. Wages and benefits decreased \$0.2 million in the three months ended September 30, 2018 due to headcount reduction, offset by an increase of \$0.2 million due to the allocation of additional overhead to general and administrative expenses as a result of the closure of our manufacturing facility.

Investment and Other Income, Net. Investment and other income, net, increased \$2.5 million to \$2.6 million for the three months ended September 30, 2018, from \$0.1 million for the three months ended September 30, 2017 primarily due to a \$2.3 million gain on the sale of assets to Genopis.

Nine Months Ended September 30, 2018, Compared with Nine Months Ended September 30, 2017

**Total Revenues.** Total revenues decreased \$8.4 million, or 84.8%, to \$1.5 million for the nine months ended September 30, 2018, from \$9.9 million for the nine months ended September 30, 2017. This decrease was primarily due to a decrease in Astellas contract revenues due to the termination of the ASP0113 program in January 2018.

**Research and Development Expenses.** Research and development expenses decreased \$0.2 million, or 1.7%, to \$9.8 million for the nine months ended September 30, 2018, from \$10.0 million for the nine months ended September 30, 2017. This decrease was primarily due to lower HSV-2 clinical trial costs, offset by higher patent expenses as a result of the write-off of capitalized patent costs associated with the terminated ASP0113 program and the recognition of restructuring costs in January 2018.

**Manufacturing and Production Expenses.** Manufacturing and production expenses decreased \$3.3 million, or 69.4%, to \$1.4 million for the nine months ended September 30, 2018, from \$4.7 million for the nine months ended September 30, 2017. This decrease was primarily due to a decrease in salaries and benefits and allocated overhead due to the termination of the ASP0113 program and the closure of our manufacturing facility. These decreases were partially offset by a net decrease in deferred costs capitalized during the nine months ended September 30, 2018 related to materials manufactured under our supply agreement with Astellas. We have discontinued all manufacturing and production activities and, as a result, we do not expect to incur any future manufacturing or production expenses.

**General and Administrative Expenses.** General and administrative expenses increased \$1.3 million, or 26.4%, to \$6.0 million for the nine months ended September 30, 2018, from \$4.7 million for the nine months ended September 30, 2017. This increase was primarily due to the allocation of additional overhead to general and administrative expenses as a result of the closure of our manufacturing facility.

**Investment and Other Income, Net.** Investment and other income, net, increased \$2.7 million to \$3.0 million for the nine months ended September 30, 2018, from \$0.3 million for the nine months ended September 30, 2017 primarily due to a \$2.3 million gain on the sale of assets to Genopis.

#### Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private placements and public offerings of equity securities, and revenues from our operations. Cash, cash equivalents, marketable securities, and long-term investments, including restricted cash, totaled \$52.8 million at September 30, 2018, compared with \$62.9 million at December 31, 2017. The decrease in our cash, cash equivalents and marketable securities for the nine months ended September 30, 2018, was primarily the result of the use of cash to fund our operations.

Net cash used in operating activities was \$11.9 million and \$6.9 million for the nine months ended September 30, 2018 and 2017, respectively. The increase in net cash used in operating activities for the nine months ended September 30, 2018, compared with the prior year period, was primarily the result of the payment of employee termination benefits and a decrease in cash receipts from Astellas due to the termination of the ASP0113 program.

Net cash (used in) provided by investing activities was \$(0.9) million and \$7.8 million for the nine months ended September 30, 2018 and 2017, respectively. The increase in net cash used in investing activities for the nine months ended September 30, 2018, compared with the prior year period, was primarily the result of an increase of \$10.3 million in net purchases of marketable securities, offset by \$1.7 million received for the sale of assets to Genopis.

Net cash provided by financing activities was \$0.0 million and \$1.1 million for the nine months ended September 30, 2018 and 2017, respectively. The decrease in net cash provided by financing activities for the nine months ended

September 30, 2018, compared with the prior year period, was the result of \$1.1 million in net proceeds from the sale of our common stock during the nine months ended September 30, 2017.

A discussion of our exposure to auction rate securities is included in Part I, Item 3 of this Report under the heading “Quantitative and Qualitative Disclosures About Market Risk.”

In the long-term, we expect to incur substantial additional research and development expenses and general and administrative expenses, including increases in costs related to personnel, preclinical and clinical testing, outside services, intellectual property and possible commercialization. Our future capital requirements will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of preclinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting, enforcing and defending patent claims, the impact of

competing technological and market developments, the cost of manufacturing scale-up and validation, and possible commercialization activities and arrangements. We may seek additional funding through research and development relationships with suitable potential corporate collaborators. We may also seek additional funding through public or private financings. For example, in November 2017, we sold 9,194,286 shares of our common stock and pre-funded warrants to purchase 7,234,285 shares of our common stock in a public offering for gross proceeds of approximately \$28.7 million.

We currently have on file an effective shelf registration statement that allows us to raise up to \$40.0 million from the sale of common stock, preferred stock, debt securities and/or warrants, subject to limitations on the amount of securities that we may sell under the registration statement in any 12-month period.

Despite our current shelf registration statement, additional financing through these or other means may not be available on favorable terms or at all. If additional financing is not available, we anticipate that our available cash and existing sources of funding will be adequate to satisfy our cash needs at least through December 31, 2019.

#### Contractual Obligations

We may be required to make future payments to our licensors based on the achievement of milestones set forth in various in-licensing agreements. In most cases, these milestone payments are based on the achievement of development or regulatory milestones, including the exercise of options to obtain licenses related to specific disease targets, commencement of various phases of clinical trials, filing of product license applications, approval of product licenses from the FDA or a foreign regulatory agency, and the first commercial sale of a related product. Payment for the achievement of milestones under our in-license agreements is highly speculative and subject to a number of contingencies.

The aggregate amount of additional milestone payments that we could be required to pay under our active in-license agreements in place at September 30, 2018, is approximately \$99.0 million. These amounts assume that all remaining milestones associated with the milestone payments are met. In the event that product license approval for any of the related products is obtained, we may be required to make royalty payments in addition to these milestone payments. Although we believe that some of the milestones contained in our in-license agreements may be achieved, it is highly unlikely that a significant number of them will be achieved. Because the milestones are contingent, we are not in a position to reasonably estimate how much, if any, of the potential milestone payments will ultimately be paid, or when. Additionally, under the in-license agreements, many of the milestone events are related to progress in clinical trials which will take several years to achieve.

In addition, under the indemnification agreements with our officers and directors, we have agreed to indemnify those individuals for any expenses and liabilities in the event of a threatened, pending or actual investigation, lawsuit, or criminal or investigative proceeding.

We have an employment agreement that contains severance arrangements with our chief executive officer, or CEO, and severance agreements with six of our other employees. Under the agreement with our CEO, we are obligated to pay severance if we terminate the CEO's employment without "cause," or if the CEO resigns for "good reason," as defined in the agreement, within the periods set forth therein. The severance for the CEO consists of continued base salary payments at the then-current rate, including the payment of health insurance premiums for 18 months, plus a payment equal to one and one-half times the CEO's cash bonus in the previous year. In addition, the CEO receives accelerated vesting on all his unvested stock awards as if he had remained employed by us for 18 months from the date of termination. In the event that the termination occurs within 24 months of a "change in control," as defined in the agreement, the severance for the CEO consists of a lump sum payment equal to 24 months of base salary at the then-current rate, the payment of health insurance premiums for 18 months, plus a payment equal to one and one-half



times the CEO's cash bonus in the previous year. In addition, all outstanding unvested stock awards will vest immediately. Under the agreements with our other six executives, we are obligated to pay severance if we terminate the executive's employment without "cause," or if the executive resigns for "good reason," as defined in the agreements, within the periods set forth therein. The severance for three of these executives consists of a lump-sum payment equal to 12 months of base salary at the then-current rate, including the payment of health insurance premiums for 12 months, plus a payment equal to the executive's cash bonus in the previous year. In addition, the executive receives accelerated vesting on all his unvested stock awards as if he had remained employed by us for 12 months from the date of termination. In the event that the termination occurs within 12 months of a "change in control," as defined in the agreements, the severance consists of a lump sum payment equal to 18 months of base salary at the then-current rate, the payment of health insurance premiums for 12 months, plus a payment equal to the executive's cash bonus in the previous year. In addition, all outstanding unvested stock awards will vest immediately. The severance for the remaining three employees consists of a lump-sum payment equal to six months of base salary at the then-current rate, including the payment of health insurance premiums for six months, plus a bonus payment of \$75,000. The maximum payments due under these agreements would have been \$4.0 million if each such employee was terminated at September 30, 2018.

#### Off-Balance Sheet Arrangements

As of September 30, 2018, we did not have any off-balance sheet arrangements.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are subject to interest rate risk. Our investment portfolio is maintained in accordance with our investment policy which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. Our investment portfolio consists of cash equivalents, both restricted and non-restricted, marketable securities and long-term investments. The average maturity of our investments, excluding our auction rate securities, is approximately four months. Our investments are classified as available-for-sale securities.

To assess our interest rate risk, we performed a sensitivity analysis projecting an ending fair value of our cash equivalents and current marketable securities using the following assumptions: a four-month average maturity and a 150-basis-point increase in interest rates. This pro forma fair value would have been \$0.2 million lower than the reported fair value of our investments at September 30, 2018.

Our investment securities consist of auction rate securities, corporate debt securities and government agency securities. As of September 30, 2018, our long-term investments included a (at par value) \$2.5 million auction rate security secured by municipal bonds. At September 30, 2018, the auction rate security we held maintained a Standard and Poor's credit rating of BBB. Our auction rate security is a debt instrument with a long-term maturity and with an interest rate that is reset in short intervals through auctions. The conditions in the global credit markets have prevented some investors from liquidating their holdings of auction rate securities because the amount of securities submitted for sale has exceeded the amount of purchase orders for such securities. If there is insufficient demand for the securities at the time of an auction, the auction may not be completed and the interest rates may be reset to predetermined higher rates. When auctions for these securities fail, the investments may not be readily convertible to cash until a future auction of these investments is successful or they are redeemed or mature.

Since February 2008, there has been insufficient demand at auction for our auction rate security held at September 30, 2018. As a result, this security is currently not liquid, and we could be required to hold it until it is redeemed by the issuer or to maturity. As of September 30, 2018, we had recognized \$0.4 million of losses related to the auction rate security by adjusting its carrying value. The market value of the security has partially recovered from the lows that created the losses. As of September 30, 2018, we had recorded cumulative unrealized gains of \$0.4 million. Any future decline in market value may result in additional losses being recognized.

The valuation of our auction rate security is subject to uncertainties that are difficult to predict. The fair value of the security is estimated utilizing a discounted cash flow analysis or other type of valuation model as of September 30, 2018. The key drivers of the valuation model include the expected term, collateralization underlying the security investments, the creditworthiness of the counterparty, the timing of expected future cash flows, discount rates, and the expected holding period. The security was also compared, when possible, to other observable market data for securities with similar characteristics.

In the event we need to access the funds that are not currently liquid, we will not be able to do so without the possible loss of principal, until a future auction for this investment is successful or it is redeemed by the issuer or it matures. If we are unable to sell the security in the market or it is not redeemed, then we may be required to hold it until 2038 when it matures. We do not anticipate a need to access these funds for operational purposes for the foreseeable future. We will continue to monitor and evaluate the investment on an ongoing basis for impairment. Based on our ability to access our cash and other short-term investments, our expected operating cash flows, and our other sources of cash, we do not anticipate that the potential illiquidity of this investment will affect our ability to execute our current business plan.

ITEM 4. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive and financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) promulgated under the Exchange Act as of the end of the period covered by this Report. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective and were operating at a reasonable assurance level as of September 30, 2018.

Changes in Internal Control over Financial Reporting

Management has determined that there were no significant changes in our internal control over financial reporting that occurred during the three months ended September 30, 2018, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### ITEM 1A. RISK FACTORS

You should consider carefully the risks described below, together with all of the other information included in this Report and in our other filings with the SEC, before deciding whether to invest in or continue to hold our common stock. The risks described below are all material risks currently known, expected or reasonably foreseeable by us. If any of these risks actually occur, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

The risk factors set forth below with an asterisk (\*) next to the title are new risk factors or risk factors containing changes, including material changes, from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC.

(\*)None of our product candidates has been approved for sale, and we have a limited number of product candidates in development. If we do not develop commercially successful products, we may be forced to curtail or cease operations.

All of our product candidates are either in research or development. We must conduct a substantial amount of additional research and development before any U.S. or foreign regulatory authority will approve any of our product candidates. Limited data exist regarding the efficacy of DNA vaccines or therapeutics compared with conventional vaccines or therapeutics. Results of our research and development activities may indicate that our product candidates are unsafe or ineffective. In this case, we may stop development and regulatory authorities will not approve them. For example, earlier this year, development of ASP0113, an investigational CMV therapeutic vaccine developed by us and based on our DNA delivery technology, was terminated following negative results from a Phase 3 trial, and in June 2018 we terminated further development of our HSV-2 vaccine candidate following negative results from a Phase 2 trial.

We have an on-going Phase 2 clinical trial of VL-2397, our novel antifungal candidate, but the results of this trial may not be positive and the favorable results or trends observed in our previously completed clinical trial for this product candidate may not continue in the Phase 2 clinical trial. Our ongoing Phase 2 clinical trial and any future trial may not demonstrate sufficient safety or efficacy to support further product development. Because we have a limited number of product candidates, if we experience a significant delay, set-back or failure in the development of any of our product candidates, it could have a material adverse impact on our business prospects.

Even if we complete clinical development, the results of clinical trials may not support approval by the FDA or comparable foreign agencies or, if approved, our products may not be commercially successful, particularly if they do not gain market acceptance among physicians, patients, healthcare payers and relevant medical communities. If we fail to develop and commercialize our product candidates, we may be forced to curtail or cease operations.

(\*)Our clinical trials or those of our partners may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and

efficacy profile despite having progressed through preclinical studies and initial clinical trials. We and our licensees have in the past suffered significant setbacks in advanced clinical trials due to lack of efficacy, notwithstanding promising results in earlier trials. For example, in 2013 we ceased development of Allovectin<sup>®</sup>, an investigational intratumoral cancer immunotherapy, following negative results from a Phase 3 trial. In June 2015 and in June 2018, we announced that our HSV-2 product candidate did not meet the primary endpoint in a Phase 1/2 and a Phase 2 clinical study, respectively. In September 2016, we and Astellas announced that ASP0113 did not meet its primary endpoint in a Phase 2 clinical study in kidney transplant patients and in January 2018, we and Astellas announced that ASP0113 did not meet its primary endpoint in a Phase 3 clinical study in CMV end organ disease, after which Astellas informed us that it was terminating further development. Most product candidates that commence clinical trials are never approved as products.

There are a number of factors that could cause a clinical study to fail or be delayed, including:

- the clinical study may not be designed properly or may produce negative or inconclusive results;
- regulators, monitoring boards or other entities may not grant permission to start a clinical study or require that we hold, suspend or terminate clinical research for safety, ethical or regulatory reasons, including adverse events, or AEs, reported during the trial;
- we may encounter delays in reaching agreement with regulators on final clinical study design;
- we may decide, or regulators may require us, to conduct additional preclinical testing or clinical studies;
- enrollment in our clinical studies may be slower than we anticipate;
- we may encounter delays in engaging prospective clinical research organizations and clinical trial sites to conduct our clinical studies or may have disagreements with these entities;
- the cost of our clinical studies may be greater than we anticipate;
- we may not be able to raise funding necessary to initiate or complete our on-going or planned clinical studies; and
- the supply or quality of our product candidates or other materials necessary to conduct our clinical studies may be insufficient, inadequate or delayed.

If initiation or completion of our clinical studies or those of our collaborators are delayed, our development costs may increase, the approval process for our product candidates would be delayed, any periods during which we may have the exclusive right to commercialize our product candidates may be reduced and our competitors may have more time to bring products to market or establish market positions.

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

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of the approved labeling, or result in significant negative consequences following marketing approval, if any.

There is risk that our product candidates may induce AEs, many of which may be unknown at this time. If an unacceptable frequency and/or severity of AEs are reported in clinical studies for our product candidates, our ability to obtain regulatory approval for may be negatively impacted. Even if we receive regulatory approval, AEs associated with any approved products could have significant negative consequences, including:

- regulatory authorities may approve the product only with a risk evaluation and mitigation strategy (REMS), potentially with restrictions on distribution and other elements to assure safe use (ETASU);
- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in a form of a modified REMS;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or to conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining regulatory approvals or market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.



(\* )Our revenues have depended on the development and commercialization of products in collaboration with others to whom we have licensed our technologies. If we are unable to find additional collaborators or licensees, or if future collaborators or licensees do not successfully develop and commercialize products covered by such arrangements, we may not be able to derive collaboration and licensing revenues, we may lose opportunities to validate our DNA delivery technologies, or we may be forced to curtail our development and commercialization efforts in these areas.

We have licensed, and may continue to license, our technologies to corporate collaborators and licensees for the research, development and commercialization of specified product candidates. Our revenues have partially depended upon the ability of these collaborators and licensees to successfully develop and commercialize products covered by these arrangements. For example, we previously entered into license agreements with Astellas related to ASP0113, an investigational CMV therapeutic vaccine, and these agreements were subsequently terminated following negative results from a Phase 3 clinical trial. Prior to the termination, the revenue received by us under this collaboration accounted for a significant amount of our revenue generated over the past three years. During the years ended December 31, 2017, 2016 and 2015, we recognized \$0.3 million, \$1.5 million and \$1.8 million, respectively, of revenue related to license fees, and \$13.5 million, \$12.5 million and \$14.7 million, respectively, of revenue related to contract services and product supply. During the nine months ended September 30, 2018 and 2017, we recognized \$1.2 million and \$9.3 million, respectively, of revenue from Astellas. If we are unable to enter into new collaboration or licensing arrangements with third parties, we will not receive additional revenues from these sources and our financial results will be negatively impacted. The development and commercialization efforts of our collaborators and licensees are subject to the same risks and uncertainties described above with respect to our independently developed product candidates.

Some collaborators or licensees may not succeed in their product development efforts. It is possible that our collaborators or licensees may be unable to obtain regulatory approval of product candidates using our technologies or successfully market and commercialize any such products for which regulatory approval is obtained. Other collaborators or licensees may not devote sufficient time or resources to the programs covered by these arrangements, and we may have limited or no control over the time or resources allocated by these collaborators or licensees to these programs. The occurrence of any of these events may cause us to derive little or no revenue from these arrangements, lose opportunities to validate our DNA delivery technologies, or force us to curtail or cease our development and commercialization efforts in these areas.

Our collaborators and licensees may breach or terminate their agreements with us, including some that may terminate their agreements without cause at any time subject to certain prior written notice requirements, and we may be unsuccessful in entering into and maintaining other collaborative arrangements for the development and commercialization of products using our technologies. If we are unable to maintain existing collaboration arrangements or enter into new ones, our ability to generate licensing, milestone or royalty revenues would be materially impaired.

Some of our independent product candidates and some of those under development by our sublicensees incorporate technologies we have licensed from others. If we are unable to retain rights to use these technologies, we or our sublicensees may not be able to market products incorporating these technologies on a commercially feasible basis, if at all.

We have licensed certain technologies from corporate collaborators and research institutions, and sublicensed certain of such technologies to others, for use in the research, development and commercialization of product candidates. Our product development efforts and those of our sublicensees partially depend upon continued access to these technologies. For example, we or our licensors may breach or terminate our agreements, or disagree on interpretations of those agreements, which could prevent continued access to these technologies. If we were unable to resolve such matters on satisfactory terms, or at all, we or our sublicensees may be unable to develop and commercialize our



products, and we may be forced to curtail or cease operations.

We licensed rights to patents and know-how for VL-2397 from Astellas pursuant to an in-license agreement that contains obligations to pay Astellas regulatory and sales milestone payments relating to VL-2397, as well as royalties on net sales of VL-2397. If we fail to make a required payment to Astellas or otherwise materially breach our in-license agreement with Astellas and do not cure the failure within the required time period, Astellas may be able to terminate the license to the VL-2397 patents and know-how, which would have a material adverse effect on our business, financial condition and results of operations.

(\* )We have a history of net losses. We expect to continue to incur net losses and we may not achieve or maintain profitability.

To date, we have not sold, or received approval to sell, any pharmaceutical products. We do not expect to sell any pharmaceutical products for at least the next several years. Our net losses were approximately \$13.0 million, \$9.0 million and \$9.2 million for the years ended December 31, 2017, 2016 and 2015, respectively. As of September 30, 2018, we had incurred cumulative net losses totaling approximately \$438.5 million. Moreover, we expect that our net losses will continue and may increase for the foreseeable future. We may not be able to achieve projected results if we generate lower revenues or receive lower investment income than expected, or we incur greater expenses than expected, or all of the above. Over the past several years our revenues have been largely dependent on manufacturing and research services performed under our license agreement with Astellas. In February

2018, Astellas exercised its rights to terminate the ASP0113 license agreements, and we will therefore not receive any further payments under these agreements. We may never generate sufficient product revenue to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses, and losses, some of which could be significant.

(\*We may need additional capital in the future. If additional capital is not available, we may have to curtail or cease operations.

We may need to raise more money to continue the research and development necessary to bring our products to market and to establish marketing and additional manufacturing capabilities. We may seek additional funds through public and private stock offerings, government contracts and grants, arrangements with corporate collaborators, borrowings under lines of credit or other sources. We currently have on file a shelf registration statement that allows us to raise up to an aggregate of \$40.0 million from the sale of common stock, preferred stock, debt securities and/or warrants, subject to limitations on the amount of securities we may sell under the registration statement in any 12-month period. However, we may not be able to raise additional funds on favorable terms, or at all. Conditions in the credit markets and the financial services industry may make equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants, such as limitations on our ability to incur additional indebtedness and other operating restrictions that could adversely impact our ability to conduct our business.

If we are unable to obtain additional funds, we may have to scale back our development of new products, reduce our workforce or license to others products or technologies that we otherwise would seek to commercialize ourselves. The amount of money we may need would depend on many factors, including:

- The progress of our research and development programs;
- The scope and results of our preclinical studies and clinical trials;
- The amount of our legal expenses and any settlement or damages payments associated with litigation; and
- The time and costs involved in: obtaining necessary regulatory approvals; filing, prosecuting and enforcing patent claims; scaling up our manufacturing capabilities; and the commercial arrangements we may establish.

(\*If we do not realize the expected benefits and successfully manage the transition from the restructuring that we announced in January 2018, our operations and financial condition may be negatively impacted.

In January 2018, we implemented a restructuring designed to conserve capital and focus our efforts on our VL-2397 antifungal drug product candidate and VCL-HB01 vaccine candidate. In addition, in July 2018, we entered into an agreement with Genopis, Inc., or Genopis, to sell our idle manufacturing assets and sublease our manufacturing facilities space. If we are unable to realize the expected operational efficiencies and cost savings from our restructuring and sale of our manufacturing assets, our operating results and financial condition would be adversely affected. We cannot guarantee that we will not have to undertake additional restructuring activities or that any of our restructuring efforts will be successful.

We will also need to effectively manage our operations and facilities in order to advance our drug development programs and support our collaboration arrangements. Following our January 2018 restructuring and July 2018 sale of our manufacturing assets, it is possible that our infrastructure may be inadequate to support our future efforts and business strategy or to maintain effective operational, financial and management controls and reporting systems and procedures. If we cannot successfully manage the transition of our restructured operations, we may be unsuccessful in executing our business strategy.

(\*We are reviewing strategic alternatives and there can be no assurance that we will be successful in identifying or completing any strategic transaction, that any such strategic transaction will result in additional value for our stockholders or that the process will not have an adverse impact on our business.

We recently announced that our board of directors is conducting a review of strategic alternatives and that we had retained MTS Health Partners, L.P. as our financial advisor to assist in the review process. These alternatives could include, but are not limited to, merger or acquisition transactions, issuing or transferring shares of our common stock, or the license, purchase or sale of specific assets, in addition to other potential actions aimed at increasing stockholder value. There can be no assurance that the review of strategic alternatives will result in the identification or consummation of any transaction. Our board of directors may also determine that our most effective strategy is to continue to execute on our current development strategy. The process of reviewing strategic alternatives may be time consuming and disruptive to our business operations and, if we are unable to effectively manage the process, our business, financial condition and results of operations could be adversely affected. We could incur substantial expenses associated with identifying, evaluating and negotiating potential strategic alternatives. There can be no assurance that any potential transaction or

other strategic alternative, if consummated, will provide greater value to our stockholders than that reflected in the current price of our common stock. Until the review process is concluded, perceived uncertainties related to our future may result in the loss of potential business opportunities and volatility in the market price of our common stock and may make it more difficult for us to attract and retain qualified personnel and business partners.

The regulatory approval process is expensive, time consuming and uncertain, which may prevent us and our collaborators and licensees from obtaining required approvals for the commercialization of our products.

Our product candidates under development and those of our collaborators and licensees are subject to extensive and rigorous regulations by numerous governmental authorities in the United States and other countries. The regulatory approval process takes many years and will require us to expend substantial resources.

U.S. or foreign regulations evolve and could prevent or delay regulatory approval of our products or limit our and our collaborators and licensees' ability to develop and commercialize our products. Delays could:

- ◆ Impose costly procedures on our activities and those of our collaborators and licensees;
- ◆ Delay or prevent our receipt of developmental or commercial milestones from our collaborators and licensees;
  - Diminish any competitive advantages that we or our products attain; or
- ◆ Otherwise negatively affect our results of operations and cash flows.

We have no experience in submitting a BLA or an NDA to the FDA. Because these applications must be submitted to and approved by the FDA before any of our product candidates may be commercialized, our lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, which in turn would delay or prevent us from commercializing those products. Similarly, our lack of experience with respect to obtaining regulatory approvals in countries other than the United States may impede our ability to commercialize our products in those countries.

The FDA and comparable foreign regulatory bodies will regulate separately each DNA product containing a particular gene depending on its intended use. Presently, to commercialize any product we and our collaborators and licensees must file a regulatory application for each proposed use. We and our collaborators and licensees must conduct clinical studies to demonstrate the safety and efficacy of the product necessary to obtain FDA or foreign regulatory authority approval. The results obtained so far in our clinical trials and those of our collaborators and licensees may not be replicated in ongoing or future trials, or the results may be subject to varying interpretation on whether they are sufficient to support approval for commercialization. This may prevent any of our product candidates from receiving approval for commercial sale.

If any of our product candidates receive regulatory approval, the FDA or other foreign regulatory agencies may still impose significant restrictions on the indicated uses or marketing of our product candidates or impose ongoing requirements for potentially costly post-approval studies. In addition, regulatory agencies subject a product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product or a product class, including AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or product class, our collaborators and licensees or us, including requiring withdrawal of a product from the market. Our product candidates will also be subject to ongoing FDA and other foreign regulatory agency requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the product. If we or our collaborators and licensees fail to maintain regulatory compliance after receiving marketing approval, we or our collaborators and licensees may be unable to market our products and our business could suffer.

Adverse events or the perception of adverse events in the field of gene therapy, or with respect to our product candidates, may negatively impact regulatory approval or public perception of our products.

The commercial success of some of our product candidates will depend in part on public acceptance of the use of gene therapy for preventing or treating human diseases. Serious AEs, including patient deaths, have occurred in clinical trials utilizing viral delivery systems to deliver therapeutic genes to the patient's targeted cells. Although none of our current products or studies utilize viral delivery systems, these AEs, as well as any other AEs in the field of gene therapy that may occur in the future, may negatively influence public perception of gene therapy in general. If public perception is influenced by claims that gene therapy is unsafe, our product candidates may not be accepted by the general public or the medical community.

Future AEs in gene therapy or the biotechnology industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approval of our potential products. Any increased scrutiny could delay or increase the costs of our product development efforts or clinical trials. In addition, any AEs that may occur in our clinical trials and any resulting publicity may cause regulatory delays or otherwise affect our product development efforts or clinical trials.

Some of our potential products may be administered to patients who are suffering from, or are vulnerable to, serious diseases or other conditions which can themselves be life-threatening and often result in the death of the patient. Patient deaths in our clinical trials, even if caused by pre-existing diseases or conditions, could negatively affect the perception of our product candidates. In addition, although we do not believe our vaccine candidates could cause the diseases they are designed to protect against, a temporal relationship between vaccination and disease onset could be perceived as causal. Some of our products are designed to stimulate immune responses, and those responses, if particularly strong or uncontrolled, could result in local or systemic AEs, including latent AEs.

(\* )Our patents and proprietary rights may not provide us with any benefit and the patents of others may prevent us from commercializing our products.

As of September 30, 2018, we were the assignee or co-assignee of 34 issued U.S. and foreign patents. We maintain our issued patents by paying maintenance fees to the patent office in each country when due. Where appropriate, we participate in legal proceedings to vigorously defend against the revocation or withdrawal of our patents. The scope and nature of these proceedings generally differ depending on the country in which they are initiated. If we are not successful in defending our patents, we may lose all or part of our proprietary rights related to those patents in these geographic regions.

As of September 30, 2018, we were also prosecuting one pending patent application in the United States, not including patent applications for which we are a co-assignee and that are being prosecuted by our partners.

We may not receive any patents from our current patent applications. Issued patents provide exclusivity for only a limited time period, after which they no longer serve to protect proprietary technologies or to provide any commercial advantage. Moreover, if patents are issued to us, governmental authorities may not allow claims sufficient to protect our technologies and products. Others may also challenge or seek to circumvent or invalidate our patents. In that event, the rights granted under our patents may be inadequate to protect our proprietary technologies or to provide any commercial advantage.

An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Some components of our gene-based product candidates are, or may become, patented by others. As a result, we may be required to obtain licenses to conduct research, to manufacture, or to market such products. Licenses may not be available on commercially reasonable terms, or at all, which may impede our ability to commercialize our products.

The legal proceedings to obtain and defend patents, and litigation of third-party claims of intellectual property infringement, could require us to spend money and could impair our operations.

Our and our collaborators' success will depend in part on our, or our collaborators', ability to obtain patent protection for our products and processes, both in the United States and in other countries. The patent positions of biotechnology and pharmaceutical companies, however, can be highly uncertain and involve complex legal and factual questions. Therefore, it is difficult to predict the breadth of claims allowed in the biotechnology and pharmaceutical fields.

We also rely on confidentiality agreements with our corporate collaborators, employees, consultants and certain contractors to protect our proprietary technologies. However, these agreements may be breached and we may not have adequate remedies for such breaches. In addition, our trade secrets may otherwise become known or independently discovered by our competitors.

Protecting intellectual property rights can be very expensive. Litigation may be necessary to enforce patents issued to us or to determine the scope and validity of third-party proprietary rights. If we or, as applicable, our commercialization partners, including Astellas pursuant to its first right to enforce patents licensed to it under our license agreements, choose to go to court to stop someone else from using our inventions, that individual or company has the right to ask the court to rule that the underlying patents are invalid and/or should not be enforced against that third party. Moreover, if a competitor were to file a patent application claiming technology also invented by us or our collaborators or licensees, we would have to participate in an interference proceeding before the U.S. Patent and Trademark Office to determine the priority of the invention. We or our collaborators or licensees may be drawn into interferences with third parties or may have to provoke interferences ourselves to unblock third-party patent rights to allow us or our collaborators or licensees to commercialize products based on our technologies. Litigation could result in substantial costs and the diversion of management's efforts regardless of the results of the litigation. An unfavorable result in litigation could subject us to significant liabilities to third parties, require disputed rights to be licensed or require us to cease using some technologies.

Our products and processes may infringe, or be found to infringe, patents not owned or controlled by us. Patents held by others may require us to alter our products or processes, obtain licenses, or stop activities. If relevant claims of third-party patents are upheld as valid and enforceable, we or our collaborators or licensees could be prevented from practicing the subject matter claimed in the patents, or may be required to obtain licenses or redesign our products or processes to avoid infringement. In addition, we or our collaborators or licensees could be required to pay money damages. A number of genetic sequences or proteins encoded by genetic sequences that we are investigating are, or may become, patented by others. As a result, we or our collaborators or licensees may have to obtain licenses to test, use or market these products. Our business will suffer if we or our collaborators or licensees are not able to obtain licenses at all or on terms commercially reasonable to us or them and we or they are not able to redesign our products or processes to avoid infringement.

We have incurred costs in several legal proceedings involving our intellectual property rights in Europe, Japan and Canada. We may continue to incur costs to defend and prosecute patents and patent applications in these and other regions.

Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with companies, including major pharmaceutical and biotechnology firms that are pursuing other forms of treatment or prevention for diseases that we target. We also may experience competition from companies that have acquired or may acquire technologies from universities and other research institutions. As these companies develop their technologies, they may develop proprietary positions which may prevent us from successfully commercializing products.

Some of our competitors are established companies with greater financial and other resources than we have. Other companies may succeed in developing products and obtaining regulatory approval from the FDA or comparable foreign agencies faster than we do, or in developing products that are more effective than ours. Research and development by others may seek to render our technologies or products obsolete or noncompetitive or result in treatments or cures superior to any therapeutics developed by us.

The internet site [ClinicalTrials.gov](http://ClinicalTrials.gov) provides public access to information on clinical trials and their results for a wide range of diseases and conditions. Future disclosures of such confidential commercial information may result in loss of advantage of competitive secrets.

If we lose our key personnel or are unable to attract and retain additional personnel, we may not be able to achieve our business objectives.

We are highly dependent on our principal scientific, clinical, regulatory and management personnel, including Vijay B. Samant, our President and Chief Executive Officer. The loss of the services of these individuals might significantly delay or prevent the achievement of our objectives. For example, due to the loss of various scientific personnel as a result of our January 2018 restructuring, we may be less effective in advancing our product candidates. We do not maintain “key person” life insurance on any of our personnel. We depend on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We face competition for qualified individuals from other companies, academic institutions, government entities and other organizations in attracting and retaining personnel. To pursue our product development plans, we may need to hire additional management personnel and additional scientific personnel to perform research and development, as well as additional personnel with expertise in clinical trials, government regulation and manufacturing. However, due to the reasons noted above, we may not be successful in hiring or retaining qualified personnel and therefore we may not be able to achieve our business objectives.



(\* )We currently depend on third parties to conduct our clinical trials and manufacture our product candidates.

We rely on third parties, including clinical research organizations, medical institutions and contract laboratories, to perform critical services for us in connection with our clinical trials. These third parties are responsible for many aspects of the trials, including finding and enrolling subjects for testing and administering the trials. Although we rely on these third parties to conduct our clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its protocol and applicable regulations, including good clinical practices established by the FDA and foreign regulatory authorities, which govern the conduct, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that trial subjects are adequately informed of the potential risks associated with participating in clinical trials. Our reliance on third parties does not relieve us of the responsibility to ensure these requirements are met. These third parties may not comply with all regulatory and contractual requirements or may not otherwise perform their services in a timely or acceptable manner, and we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. In addition, if such third parties fail to perform their obligations in compliance with our clinical trial protocols or applicable good clinical practice regulations, our clinical trials may not meet regulatory requirements or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the product candidate being tested in such trials. These risks also apply to the development activities of our collaborators and licensees, and we do not control our collaborators' and licensees' research and development, clinical trials or regulatory activities.

We also depend on collaborators, licensees or other third parties to manufacture our product candidates, and this reliance has increased following the sale of our manufacturing assets in July 2018. There are a limited number of third parties that could manufacture our product candidates. We may be unable to enter into any arrangement for the manufacture of our product candidates, and any arrangement we secure may not meet our requirements for manufacturing quality or quantity. Our dependence on third parties for the manufacture of our product candidates may also reduce our profit margins and our ability to develop and deliver products in a timely manner.

We have no marketing or sales experience, and if we are unable to develop our own sales and marketing capability, we may not be successful in commercializing our products.

Our current strategy is to market our proprietary products directly in the United States, but we currently do not possess pharmaceutical marketing or sales capabilities. To market and sell our proprietary products, we will need to develop a sales force and a marketing group with relevant pharmaceutical industry experience, or make appropriate arrangements with strategic partners to market and sell these products. Developing a marketing and sales force is expensive and time-consuming and could delay any product launch. If we are unable to successfully employ qualified marketing and sales personnel or develop other sales and marketing capabilities, we may not be able to generate sufficient product revenue to become profitable.

If we fail to comply with federal and state healthcare laws, including fraud and abuse, transparency, and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors 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 any product for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid;
- the federal false claims and civil monetary penalties laws, including the civil False Claims Act and its qui tam or whistleblower provisions, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes obligations, including mandatory contractual terms, on certain types of individuals and entities and their respective business associates with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable

manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members; and analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by third-party payors, 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 federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians, other healthcare providers, and healthcare entities, or marketing expenditures; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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Efforts to ensure that our current and future business arrangements with third parties will 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 healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity obligations, such as additional reporting and/or oversight requirements if we become subject to a corporate integrity agreement or similar agreement with a governmental authority, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and 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.

Healthcare reform and restrictions on reimbursement may limit our returns on potential products.

Our ability to earn sufficient returns on our products will depend in part on how much, if any, reimbursement for our products and related treatments will be available from:

- ◆ Government health administration authorities;
- ◆ Government agencies procuring biodefense products for military or public use, including some for which we may become a sole-source vendor;
- ◆ Private health coverage insurers;
- ◆ Managed care organizations; and
- ◆ Other organizations.

Such third-party payers decide which drugs and treatments they will cover and the amount of reimbursement, and no uniform policy exists. Therefore, coverage and reimbursement for products can differ significantly from payer to payer. Further, the coverage determination process is a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payer separately. Patients rely on third-party payers to reimburse all or part of the cost associated with treatment. If we fail to obtain adequate reimbursement, we could be prevented from successfully commercializing our potential products.

There are ongoing efforts by governmental and third-party payers to contain or reduce the costs of healthcare through various reform measures. For example, in the United States, the Federal government passed comprehensive healthcare reform legislation, the ACA, in 2010. With respect to pharmaceutical products, the ACA, among other things, expanded and increased industry rebates for drugs covered by Medicaid and made changes to the coverage requirements under Medicare Part D, Medicare's prescription drug benefits program. Since its enactment there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of any certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law, including the repeal, effective January 1, 2019, of the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated by the ACA, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Moreover, the Bipartisan Budget Act of 2018, among other things, amends the ACA,

effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. Congress may consider other legislation to repeal or repeal and replace elements of the ACA. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, drug pricing by pharmaceutical companies has recently come under increased scrutiny. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the out-of-pocket cost of prescription drugs, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies. At the federal level, the Trump administration’s budget proposal for fiscal year 2019 contains additional drug price

control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly 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. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our current product candidates and those for which we may receive regulatory approval in the future.

Further, third-party payers are increasingly challenging the price of medical products and services. If purchasers or users of our products are not able to obtain adequate reimbursement for the cost of using our products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and whether adequate third-party coverage will be available.

(\* )Our internal computer systems, or those used by our contractors or consultants, may fail or suffer security breaches.

We are dependent upon our own or third-party information technology systems, infrastructure and data, including mobile technologies, to operate our business. The multitude and complexity of our computer systems may make them vulnerable to service interruption or destruction, malicious intrusion, or random attack. Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data, including our clinical trial data, intellectual property, trade secrets or personal information of our employees, patients, customers or other business partners may be exposed to unauthorized persons or to the public. Cyber-attacks are increasing in their frequency, sophistication and intensity. Cyber-attacks could include the deployment of harmful malware, denial-of-service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Third party sites that take part in clinical trials we or our collaborators sponsor face similar risks and any security breach of their systems could adversely affect us. A security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to litigation or other liability under laws and regulations that protect personal data, any of which could disrupt our business and/or result in increased costs or loss of revenue. Moreover, 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, trade secrets or other intellectual property. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches.

We use hazardous materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled storage, use and disposal of hazardous materials and biological materials. Our hazardous materials include certain compressed gases, flammable liquids, acids and bases, and other toxic compounds. We are subject to federal, state and local regulations governing the use, manufacture,

storage, handling and disposal of materials and waste products. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result. We could incur significant costs to comply with current or future environmental laws and regulations.

We may have significant product liability exposure.

We face an inherent business risk of exposure to product liability and other claims in the event that our technologies or products are alleged to have caused harm. We also have potential liability for products manufactured by us on a contract basis for third parties. Although we currently maintain product liability insurance in the amount of \$10 million in the aggregate plus additional coverage specific to the foreign countries where our clinical trials are being conducted, this insurance coverage may not be sufficient, and we may not be able to obtain sufficient coverage in the future at a reasonable cost. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of any products developed by us or our collaborators, or our ability to manufacture products for third parties. If we are sued for any injury caused by our technologies or products, or by third-party products that we manufacture, our liability could exceed our insurance coverage and total assets.

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

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

(\* )Our stock price could continue to be highly volatile and you may not be able to resell your shares at or above the price you pay for them.

The market price of our common stock, like that of many other life sciences companies, has been and is likely to continue to be highly volatile. From January 1, 2015, to September 30, 2018, our stock price has ranged from \$1.02 to \$15.50. The following factors, among others, could have a significant impact on the market price of our common stock:

- The results of our preclinical studies and clinical trials or announcements regarding our plans for future studies or trials, or those of our collaborators, licensees or competitors;
- Evidence or lack of evidence of the safety or efficacy of our potential products or those of our collaborators, licensees or competitors;
- Our ability to enter into new collaboration and licensing agreements and the success of any collaborators and licensees in the development or commercialization of our product candidates;
- The announcement by us or our collaborators, licensees or competitors of technological innovations or new products;
- Developments concerning our patent or other proprietary rights or those of our collaborators, licensees or competitors, including litigation and challenges to our proprietary rights;
- Other developments with our collaborators or licensees, including our entry into new collaborative or licensing arrangements;
- Geopolitical developments, natural or man-made disease threats, or other events beyond our control;
- U.S. and foreign governmental regulatory actions;
- Changes or announcements in reimbursement policies;
- Period-to-period fluctuations in our operating results;
- Market conditions for life science stocks in general;
- Changes in the collective short interest in our stock;
- Changes in estimates of our performance by securities analysts; and
- Our cash balances, need for additional capital, and access to capital.

We are at risk of future securities class action litigation due to our past and expected stock price volatility.

In the past, stockholders have brought securities class action litigation against a company following a decline in the market price of its securities. This risk is especially acute for us because life science companies have experienced greater than average stock price volatility in recent years and, as a result, have been subject to, on average, a greater



number of securities class action claims than companies in other industries. Even if such claims are not successful, any litigation could result in substantial costs and divert our management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

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

Our certificate of incorporation and bylaws include anti-takeover provisions, such as a classified board of directors, a prohibition on stockholder actions by written consent, the authority of our board of directors to issue preferred stock without stockholder approval, and supermajority voting requirements for specified actions. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years. These provisions may delay or prevent an acquisition of us, even if the acquisition may be considered beneficial by some stockholders. In addition, they may discourage or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

In addition, in August 2016, we completed a private placement of 1,841,420 shares of common stock to AnGes. In connection with the private placement, AnGes agreed to vote all of its shares in accordance with the recommendations of our board of directors on any matter brought before our stockholders for a vote, subject to certain limitations. This voting provision may also discourage or prevent attempts by other stockholders to replace members of our board of directors or engage in acquisition activities that our board of directors does not determine to be in the best interests of our stockholders.

(\*The issuance of preferred stock could adversely affect our common stockholders.

We currently have on file a shelf registration statement that allows us to raise up to an aggregate of \$40.0 million from the sale of common stock, preferred stock, debt securities and/or warrants (subject to limitations on the amount of securities that we may sell under the registration statement in any 12-month period) and our restated certificate of incorporation authorizes us to issue up to 5,000,000 shares of preferred stock. The issuance of preferred stock could adversely affect the voting power of holders of our common stock, and reduce the likelihood that our common stockholders will receive dividend payments and payments upon liquidation. The issuance of preferred stock could also decrease the market price of our common stock, or have terms and conditions that could discourage a takeover or other transaction that might involve a premium price for our shares or that our stockholders might believe to be in their best interests.

ITEM 6. EXHIBITS

Exhibit

Number Description of Document

3.1(1)	Restated Certificate of Incorporation. (P)
3.2(2)	<u>Amended and Restated Bylaws.</u>
3.3(3)	<u>Certificate of Amendment to Restated Certificate of Incorporation.</u>
3.4(4)	<u>Certificate of Amendment to Restated Certificate of Incorporation.</u>
3.5(5)	<u>Certificate of Amendment to Restated Certificate of Incorporation.</u>
3.6(6)	<u>Certificate of Amendment to Restated Certificate of Incorporation.</u>
4.1(1)	Specimen Common Stock Certificate. (P)
10.1(7)	<u>Amended and Restated Stock Incentive Plan of Vical Incorporated.</u>
31.1	<u>Certification of Vijay B. Samant, Chief Executive Officer, pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2	<u>Certification of Anthony A. Ramos, Chief Financial Officer, pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1	<u>Certification of Vijay B. Samant, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2	<u>Certification of Anthony A. Ramos, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

(P)Paper exhibit

- (1) Incorporated by reference to the exhibit of the same number filed with the Company's Registration Statement on Form S-3 (No. 333-95812) filed on August 15, 1995.
- (2) Incorporated by reference to the exhibit of the same number filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010 (No. 000-21088) filed on August 6, 2010.
- (3) Incorporated by reference to exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 1, 2017.
- (4) Incorporated by reference to exhibit 3.1 to the Company's Current Report on Form 8-K filed on May 25, 2016.
- (5) Incorporated by reference to exhibit 3.3 filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010 (No. 000-21088) filed on August 6, 2010.
- (6) Incorporated by reference to exhibit 4.2 filed with the Company's Registration Statement on Form S-8 (No. 333-135266) filed on June 23, 2006.
- (7) Incorporated by reference to exhibit 99.1 filed with the Company's Current Report on Form 8-K filed on June 7, 2018.



SIGNATURE

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.

Vical Incorporated

Date: October 29,  
2018

By: /s/ ANTHONY A. RAMOS

Anthony A. Ramos

Vice President, Chief Financial Officer (on behalf of the registrant and as the registrant's  
Principal Financial and Accounting Officer)