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 June 30, 2018

OR

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

For the transition period from _____ to _____

Commission File Number 001-38529

Verrica Pharmaceuticals Inc.
(Exact name of registrant as specified in its charter)

Delaware	**46-3137900**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

10 North High Street, Suite 200
West Chester, PA 19380
(Address including zip code of principal executive offices)

(484) 453-3300
(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 ☒ (Do not check if a smaller reporting company)	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 ☒

Class of Common Stock	**Outstanding Shares as of August 7, 2018**
Common Stock, $0.0001 par value	25,696,371

VERRICA PHARMACEUTICALS INC.
QUARTERLY REPORT ON FORM 10-Q
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PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Financial Statements

VERRICA PHARMACEUTICALS INC.
CONDENSED BALANCE SHEETS
(in thousands, except share and per share amounts)
(Unaudited)

	June 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 103,149	$ 8,663
Prepaid expenses and other assets	1,441	420
Total current assets	104,590	9,083
Property, plant and equipment, net	112	—
Deposits	14	—
Total assets	**$ 104,716**	**$ 9,083**
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,081	$ 153
Accrued expenses	2,008	449
Accounts payable and accrued expenses - related party	36	14
Total current liabilities	3,125	616
Total liabilities	**3,125**	**616**
Commitments and Contingencies (Note 5)		
Convertible preferred stock - Series A - 0 and 21,302,972 shares authorized, issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	—	10,508
Convertible preferred stock - Series B - 0 and 1,937,984 shares authorized, issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	—	5,000
Total convertible preferred stock	**—**	**15,508**
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of June 30, 2018 and December 31, 2017	—	—
Common stock, $0.0001 par value; 200,000,000 and 33,236,900 shares authorized as of June 30, 2018 and December 31, 2017, respectively; 25,801,515 shares issued and 25,696,371 shares outstanding as of June 30, 2018 and 3,804,643 shares issued and 3,699,499 shares outstanding as of December 31, 2017, respectively	3	—
Treasury stock, at cost, 105,144 shares as of June 30, 2018 and December 31, 2017	—	—
Additional paid-in capital	121,856	5,394
Accumulated deficit	(20,268)	(12,435)
Total stockholders' equity (deficit)	101,591	(7,041)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	**$ 104,716**	**$ 9,083**

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

VERRICA PHARMACEUTICALS INC.
CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)
(Unaudited)

	For the three months ended June 30,		For the six months ended June 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 3,609	$ 977	$ 4,538	$ 1,493
General and administrative	2,503	118	3,489	172
Total operating expenses	6,112	1,095	8,027	1,665
Loss from operations	(6,112)	(1,095)	(8,027)	(1,665)
Other income:				
Interest income	153	—	194	—
Total other income	153	—	194	—
Net loss	**$ (5,959)**	**$ (1,095)**	**$ (7,833)**	**$ (1,665)**
Net loss per share, basic and diluted	$ (1.04)	$ (0.38)	$ (1.82)	$ (0.58)
Weighted average common shares outstanding, basic and diluted	5,751,326	2,850,471	4,308,996	2,849,891

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

VERRICA PHARMACEUTICALS INC.
CONDENSED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share amounts)
(Unaudited)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Treasury Stock at Cost	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of December 31, 2017	**21,302,972**	**$ 10,508**	**1,937,984**	**$ 5,000**	**—**	**$ —**	**3,804,643**	**$ —**	**$ 5,394**	**$ (12,435)**	**$ —**	**$ (7,041)**
Stock-based compensation	—	—	—	—	—	—	—	—	1,583	—	—	1,583
Series C convertible preferred stock	—	—	—	—	4,606,267	21,000	—	—	—	—	—	—
Issuance costs for Series C preferred	—	—	—	—	—	(7)	—	—	—	—	—	—
Conversion of preferred stock into common stock	(21,302,972)	(10,508)	(1,937,984)	(5,000)	(4,606,267)	(20,993)	16,246,872	2	36,499	—	—	36,501
Issuance of common stock in connection with IPO, net of offering costs	—	—	—	—	—	—	5,750,000	1	78,380	—	—	78,381
Net loss	—	—	—	—	—	—	—	—	—	(7,833)	—	(7,833)
Balance as of June 30, 2018	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**25,801,515**	**$ 3**	**$ 121,856**	**$ (20,268)**	**$ —**	**$ 101,591**

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

VERRICA PHARMACEUTICALS INC.
CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	For the six months ended June 30, 2018	2017
Cash flows from operating activities		
Net loss	$ (7,833)	$ (1,665)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,583	3
Depreciation expense	5	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,035)	(375)
Accounts payable	573	303
Accrued expenses	851	48
Accounts payable and accrued expenses - related party	22	25
Net cash used in operating activities	(5,834)	(1,661)
Cash flows from investing activities		
Purchases of property, plant and equipment	(111)	—
Net cash used in investing activities	(111)	—
Cash flows from financing activities		
Proceeds from the issuance of common stock in connection with IPO	86,250	—
Payment of offering cost in connection with issuance of common stock in connection with IPO	(6,812)	—
Proceeds received from Series A preferred stock subscription receivable	—	1,700
Stock issuance costs related to Series A preferred stock	—	(60)
Proceeds received from issuance of Series C preferred stock	21,000	—
Stock issuance costs related to Series C preferred stock	(7)	—
Net cash provided by financing activities	100,431	1,640
Net increase (decrease) in cash and cash equivalents	94,486	(21)
Cash and cash equivalents at the beginning of the period	8,663	527
Cash and cash equivalents at the end of the period	**$ 103,149**	**$ 506**
Supplemental disclosure of noncash investing and financing activities:		
Fixed asset purchases accrued at period end	$ 6	$ —
Issuance costs included in accounts payable and accrued expenses	$ 1,057	$ —
Conversion of preferred stock into common stock	$ 36,501	$ —

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

VERRICA PHARMACEUTICALS INC.
Notes to Condensed Financial Statements
(Unaudited)

Note 1—Organization and Description of Business Operations

Verrica Pharmaceuticals Inc. (the "Company") was formed on July 3, 2013 and is incorporated in the State of Delaware. The Company is a clinical-stage medical dermatology company focused on identifying, developing and commercializing innovative pharmaceutical products for the treatment of skin diseases with significant unmet needs, with an initial focus on addressing molluscum contagiosum.

Reverse Stock Split

On June 4, 2018, the Company effected a 1.714-for-one reverse stock split of Company's common stock. No fractional shares were issued in connection with the stock split. The par value and other terms of the common stock were not affected by the stock split.

All share and per share amounts, including stock options, have been retroactively adjusted in these condensed financial statements for all periods presented to reflect the 1.714-for-one reverse stock split. Further, exercise prices of stock options have been retroactively adjusted in these condensed financial statements for all periods presented to reflect the 1.714-for-one reverse stock split. The number of shares of the Company's preferred stock were not affected by the reverse stock split; however, the conversion ratios were adjusted to reflect the reverse stock split.

Liquidity and Capital Resources

The Company has incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of June 30, 2018, the Company had an accumulated deficit of $20.3 million.

On February 20, 2018 and March 7, 2018, the Company issued an aggregate of 4,606,267 shares of Series C convertible preferred stock, at an issuance price of $4.559 per share, for gross proceeds of $21.0 million.

On June 19, 2018, the Company completed an initial public offering ("IPO") of its common stock, which resulted in the issuance and sale of 5,750,000 shares of its common stock at a public offering price of $15.00 per share, generating net proceeds of $78.4 million after deducting underwriting discounts and other offering costs. Upon the closing of the IPO, all outstanding shares of the Company's Series A, Series B and Series C convertible preferred stock were automatically converted into 16,246,872 shares of the Company's common stock. In addition, upon the closing of the IPO, the Company's amended and restated certificate of incorporation authorized the Company to issue up to 200,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share, all of which shares of preferred stock will be undesignated.

Note 2—Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") as determined by Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the unaudited interim condensed financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results for the periods presented. They may not include all of the information and footnotes required by GAAP for complete financial statements. Therefore, these financial statements should be read in conjunction with the Company's audited financial statements and notes thereto for the year ended December 31, 2017 included in the Company's final prospectus for its IPO dated as of June 14, 2018 and filed with the Securities and Exchange Commission (the "SEC") on June 15, 2018 pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended. The results of operations for any interim periods are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

VERRICA PHARMACEUTICALS INC.
Notes to Condensed Financial Statements
(Unaudited)

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The most significant estimates in the Company's financial statements relate to the valuation of common stock and stock options. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include cash held in banks and money market mutual funds.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Cash and cash equivalents are financial instruments that are potentially subject to concentrations of credit risk. The Company's cash and cash equivalents are deposited in accounts at large financial institutions, and amounts may exceed federally insured limits. The Company believes it is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash and cash equivalents are held. The Company has no financial instruments with off-balance sheet risk of loss.

Research and Development Costs

The Company's research and development expenses consist primarily of costs associated with the Company's clinical trials, salaries, payroll taxes, employee benefits, and equity-based compensation charges for those individuals involved in ongoing research and development efforts. Research and development costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Fair Value Measurement

ASC 820, *Fair Value Measurements*, provides guidance on the development and disclosure of fair value measurements. Under this accounting guidance, fair value is defined 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 a liability.

The accounting guidance classifies fair value measurements in one of the following three categories for disclosure purposes:

Level 1:	Quoted prices in active markets for identical assets or liabilities.
Level 2:	Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.
Level 3:	Unobservable inputs which are supported by little or no market activity and values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

VERRICA PHARMACEUTICALS INC.
Notes to Condensed Financial Statements
(Unaudited)

Included in cash and cash equivalents as of June 30, 2018 is a money market fund with a carrying value and fair value of $103.0 million based upon a Level 1 fair value assessment. The carrying amounts for the Company's other financial instruments approximate fair values.

Stock-Based Compensation

The Company expenses stock-based compensation to employees and board members over the requisite service period based on the estimated grant-date fair value of the awards. The Company accounts for forfeitures as they occur. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. The Company estimates the fair value of stock option grants using the Black-Scholes option-pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. All stock-based compensation costs are recorded in general and administrative or research and development costs in the statements of operations based upon the underlying individual's role at the Company.

Stock-based compensation for non-employee stock options is recorded over the vesting period and remeasured at fair value until they vest.

Income Taxes

Income taxes are recorded in accordance with ASC 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. In its interim financial statements, the Company utilizes an expected annual effective tax rate in determining its income tax provisions for the interim periods. The expected annual effective tax rate differs from U.S. statutory rates primarily as a result of a valuation allowance related to the Company's net operating loss carryforward as a result of the historical losses of the Company.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company recognizes any interest and penalties accrued related to unrecognized tax benefits as income tax expense.

Net Loss Per Share

Net loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share excludes the potential impact of Series A, Series B and Series C Preferred Stock, common stock options and unvested shares of restricted stock because their effect would be anti-dilutive due to the Company's net loss. Since the Company had a net loss in each of the periods presented, basic and diluted net loss per common share are the same.

VERRICA PHARMACEUTICALS INC.
Notes to Condensed Financial Statements
(Unaudited)

The table below provides potential shares outstanding that were not included in the computation of diluted net loss per common share, as the inclusion of these securities would have been anti-dilutive:

	As of June 30,	
	2018	2017
Shares issuable upon conversion of Series A Preferred	—	12,428,773
Shares issuable upon exercise of stock options	1,383,582	90,429
Non-vested shares under restricted stock grants	848,859	848,859

Recently Adopted Accounting Pronouncements

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The Company adopted this guidance effective January 1, 2018 and the adoption of the guidance had no impact on the Company's financial statements and related disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. Under the new guidance, lessees will be required to recognize all leases (with the exception of short-term leases) on the balance sheet as a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently assessing the provisions of the guidance and has not determined the impact of adoption on its financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The changes take effect for public companies for fiscal years starting after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of ASC 606, *Revenue from Contracts with Customers*. The Company is currently evaluating the impact of adopting this standard on its financial statements and related disclosures but does not expect it to have a material impact.

Note 3—Related Party Transactions

Prior to the IPO, the Company was controlled by PBM VP Holdings, LLC ("PBM VP Holdings"), an affiliate of PBM Capital Group, LLC. Paul B. Manning, who is the President and Chief Executive Officer of PBM Capital Group, LLC and the current chairman of the Company's Board of Directors (the "Board"), and certain entities affiliated with Mr. Manning, continue to be the Company's largest shareholder on a collective basis.

On December 2, 2015, the Company entered into a Services Agreement (a "SA") with PBM Capital Group, LLC. Pursuant to the terms of the SA, which had an initial term of twelve months (and was automatically renewable for successive monthly periods), PBM Capital Group, LLC rendered advisory and consulting services to the Company. Services provided under the SA included certain business development, operations, technical, contract, accounting and back office support services. In consideration for these services, the Company was obligated to pay PBM Capital Group, LLC a monthly management fee of $2,500.

On March 29, 2018, the Company amended the SA with PBM Capital Group, LLC, effective as of April 1, 2018. Pursuant to the terms of the SA, as amended, which has an initial term of twelve months (and is automatically renewable for successive monthly periods), PBM Capital Group, LLC will render advisory and consulting services to the Company. Services provided under the SA may include certain business development, operations, technical, contract, accounting and back office support services. In consideration for these services, the Company is obligated to pay PBM Capital Group, LLC a monthly management fee of $50,000. The SA, as amended, provides for the termination by the Company with 30 days advance notice or a mutually agreed upon effective date for transition as individual services are cancelled with a corresponding reduction in the monthly management fee.

VERRICA PHARMACEUTICALS INC.
Notes to Condensed Financial Statements
(Unaudited)

For the three months ended June 30, 2018 and 2017, the Company incurred expenses under the SA of $150,000 and $7,500, respectively, which were primarily included in general and administrative expenses. For the six months ended June 30, 2018 and 2017, the Company incurred expenses under the SA of $157,500 and $15,000, respectively, which were primarily included in general and administrative expenses.

As of June 30, 2018 and December 31, 2017, the Company had a payable due to PBM Capital Group, LLC and its affiliates of $36,000 and $14,000, respectively.

Note 4—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	As of June 30, 2018	As of December 31, 2017
Compensation and related costs	$ 508	$ 49
Clinical trials and drug development	184	233
Initial Public Offering costs	697	—
Consulting - former Chief Scientific Officer	382	—
Professional fees	53	129
Other	184	38
Total accrued expenses	$ 2,008	$ 449

Note 5—Commitments and Contingencies

Litigation

As of June 30, 2018 and December 31, 2017, there was no litigation against the Company.

Purchase Order

On March 22, 2018, the Company executed a purchase order with a supplier, denominated in Chinese yuan, pursuant to which the Company agreed to purchase approximately $2.3 million of crude cantharidin material. As of June 30, 2018, the Company purchased approximately $0.5 million of crude cantharidin material under this purchase order. On July 16, 2018, the Company entered into a supply agreement with the supplier. The executed purchase order is covered under the terms of the supply agreement. Refer to ‘Note 8 – Subsequent Event’ for further description of the supply agreement.

Agreements with Former Chief Scientific Officer

On May 31, 2018, the Company and the former Chief Scientific Officer (“CSO”) executed a transition agreement to resign from employment as well as a Consulting Agreement (the “Consulting Agreement”) that began upon the closing of the IPO.

The Consulting Agreement provides for cash payments to the former CSO of $29,375 per month for the first 12 months of the agreement. After the first 12 months, the former CSO will receive $300 per hour for each hour of consulting services provided. The Company accrued $0.4 million as of June 30, 2018 under this Consulting Agreement.

Note 6—Stockholders’ Equity

Common Stock

The Company has authorized 200,000,000 and 33,236,900 shares of common stock, $0.0001 par value per share, as of June 30, 2018 and December 31, 2017, respectively. Each share of common stock is entitled to one voting right. Common stock owners are entitled to dividends when funds are legally available and declared by the Board.

On June 19, 2018, the Company completed an IPO of its common stock, which resulted in the issuance and sale of 5,750,000 shares of its common stock at a public offering price of $15.00 per share, generating net proceeds of $78.4 million after deducting underwriting discounts and other offering costs. The shares commenced trading on the Nasdaq Global Market on June 15, 2018 under the ticker symbol “VRCA.”

Restricted Stock

Pursuant to an Amended and Restated Stock Purchase Agreement (the “Amended and Restated Agreement”) between the Company and the former CSO, 848,859 shares held by the former CSO are subject to repurchase at $0.0001 per share. These shares will be released from the repurchase option on the earliest to occur of (i) a change in control, (ii) regulatory approval of the Company’s new drug application for cantharidin, (iii) commercial sale of products and (iv) a covered termination, as defined in the Amended and Restated Agreement.

VERRICA PHARMACEUTICALS INC.
Notes to Condensed Financial Statements
(Unaudited)

Convertible Preferred Stock

On December 2, 2015, the Company issued an aggregate of 21,302,972 shares of Series A Preferred Stock to fourteen investors for cash consideration of $1.9 million, conversion of previously outstanding notes payable and accrued interest of $0.5 million and a stock subscription receivable of $8.5 million. The Company incurred aggregate issuance costs of $0.4 million, related to the issuance of the Series A Preferred Stock and subsequent settlement of the stock subscription receivable. PBM VP Holdings paid the Company $0.5 million during the year ended December 31, 2016, and $8.0 million during the year ended December 31, 2017 to settle the stock subscription receivable. Upon the closing of the IPO on June 19, 2018, all outstanding shares of the Company's Series A Preferred Stock were automatically converted into 12,428,773 shares of the Company's common stock.

On December 15, 2017, the Company issued and sold an aggregate of 1,937,984 shares of Series B Preferred Stock, at an issuance price of $2.58 per share, for gross proceeds of $5.0 million. The Company did not incur any issuance costs for the Series B Preferred Stock. Upon the closing of the IPO on June 19, 2018, all outstanding shares of the Company's Series B Preferred Stock were automatically converted into 1,130,679 shares of the Company's common stock.

On February 20, 2018 and March 7, 2018, the Company issued and sold an aggregate of 4,606,267 shares of Series C Preferred Stock, at an issuance price of $4.559 per share, for aggregate gross proceeds of $21.0 million. Upon the closing of the IPO on June 19, 2018, all outstanding shares of the Company's Series C Preferred Stock were automatically converted into 2,687,420 shares of the Company's common stock.

The Company classified its Convertible Preferred Stock outside of stockholders' deficit because redemption of the Convertible Preferred Stock, upon a deemed liquidation event, was not solely within the Company's control.

Note 7—Stock-Based Compensation

In June 2018, the Board adopted and approved the 2018 Equity Incentive Plan (the "IPO Plan"), which amended and restated the Company's prior 2013 Equity Incentive Plan (the "2013 Plan") and became effective in connection with the IPO pricing on June 19, 2018. Prior to the effectiveness of the IPO Plan, the 2013 Plan provided for the grant of share-based awards to employees, directors and consultants of the Company. As a result of the effectiveness of the IPO Plan, no further grants may be made under the 2013 Plan.

The IPO Plan provides for the grant of incentive stock options to employees, and for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards and other forms of stock awards to employees, including officers, consultants and directors. The IPO Plan also provides for the grant of performance-based cash awards to employees, including officers, consultants and directors. The Company has initially reserved 3,738,199 shares of common stock for issuance under the IPO Plan, which is the sum of (1) 2,198,198 new shares, plus (2) the number of shares reserved for issuance under the 2013 Plan at the time the IPO Plan became effective, plus (3) any shares subject to outstanding stock options or other stock awards that would have otherwise returned to the 2013 Plan (such as upon the expiration or termination of a stock award prior to exercise). The number of shares of common stock reserved for issuance under the IPO Plan will automatically increase on January 1 each year, for a period of ten years, from January 1, 2019 through January 1, 2028, by 4% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by the Board. As of June 30, 2018, 2,112,719 shares were available for grant under the IPO Plan.

Stock Options

The Company's employee stock options generally vest as follows: 25% after 12 months of continuous services and the remaining 75% on a ratable basis over a 36-month period from 12 months after the grant date. Stock options granted during the six months ended June 30, 2018 have a maximum contractual term of 10 years. The stock options are subject to time vesting requirements through 2022, are nontransferable, and have term expiration dates set to expire in June 2028.

In January 2017, the Company granted 17,502 common stock options to an employee, subject to the terms and conditions of the 2013 Plan above. The stock options are subject to time vesting requirements through 2021, are nontransferable, and have term expiration dates set to expire in January 2027. At June 30, 2018, 6,199 of these options had vested.

On December 22, 2017, the Board granted a stock option award for 724,315 shares of common stock to the Company's Chief Executive Officer ("CEO Stock Option Grant") subject to the Board's approval of a valuation report as to the value of the Company common stock. On February 12, 2018, the Board determined that the exercise price of the CEO Stock Option Grant would be equal to the greater of 1) $3.75 per share or 2) the Board's approval of a valuation report as to the value of the Company common stock as of February 12, 2018. On March 28, 2018, the Board approved the valuation of the Company's common stock of $6.52 per share as of February 12, 2018, which set the exercise price for 878,923 options (including 724,315 to the Company's Chief Executive Officer and 154,608 to other employees granted by the Board on December 22, 2017 and February 12, 2018, respectively) and established an accounting grant date.

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On February 12, 2018, the Board approved stock option awards to employees for 186,696 options to acquire common stock, with the exercise price of these awards to be established at the fair value of the Company's common stock as of February 26, 2018 for 113,768 options and March 5, 2018 for 72,928 options. On April 24, 2018, the Board approved the valuation of the Company's common stock of $6.86 per share as of February 26, 2018 and March 5, 2018, which set the exercise price for the 186,696 options. On April 24, 2018, the Board also approved the valuation of the Company's common stock of $8.73 per share as of April 4, 2018, which set the exercise price for 87,514 options that were approved by the Board on March 20, 2018. An accounting grant date for these awards was established upon approval by the Board of these valuation reports on the Company's common stock as of the applicable dates on April 24, 2018.

The fair value of each employee and non-employee stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. Due to the lack of historical exercise history, the expected term of the Company's stock options for employees has been determined utilizing the "simplified" method for awards. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Prior to the Company's IPO, in order to determine the fair value, the Company considered, among other things, contemporaneous valuations of the Company's common stock, the Company's business, financial condition and results of operations, including related industry trends affecting its operations; the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or sale, given prevailing market conditions; the lack of marketability of the Company's common stock; the market performance of comparable publicly traded companies; and U.S. and global economic and capital market conditions.

The grant date fair value of employee stock option awards is determined using the Black-Scholes option-pricing model. The following assumptions were used during the three and six months ended June 30, 2018 and 2017 to estimate the fair value of employee stock option awards:

	For the three months ended June 30,		For the six months ended June 30,	
	2018	2017*	2018	2017
Exercise price	$6.86 - $15.00	—	$6.52 - $15.00	$0.90
Risk-free rate of interest	2.83% - 2.95%	—	2.58% - 2.95%	1.92% - 2.23%
Expected term (years)	6.12	—	6.11	6.25
Expected stock price volatility	71.18% - 83.67%	—	70.58% - 83.67%	79.02% - 79.12%
Weighted average estimated fair value share price	$7.52	—	$6.53	$0.12
Dividend yield	—	—	—	—

* The Company did not grant stock options during the three months ended June 30, 2017

Non-employee options are remeasured to fair value each period through operations using a Black-Scholes option-pricing model until the options vest. There were no stock options granted to non-employees during the three and six months ended June 30, 2018 and 2017. Key assumptions used to estimate the fair value of the non-employee stock options measured during the three months ended June 30, 2018 and 2017 included risk-free interest rates of 2.68% to 2.93% and 2.21% to 2.40%, an expected volatility of 73.53% to 83.81% and 78.84% to 79.07%, no expected dividend yield, a weighted average estimated fair value common share price of $17.77 and $0.16 and an expected term equal to the remaining contractual option term. Key assumptions used to estimate the fair value of the non-employee stock options measured during the six months ended June 30, 2018 and 2017 included risk-free interest rates of 2.33% to 2.93% and 2.21% to 2.48%, an expected volatility of 68.98% to 83.81% and 78.84% to 79.12%, no expected dividend yield, a weighted average common share price of $16.42 and $0.16 and an expected term equal to the remaining contractual option term.

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The following table summarizes the Company's employee stock option activity under the 2013 Plan and the IPO Plan for the six months ended June 30, 2018:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life (in years)	Aggregate intrinsic value
Outstanding as of December 31, 2017	17,502	$ 0.90		
Options granted	1,293,153	7.64		
Outstanding as of June 30, 2018	1,310,655	$ 7.55	9.7	$ 15,967,862
Options vested and exercisable as of June 30, 2018	6,199	$ 0.90	8.5	$ 116,727

The following table summarizes the Company's non-employee stock option activity under the 2013 Plan and the IPO Plan for the six months ended June 30, 2018:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life (in years)	Aggregate intrinsic value
Outstanding as of December 31, 2017	72,927	$ 0.90		
Options granted	—	—		
Outstanding as of June 30, 2018	72,927	$ 0.90	7.8	$ 1,373,215
Options vested and exercisable as of June 30, 2018	48,620	$ 0.90	7.8	$ 915,515

The aggregate intrinsic value in the above table is calculated as the difference between fair value of the Company's common stock price and the exercise price of the stock options. The weighted average grant date fair value per share for the employee stock option grants during the six months ended June 30, 2018 and 2017 was $6.53 and $0.12, respectively. As of June 30, 2018, the total unrecognized compensation related to unvested employee and non-employee stock option awards granted was $7.2 million, which the Company expects to recognize over a weighted-average period of 1.7 years.

Restricted Stock

The following table summarizes restricted stock award activities for the six months ended June 30, 2018:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2017	848,859	$ 0.33
Granted	—	—
Nonvested at June 30, 2018	848,859	$ 0.33

As of June 30, 2018, the total unrecognized compensation expense related to the nonvested shares was $0.3 million. No compensation expense has been recognized for these nonvested shares as these shares are performance-based and the triggering event was not determined to be probable as of June 30, 2018.

Stock-based compensation expense has been reported in the Company's condensed statements of operations for the three and six months ended June 30, 2018 and 2017 as follows (in thousands):

	For the three months ended June 30,		For the six months ended June 30,	
	2018	2017	2018	2017
Research and development	$ 350	$ 2	$ 467	$ 3
General and administrative	1,071	—	1,116	—
Total stock-based compensation	$ 1,421	$ 2	$ 1,583	$ 3

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Note 8—Subsequent Event

On July 16, 2018, the Company entered into a supply agreement, pursuant to which the supplier has agreed to supply naturally-sourced cantharidin to the Company for a specified fixed price. Naturally-sourced cantharidin is the raw material used to manufacture the active pharmaceutical ingredient ("API") in VP-102, the Company's lead product candidate. Pursuant to the supply agreement, the supplier has agreed that it will not supply cantharidin, any beetles or other raw material from which cantharidin is derived to any other customer in North America, subject to specified minimum annual purchase orders and forecasts. The supply agreement has an initial five-year term, which is subject to automatic renewal absent termination by either party in accordance with the terms of the supply agreement. Each party also has the right to terminate the supply agreement for other customary reasons such as material breach or bankruptcy.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with (i) our unaudited interim condensed financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and (ii) our audited condensed financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the years ended December 31, 2016 and 2017 included in our final prospectus dated June 14, 2018, filed with the Securities and Exchange Commission (the "SEC") on June 15, 2018, pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended ("the Securities Act"). Our financial statements have been prepared in accordance with U.S. GAAP.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words "expect," "anticipate," "intend," "believe," "may," "plan", "seek" or similar language. All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Our business and financial performance are subject to substantial risks and uncertainties. Actual results could differ materially from those projected in the forward-looking statements. In evaluating our business, you should carefully consider the information set forth in this Quarterly Report under Part II - Item 1A "Risk Factors," and in our other filings with the SEC.

Overview

We are a clinical-stage medical dermatology company focused on identifying, developing and commercializing innovative pharmaceutical products for the treatment of skin diseases with significant unmet needs. Our lead product candidate, VP-102, is a proprietary drug-device combination of our novel topical solution of cantharidin, a widely recognized, naturally sourced agent to treat topical dermatological conditions, administered through our single-use precision applicator. We are initially developing VP-102 for the treatment of molluscum, a highly contagious and primarily pediatric viral skin disease, and common warts. There are currently no FDA-approved products nor is there an established standard of care for either of these diseases, resulting in significant undertreated populations in two of the largest unmet needs in dermatology. In addition to patent protection we are seeking, VP-102 has the potential to be the first FDA-approved product for molluscum and for its API to be characterized as an NCE with the five years of non-patent regulatory exclusivity associated with that designation. We also believe VP-102 has the potential to qualify for pediatric exclusivity, which would provide for an additional six months of non-patent exclusivity. We also intend to develop our second cantharidin-based product candidate, VP-103, for the treatment of plantar warts.

We have recently initiated two randomized, double-blind, multicenter placebo-controlled Phase 3 clinical trials of VP-102 for the treatment of molluscum, CAMP-1 and CAMP-2, and expect to report top-line results from these trials in the first half of 2019. If the results from these trials are favorable, we plan to submit an NDA to the FDA for VP-102 for the treatment of molluscum in 2019. CAMP-1 is being conducted under an SPA with the FDA. We are also enrolling patients in a Phase 2 clinical trial of VP-102 for the treatment of common warts. We expect to report top-line results from this trial in the first half of 2019. We retain exclusive, royalty-free rights to our product candidates across all indications.

Our strategy is to advance VP-102 through regulatory approval and self-commercialize in the United States for the treatment of several skin diseases. We intend to build a specialized sales organization in the United States focused on pediatric dermatologists, dermatologists and select pediatricians. In the future, we also intend to develop VP-102 for commercialization in additional geographic regions, either alone or together with a strategic partner.

We have a limited operating history. Since our inception in 2013, our operations have focused on developing VP-102, organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting clinical trials. We do not have any product candidates approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through the sale of equity and equity-linked securities. On June 19, 2018, we completed an IPO of common stock, which resulted in the issuance and sale of 5,750,000 shares of common stock at a public offering price of $15.00 per share, generating net proceeds of $78.4 million after deducting underwriting discounts and other offering costs. We believe that the net proceeds from the IPO, together with our existing cash and cash equivalents, will enable us to fund our operations in the normal course of business for at least the next 24 months.

Since inception, we have incurred significant operating losses. For the six months ended June 30, 2018 and 2017, our net loss was $7.8 million and $1.7 million, respectively. As of June 30, 2018, we had an accumulated deficit of $20.3 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- complete clinical development of VP-102 for the treatment of molluscum, including our ongoing Phase 3 clinical trials;

- prepare and file for regulatory approval of VP-102 for the treatment of molluscum;
- continue to invest in the clinical development of VP-102 for the treatment of common warts and other indications;
- develop our second cantharidin-based product candidate, VP-103, for the treatment of plantar warts;
- prepare for commercialization of VP-102, if approved, including the hiring of sales and marketing personnel;
- manufacture our product candidates or otherwise secure the clinical and commercial supply of our product candidates;
- hire additional research and development and selling, general and administrative personnel;
- maintain, expand and protect our intellectual property portfolio;
- potentially pursue our strategy to in-license or acquire additional product candidates; and
- incur additional costs associated with operating as a newly public company.

Services Agreement with PBM Capital Group, LLC

In December 2015, we entered into a services agreement with PBM Capital Group, LLC, an affiliate of PBM Capital Investments, LLC, or the services agreement, to engage PBM Capital Group, LLC for certain business development, operations, technical, contract, accounting and back office support services. We agreed to pay PBM Capital Group, LLC a fee of $2,500 per month for these services. The services agreement had an initial term of 12 months and automatically renewed monthly thereafter.

In March 2018, we entered into an amendment to the services agreement with PBM Capital Group, LLC effective as of April 1, 2018, which extended the term of the services agreement until March 31, 2019 and increased the management fee we are obligated to pay to PBM Capital Group, LLC to $50,000 per month. The services agreement as amended, provides for termination by us with 30 days advance notice or a mutually agreed upon effective date for transition as individual services are cancelled with a corresponding reduction in the monthly management fee.

Components of Results of Operations

Revenue

We have not generated any revenue since inception and do not expect to generate any revenue from the sale of products in the near future.

Operating Expenses

Research and Development Expenses

Research and development expenses consist of expenses incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our clinical trials and preclinical studies;
- manufacturing and supply scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial supply and commercial supply, including manufacturing validation batches;
- outsourced professional scientific development services;

- employee-related expenses, which include salaries, benefits and stock-based compensation;
- expenses relating to regulatory activities; and
- laboratory materials and supplies used to support our research activities.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, conduct our pivotal Phase 3 clinical trials for VP-102 in patients with molluscum, conduct our ongoing Phase 2 clinical trial of VP-102 in patients with common warts and conduct other clinical trials and prepare regulatory filings for our product candidates.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the number of doses patients receive;
- the duration of patient follow-up; and
- the results of our clinical trials.

Our expenditures are subject to additional uncertainties, including the manufacturing process for our product candidates, the terms and timing of regulatory approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may never succeed in achieving regulatory approval for our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of our product candidates. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Product commercialization will take several years and millions of dollars in development costs.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive and administrative functions, including stock-based compensation, travel expenses and recruiting expenses. Other general and administrative expenses include market research costs, professional fees for legal, accounting and tax-related services, insurance costs, as well as payments made under our services agreement with PBM Capital Group, LLC.

We anticipate that our general and administrative expenses will increase as a result of increased payroll, expanded infrastructure and higher consulting, legal and tax-related services associated with maintaining compliance with stock exchange listing and SEC requirements, accounting and investor relations costs, and director and officer insurance premiums associated with being a public company. In addition, we expect to incur, at an increased rate compared to prior periods, significantly higher expenses associated with building a sales and marketing team in connection with the potential regulatory filing and approval of VP-102 for the treatment of molluscum. As a result, we expect to report significantly higher general and administrative expenses in 2018 and 2019.

Income Taxes

Since our inception in 2013, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year due to our uncertainty of realizing a benefit from those items. As of December 31, 2017, we had federal and state net operating loss carryforwards of $7.0 million. The federal and state net operating loss carryforwards generated in the 2016 and 2017 tax years will begin to expire, if not utilized, by 2036. Utilization of the net operating loss carryforwards may be subject to an annual limitation according to Section 382 of the Internal Revenue Code of 1986 as amended, and similar provisions.

Results of Operations for the Three Months Ended June 30, 2018 and 2017

The following table summarizes our results of operations for the three months ended June 30, 2018 and 2017 (in thousands):

	For the three months ended June 30,		
	2018	2017	Change
Operating expenses:			
Research and development	$ 3,609	$ 977	$ 2,632
General and administrative	2,503	118	2,385
Total operating expenses	6,112	1,095	5,017
Loss from operations	(6,112)	(1,095)	(5,017)
Other income:			
Interest income	153	—	153
Total other income	153	—	153
Net loss	**$ (5,959)**	**$ (1,095)**	**$(4,864)**

Research and Development Expenses

Research and development expenses were $3.6 million for the three months ended June 30, 2018, compared to $1.0 million for the three months ended June 30, 2017. The increase of $2.6 million was primarily attributable to costs associated with Phase 2 and Phase 3 clinical activities for VP-102, stock compensation costs for research and development staff, a charge related to a consulting agreement with our former Chief Scientific Officer, and an increase in clinical support staff.

General and Administrative Expenses

General and administrative expenses were $2.5 million for the three months ended June 30, 2018, compared to $0.1 million for the three months ended June 30, 2017. The increase of $2.4 million was primarily attributable to increases in salary costs, stock compensation costs for general and administrative staff, and external service provider expenses.

Other Income

Other income for the three months ended June 30, 2018 consisted entirely of interest income on our cash and cash equivalents. There was no other income for the three months ended June 30, 2017.

Results of Operations for the Six Months Ended June 30, 2018 and 2017

The following table summarizes our results of operations for the six months ended June 30, 2018 and 2017 (in thousands):

	For the six months ended June 30, 2018	2017	Change
Operating expenses:			
Research and development	$ 4,538	$ 1,493	$ 3,046
General and administrative	3,489	172	3,317
Total operating expenses	8,027	1,665	6,362
Loss from operations	(8,027)	(1,665)	(6,362)
Other income:			
Interest income	194	—	194
Total other income	194	—	194
Net loss	**$ (7,833)**	**$ (1,665)**	**$(6,168)**

Research and Development Expenses

Research and development expenses were $4.5 million for the six months ended June 30, 2018, compared to $1.5 million for the six months ended June 30, 2017. The increase of $3.0 million was primarily attributable to costs associated with Phase 2 and Phase 3 clinical activities, stock compensation costs for research and development staff, an increase in clinical support staff, and a charge related to a consulting agreement with our former Chief Scientific Officer.

General and Administrative Expenses

General and administrative expenses were $3.5 million for the six months ended June 30, 2018, compared to $0.2 million for the six months ended March 31, 2017. The increase of $3.3 million was primarily attributable to increases in salary costs, stock compensation costs for general and administrative staff, external service provider expenses, including market research, accounting, recruiting and legal fees, and travel and expense costs.

Other Income

Other income for the six months ended June 30, 2018 consisted entirely of interest income on our cash and cash equivalents. There was no other income for the six months ended June 30, 2017.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue and have incurred net losses and negative cash flows from our operations. We have financed our operations since inception through sales of our convertible debt and convertible preferred stock and the sale of our common stock in our IPO, receiving aggregate gross proceeds of $123.2 million.

As of June 30, 2018, we had cash and cash equivalents of $103.1 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

We currently have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years.

Cash Flows

The following table summarizes our cash flows for the six months ended June 30, 2018 and 2017 (in thousands):

	For the six months ended June 30,	
	2018	2017
Net cash used in operating activities	$ (5,834)	$ (1,661)
Net cash used in investing activities	(111)	—
Net cash provided by financing activities	100,431	1,640
Net increase (decrease) in cash and cash equivalents	$ 94,486	$ (21)

Operating Activities

During the six months ended June 30, 2018, operating activities used $5.8 million of cash, primarily resulting from a net loss of $7.8 million, partially offset by cash provided by changes in operating assets and liabilities of $0.4 million, and non-cash stock-based compensation of $1.6 million. Net cash provided by changes in operating assets and liabilities consisted primarily of increases in accounts payable and accrued expenses of $1.4 million, partially offset by increases in prepaid expenses and other assets of $1.0 million. The increase in accounts payable and accrued expenses was primarily due to clinical development activities, an accrual related to a consulting agreement with our former Chief Scientific Officer, and an accrual for discretionary annual employee bonuses. The increase in prepaid expenses and other assets was primarily due to prepayments for clinical development activities and an upfront payment to our API contract manufacturer for equipment purchases and installation. The Company will record the cost associated with the equipment purchases as a component of research and development expense if there is no alternative future use of the equipment without FDA approval.

During the six months ended June 30, 2017, operating activities used $1.7 million of cash, primarily resulting from a net loss of $1.7 million.

Investing Activities

During the six months ended June 30, 2018, net cash used in investing activities was primarily related to the purchase of computer hardware. For the six months ended June 30, 2017, no cash was used in investing activities.

Financing Activities

During the six months ended June 30, 2018, net cash provided by financing activities was $100.4 million consisting of the net proceeds from the issuance of common stock in connection with the IPO and from the issuance of Series C preferred shares in February and March 2018.

During the six months ended June 30, 2017, net cash provided by financing activities was $1.6 million consisting of net proceeds received from the Series A preferred stock subscription receivable.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we may need to obtain additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 months. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of our clinical trials;
- the scope, prioritization and number of our research and development programs;

- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs to scale up and secure manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of a product candidate that we do not expect to be commercially available in the near term, if at all. We may not achieve significant revenue from product sales prior to the use of the net proceeds from our IPO. Accordingly, we may need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests of existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Off-Balance Sheet Arrangements

We are not party to any off-balance sheet transactions. We have no guarantees or obligations other than those which arise out of normal business operations.

Contractual Obligations and Commitments

On March 22, 2018, we executed a purchase order, denominated in Chinese yuan, with a supplier, pursuant to which we agreed to purchase approximately $2.3 million of crude cantharidin material related to clinical and commercial supply. As of June 30, 2018, the Company purchased approximately $0.5 million of crude cantharidin material and have a remaining purchase order for approximately another $1.8 million. On July 16, 2018, the Company entered into a supply agreement with the supplier. The executed purchase order is covered under the terms of the supply agreement.

On April 9, 2018, we entered into an agreement to sublease approximately 5,000 square feet of office space in West Chester, Pennsylvania. The agreement requires annual rental payments of approximately $0.1 million and is scheduled to expire on May 31, 2021.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of expenses during the reporting periods. In accordance with U.S GAAP, we evaluate our estimates and judgments on an ongoing basis.

Significant estimates include assumptions used in the determination of share-based compensation. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There were no material changes to our critical accounting policies which are disclosed in our audited financial statements for the years ended December 31, 2017 and 2016 included in our final prospectus dated June 14, 2018, and filed with the SEC on June 15, 2018 pursuant to Rule 424(b)(4).

Recent Accounting Pronouncements

See note 2 to our condensed financial statements for a description of recent accounting pronouncements applicable to our condensed financial statements.

JOBS Act Transition Period

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier to occur of (1) the last day of the fiscal year (a) December 31, 2023, which is the end of the fiscal year following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenues of at least $1.07 billion or (c) in which we are deemed to be a "large accelerated filer" under the rules of the U.S. Securities and Exchange Commission, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Item 3. Quantitative and Qualitative Disclosures About Market Risks

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments, including cash equivalents, are in the form of a money market fund invested in U.S. Treasury obligations.

We are also exposed to market risk related to changes in foreign currency exchange rates. We contract with vendors that are located outside of the United States, including in China, and certain invoices are denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these arrangements. We do not currently hedge our foreign currency exchange rate risk. As of June 30, 2018 and December 31, 2017, we had minimal or no liabilities denominated in foreign currencies, but our purchase order with a supplier, pursuant to which we agreed to purchase approximately $2.3 million of crude cantharidin material, is denominated in Chinese yuan. As of June 30, 2018, the Company purchased approximately $0.5 million of crude cantharidin material under this purchase order.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the year ended December 31, 2017 or six months ended June 30, 2018.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosure.

The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

With respect to the quarter ended June 30, 2018, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures are effective.

Management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be detected.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended June 30, 2018 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None

Item 1A. Risk Factors

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Quarterly Report on Form 10-Q and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

We are a clinical-stage medical dermatology company with limited operating history. Since inception, we have incurred significant net losses. We incurred net losses of $1.9 million and $4.5 million for the years ended December 31, 2016 and 2017, respectively, and $7.8 million for the six months ended June 30, 2018. As of June 30, 2018, we had an accumulated deficit of $20.3 million. Since inception, we have financed our operations with $123.2 million in gross proceeds raised in our initial public offering and private placements of convertible debt and convertible preferred stock. We have no products approved for commercialization and have never generated any revenue.

We have devoted substantially all of our financial resources and efforts to the development of our novel topical solution of cantharidin and our lead product candidate, VP-102, for the treatment of molluscum, including preclinical studies and clinical trials. We have completed one Phase 2 clinical trial in molluscum with our proprietary cantharidin formulation, which we use in VP-102, and we have one ongoing Phase 2 clinical trial and have initiated two Phase 3 clinical trials for VP-102 for the treatment of molluscum. In addition to developing VP-102 for the treatment of molluscum, we are also developing VP-102 as a treatment for common warts and we are enrolling patients in a Phase 2 clinical trial for this indication. We also intend to develop our second cantharidin-based product candidate, VP-103, for the treatment of plantar warts. Therefore, we expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue our ongoing clinical trials evaluating VP-102 for the treatment of molluscum and common warts as well as initiate and complete additional clinical trials, as needed;
- pursue regulatory approvals for VP-102 for the treatment of molluscum, and eventually for the treatment of common warts or any other indications we may pursue for VP-102, as well as for VP-103;
- seek to discover and develop additional product candidates;
- ultimately establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval, including VP-102 and VP-103;
- seek to in-license or acquire additional product candidates for other dermatological conditions;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;

- hire additional clinical, manufacturing and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a newly public company.

To become and remain profitable, we must succeed in developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval, and manufacturing, marketing and selling any product candidates for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

In cases where we are successful in obtaining regulatory approval to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations.

We may need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We expect to continue to incur significant expenses and operating losses over the next several years as we complete our Phase 2 clinical trial of VP-102 for the treatment of molluscum, continue enrolling patients in and complete our Phase 3 clinical trials of VP-102 for the treatment of molluscum, seek marketing approval for VP-102 for the treatment of molluscum, pursue clinical trials and marketing approval for VP-102 for the treatment of common warts and other indications, pursue clinical trials and marketing approval for VP-103 for the treatment of plantar warts and advance any of our other product candidates we may develop or otherwise acquire. In addition, our product candidates, if approved, may not achieve commercial success. Our revenue, if any, will be derived from sales of products that we do not expect to be commercially available for a number of years, if at all. If we obtain marketing approval for VP-102 for the treatment of molluscum or common warts or any other product candidates that we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. We also expect an increase in our expenses associated with creating additional infrastructure to support operations as a newly public company.

As of June 30, 2018, we had cash and cash equivalents of $103.1 million. We believe our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 months. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional product candidates, and changes in regulation. Our future capital requirements will depend on many factors, including:

- the progress and results of our ongoing Phase 2 clinical trial and two Phase 3 clinical trials of VP-102 for the treatment of molluscum;
- the progress and results of our Phase 2 clinical trial and any other additional clinical trials evaluating VP-102 as a potential treatment for common warts;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for VP-103 and any other indications of VP-102 we may decide to pursue;
- the extent to which we develop, in-license or acquire other product candidates and technologies;
- the number and development requirements of other product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;

- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to establish collaborations to commercialize VP-102 or any of our other product candidates outside the United States; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims.

We may require additional capital to commercialize VP-102 for the treatment of molluscum and/or common warts. If we receive regulatory approval for VP-102 for either indication, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

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

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, debt financings and license and collaboration agreements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have a limited operating history and no history of commercializing products, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced operations in 2013, and our operations to date have been largely focused on raising capital and developing our novel topical solution of cantharidin and our lead product candidate, VP-102, for the treatment of molluscum and common warts, including undertaking preclinical studies and conducting clinical trials. VP-102 is our only product candidate for which we have conducted clinical trials. To date, we have completed one Phase 2 clinical trial for the treatment of molluscum using our proprietary cantharidin formula, which we use in VP-102, have one ongoing Phase 2 clinical trial using VP-102 for the treatment of molluscum, have initiated two Phase 3 clinical trials using VP-102 for the treatment of molluscum, and are enrolling patients in a Phase 2 clinical trial using VP-102 for the treatment of common warts. We have not yet demonstrated our ability to successfully complete later-stage clinical trials, obtain regulatory approvals, manufacture a product on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to transition at some point from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Risks Related to the Development of Our Product Candidates

We have only one product candidate, VP-102, for the treatment of molluscum and common warts, for which we are currently conducting clinical trials. If we are unable to successfully develop, receive regulatory approval for and commercialize VP-102 for the treatment of molluscum and/or common warts or any other indications, or successfully develop any other product candidates, or experience significant delays in doing so, our business will be harmed.

We currently have no products that are approved for commercial sale. We have only one product candidate, VP-102, for which we have conducted clinical trials. To date, we have completed one Phase 2 clinical trial for the treatment of molluscum using our proprietary cantharidin formula, which we use in VP-102, have one ongoing Phase 2 clinical trial using VP-102 for the treatment of

molluscum, have initiated two Phase 3 clinical trials using VP-102 for the treatment of molluscum, and are enrolling patients in a Phase 2 clinical trial using VP-102 for the treatment of common warts. We also intend to develop our second product candidate, VP-103, for the treatment of plantar warts, but we have not conducted any clinical trials for VP-103. We have not completed the development of any product candidates and we may never be able to develop marketable products. We have invested substantially all of our efforts and financial resources in the development of our cantharidin formula and VP-102 for the treatment of molluscum and common warts. Our ability to generate revenue from our product candidates, which we do not expect will occur for a number of years, if ever, will depend heavily on their successful development, regulatory approval and eventual commercialization of these product candidates. The success of VP-102, VP-103 or any other product candidates that we develop or otherwise may acquire will depend on several factors, including:

- timely and successful completion of preclinical studies and our clinical trials;
- successful development of, or making arrangements with third-party manufacturers for, our commercial manufacturing processes for any of our product candidates that receive regulatory approval;
- receipt of timely marketing approvals from applicable regulatory authorities;
- launching commercial sales of products, if approved;
- acceptance of our products, if approved, by patients, the medical community and third-party payors, for their approved indications;
- our success in educating physicians and patients about the benefits, administration and use of VP-102 or any other product candidates, if approved;
- the prevalence and severity of adverse events experienced with VP-102 or our other product candidates;
- the availability, perceived advantages, cost, safety and efficacy of alternative treatments for molluscum and/or common warts or any other indications which we may pursue for VP-102 or any other product candidates;
- our ability to produce VP-102 or any other product candidates on a commercial scale;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our product candidates and otherwise protecting our rights in our intellectual property portfolio;
- maintaining compliance with regulatory requirements, including current good manufacturing practices, or cGMPs;
- competing effectively with other procedures; and
- maintaining a continued acceptable safety, tolerability and efficacy profile of the products following approval.

Whether regulatory approval will be granted is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. Our product candidates' success in clinical trials is not guaranteed, and even if clinical trials are successful, it will not guarantee regulatory approval. Following submission of our NDA for VP-102 for the treatment of molluscum or common warts or any other product candidate, the NDA may not be accepted for substantive review, or even if it is accepted for substantive review, the FDA or other comparable foreign regulatory authorities may require that we conduct additional studies or clinical trials, provide additional data, take additional manufacturing steps, or require other conditions before they will reconsider or approve our application. If the FDA or other comparable foreign regulatory authorities require additional studies, clinical trials or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the FDA or other comparable foreign regulatory authorities may not consider sufficient any additional required studies, clinical trials, data or information that we perform and complete or generate, or we may decide to abandon the program.

It is possible that VP-102 or any of our other product candidates we may develop or otherwise acquire will never obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would harm our business.

If the FDA does not conclude that VP-102 satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements under Section 505(b)(2) are not as we expect, the approval pathway for VP-102 may take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case, may not be successful.

We may seek FDA approval through the Section 505(b)(2) regulatory pathway for VP-102 and may pursue that pathway for potential future product candidates. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act, or the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. We may seek to rely on published literature in support of the safety and effectiveness of VP-102.

If we seek, and if the FDA does not allow us to pursue, the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this

were to occur, the time and financial resources required to obtain FDA approval for our product candidates, and complications and risks associated with the development of our product candidates, would likely substantially increase. We may need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in competitive products reaching the market before our product candidates, which could impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization, or that a competitor would not obtain approval first along with subsequent market exclusivity from the FDA, thereby delaying potential approval of our product.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2), some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its Section 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we may submit under Section 505(b)(2).

Clinical product development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

The risk of failure for product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing or at any time during the trial process. The outcome of preclinical testing and early clinical trials may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We have not completed all clinical trials required for the approval of any of our product candidates. Based on the feedback from our meeting with the FDA in September 2017, we initiated two Phase 3 clinical trials of VP-102 for the treatment of molluscum, one of which is being conducted under an SPA with the FDA. We are also enrolling patients in a Phase 2 clinical trial of VP-102 for the treatment of common warts. We cannot assure you that any clinical trial that we are conducting, or may conduct in the future, will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

We may experience delays in ongoing clinical trials for our product candidates, and we do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. For example, following the initiation of our Phase 2 trial of VP-102 for the treatment of common warts, we discovered the need to amend the treatment regimen of the protocol in order to introduce greater flexibility of the treatment interval. We intend to further amend the trial protocol in order to add a second cohort once we have established the desired treatment frequency for the trial. We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards of the institutions in which such trials are being conducted, by the data safety monitoring board for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not favorable or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize, or receive approval for, our product candidates. For example, if a competitor obtained FDA approval for a product containing cantharidin before we are able to obtain approval for our product, this could result in the approval of our product being delayed until the expiration of any NCE exclusivity or other regulatory exclusivity received by such competitor.

If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including:

- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidate in the trial;
- the availability of products and other treatments to treat the skin disease in the trial;
- the willingness of patients to be enrolled in our clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us or them to abandon one or more clinical trials altogether. For example, parents may be reluctant to enroll their children in our clinical trials that have a relatively high risk of their child being assigned to placebo when in the alternative, they could decline participation, and receive compounded cantharidin outside of the clinical trial, if available, or pursue other alternative therapies. Enrollment delays

in these clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we rely on and expect to continue to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance.

Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining patients in our clinical trials. Many of the parents of patients who end up receiving placebo may perceive that their children enrolled in the trial are not receiving VP-102, and they may decide to withdraw their children from our clinical trials to pursue other alternative therapies rather than continue the trial with the perception that their children are receiving placebo.

Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful, nor does it predict final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

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

From time to time, we may publish interim top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.

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, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety and efficacy of the product candidate studied for the target indication.

If our product candidates are associated with side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The FDA or an institutional review board may also require that we suspend, discontinue, or limit our clinical trials based on safety information, or that we conduct additional animal or human studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates or limiting the scope of the approved indication, if approved. Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the product candidate.

Additionally, if one or more of our product candidates receives marketing approval, and we or others identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;

- regulatory authorities may require additional warnings on the labels;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation and physician or patient acceptance of our products may suffer.

There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any regulatory agency in a timely manner or at all. Moreover, any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

While we have negotiated an SPA agreement with the FDA relating to one of our Phase 3 clinical trials for VP-102, this agreement does not guarantee approval of VP-102 or any other particular outcome with respect to regulatory review of the study or the product candidate.

We have initiated two Phase 3 clinical trials of VP-102 for the treatment of molluscum, one of which is being conducted under an SPA with the FDA. The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase 3 clinical trials that are intended to form the primary basis for determining a drug product's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis, within 45 days of receipt of the request. The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory submission for the product candidate with respect to the indication studied. All agreements and disagreements between the FDA and the sponsor regarding an SPA must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA.

However, an SPA agreement does not guarantee approval of a product candidate, and even if the FDA agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts. After an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

We cannot assure you that our planned Phase 3 clinical trial under the SPA will succeed, will be deemed acceptable to the FDA under our SPA agreement, or will result in any FDA approval for VP-102. If the FDA revokes or alters its agreement under the SPA, believes that the manner in which the study was conducted was not consistent with the terms of our SPA, or interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for marketing approval, which could materially adversely affect our business, financial condition and results of operations.

VP-102 is a drug-device combination involving a proprietary applicator, which may result in additional regulatory and other risks.

VP-102 is a drug-device combination for administration of our cantharidin formulation through our proprietary applicator. We may experience delays in obtaining regulatory approval of VP-102 given the increased complexity of the review process when approval of a drug and a delivery device is sought under a single marketing application. VP-102 will be regulated as a drug-device combination product, which requires coordination within the FDA and similar foreign regulatory agencies for review of the product candidate's device and drug components. The determination whether a combination product requires a single marketing application or two separate marketing applications for each component is made by the FDA on a case-by-case basis. Although a single marketing application may be sufficient for the approval of a combination product, the FDA may determine that separate marketing applications are necessary. This determination could significantly increase the resources and time required to bring a particular combination product to market. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of our product candidate due to regulatory timing constraints and uncertainties in the product development and approval process, as well as coordination between two different centers within FDA responsible for review of the different components of the combination product.

Failure to successfully develop or supply the device, delays in or failure of the studies conducted by us, our collaborators, or third-party providers, or failure of our Company, our collaborators, or third-party providers to obtain or maintain regulatory approval

or clearance of the device component of VP-102 could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in VP-102 reaching the market. Further, failure to successfully develop or supply the device, or to gain or maintain its approval, could adversely affect sales of VP-102.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

We may not be successful in our efforts to increase our pipeline of product candidates, including by pursuing additional indications for our current product candidate or in-licensing or acquiring additional product candidates for other dermatological conditions.

A key element of our strategy is to build and expand our pipeline of product candidates, including by developing VP-102 for the treatment of other dermatological conditions and VP-103 for the treatment of plantar warts. In addition, we intend to in-license or acquire additional product candidates for other dermatological conditions to build a fully integrated dermatology company. We may not be able to identify or develop product candidates that are safe, tolerable and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify, in-license or acquire may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance.

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

Because we have limited financial and management resources, we focus on development programs and product candidates that we identify for specific indications. As such, we are currently primarily focused on the development of VP-102 for the treatment of molluscum and common warts. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications for VP-102 that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. VP-102 is currently our only product candidate. We have not obtained regulatory approval for VP-102 or any product candidate and it is possible that neither VP-102 nor any product candidates we may seek to develop in the future will ever obtain regulatory approval. Neither we nor any future collaborator is permitted to market VP-102 or any future drug product candidates in the United States until we receive regulatory approval of an NDA from the FDA. To date, we have not met or discussed with the European Medicines Agency or any other comparable foreign authority regarding regulatory approval for VP-102 or any other product candidate outside of the United States.

Prior to obtaining approval to commercialize VP-102 and any other drug product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional nonclinical studies or clinical trials for our product candidates either prior to or after approval, or it may object to elements of our clinical development program.

Of the large number of products in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval or marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval or marketing authorization to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

We have invested a significant portion of our time and financial resources in the development of VP-102. Our business is dependent on our ability to successfully complete preclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize VP-102 and any future product candidates in a timely manner.

Even if we eventually complete clinical testing and receive approval of an NDA or foreign marketing application for VP-102 or any future product candidates, the FDA or the applicable foreign regulatory agency may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA or the applicable foreign regulatory agency also may approve or authorize for marketing a product candidate for a more limited indication or patient population that we originally request, and the FDA or applicable foreign regulatory agency may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

In addition, the FDA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Furthermore, even if we obtain regulatory approval for VP-102 and any future product candidates, we will still need to develop a commercial organization, establish a commercially viable pricing structure and obtain approval for adequate reimbursement from third-party and government payors. If we are unable to successfully commercialize VP-102 and any future product candidates, we may not be able to generate sufficient revenue to continue our business.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments, including for VP-102, compared to compounded cantharidin;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments, including compounded cantharidin;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- our ability to hire and retain a sales force in the United States;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for VP-102 and any other potential product candidates;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

In the case of VP-102, the failure of healthcare professionals or patients to perceive the benefits of using VP-102 instead of compounded cantharidin or other alternative therapies, such as curettage or cryotherapy, would adversely affect the commercial success of VP-102, if approved.

If we are unable to establish sales, marketing and distribution capabilities for VP-102 or any other product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have sales or marketing infrastructure. To achieve commercial success for VP-102 and any other product candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization. In the future, we expect to build a focused sales and marketing infrastructure to market or co-promote some of our product candidates in the United States, if and

when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face substantial competition, including from compounded cantharidin products that may compete with VP-102 and any other product candidates, which may result in a smaller than expected commercial opportunity and/or others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from many different sources, including major pharmaceutical and specialty pharmaceutical companies, compounding facilities, academic institutions and governmental agencies and public and private research institutions.

We are aware of several other product candidates in earlier stages of development as potential treatments for the indications we intend to target. Veloce Biopharma, Leo Pharma, and Novan have initiated clinical trials with different programs in molluscum. There are a number of companies conducting late-stage clinical trials for common warts, including Aclaris Therapeutics and Cutanea Life Sciences. In addition, other drugs have been and may continue to be used off label as treatment for molluscum and common warts, and there are other existing alternative therapies such as curettage or cryotherapy.

In addition, some of the market demand for cantharidin may be satisfied by compounding pharmacies and registered outsourcing facilities regulated under Sections 503A and 503B of the FDCA. If we receive approval for VP-102, any compounding by licensed pharmacists or licensed physicians under Section 503A would not be legally permitted to include, regularly or in inordinate amounts, the compounding of any drug that is essentially a copy of VP-102. The FDA has announced that it intends to consider a compounded drug product to be essentially a copy of a commercially available drug under Section 503A if it has the same API, has the same, similar, or an easily substitutable dosage strength, and can be used by the same route of administration. However, a compounded product would not be considered essentially a copy of VP-102, and could be compounded under Section 503A, if there were a difference between the compounded product and VP-102 that was made for an individual patient, and which the prescribing practitioner determines produces a significant difference for that patient. Similarly, any compounding by outsourcing facilities under Section 503B would not be legally permitted to include the compounding of a drug that is essentially a copy of VP-102, if approved, where the compounded drug would be considered essentially a copy if it were identical or nearly identical to VP-102 (which the FDA has interpreted to mean that it has the same active ingredient(s), route of administration, dosage form, dosage strength and excipients as the approved drug), or if it contains the active ingredient in VP-102 (cantharidin), unless there is a change from the approved drug that produces a clinical difference for an individual patient as determined by the prescribing practitioner.

Compounding pharmacies and registered outsourcing facilities may therefore be permitted to compound cantharidin drug products, even if we receive approval for VP-102, if a prescribing practitioner determines that a compounded product prescribed for a specific patient features a change from VP-102 that produces a significant difference for the patient (under Section 503A), or if a prescribing practitioner determines that a compounded cantharidin product features a change from VP-102 that produces a clinical difference for the patient (under Section 503B). Physicians may determine that such differences exist for some or all of their patients

and may choose to prescribe compounded cantharidin products for such patients. Moreover, under Section 503B, outsourcing facilities are not limited to compounding in response to prescriptions for identified, individual patients, and could compound using bulk cantharidin provided cantharidin appears on a list established by the FDA of bulk drug substances for which there is a clinical need or satisfies certain other limited conditions. Although the FDA has not yet established a list of bulk drug substances for which there is a clinical need, the FDA has announced an interim policy pursuant to which bulk drug substances may be nominated for inclusion on such list and, provided certain conditions are met, outsourcing facilities may compound with such bulk drug substances pending evaluation of the substances for inclusion on the FDA's list of bulk drug substances for which there is a clinical need. Cantharidin is currently listed among those nominated substances for which bulk drug substance may be used in compounding by outsourcing facilities pending FDA's evaluation.

In March 2018, the FDA released a draft Guidance for Industry addressing the criteria by which the FDA intends to evaluate whether there exists a clinical need for compounding with a bulk drug substance, including, in the case of a bulk drug substance that is a component of an FDA-approved drug, an evaluation of whether there exists an attribute of the approved drug that makes it medically unsuitable to treat certain patients; whether the drug product proposed to be compounded is intended to address that attribute; and whether the drug product proposed to be compounded must be compounded from a bulk drug substance rather than from the finished, FDA-approved drug product. If the FDA implements these criteria as proposed in the draft Guidance for Industry, and if VP-102 is approved, an outsourcing facility may be permitted to compound a cantharidin product using bulk cantharidin notwithstanding our approval provided it satisfies these and other criteria set forth in the FDA's draft guidance.

In addition, the FDA may, in its enforcement discretion, not prioritize enforcement of the restrictions under Sections 503A and 503B on compounding drugs that are essentially copies of VP-102, if approved, in which case compounded drug product that is essentially a copy of VP-102 could be made available to physicians and their patients. In the event compounders are authorized to continue to compound cantharidin products following approval of VP-102, if approved, we could be subject to significant competition.

In addition, our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than VP-102 or any other product that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our product, which could result in our competitors establishing a strong market position before we are able to enter the market or, if a competitor obtained FDA approval for a product containing cantharidin before we are able to obtain approval for our product, could result in the approval of our product being delayed until the expiration of any NCE exclusivity or other regulatory exclusivity received by such competitor.

Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

We intend to seek NCE exclusivity and/or pediatric exclusivity for VP-102 and future product candidates, and we may be unsuccessful.

As part of our business strategy, we intend to seek NCE exclusivity for VP-102 or future product candidates. In the United States, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of an NCE which is a drug that contains an active moiety that has not been approved by the FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification. This exclusivity period may be extended by an additional six months if certain requirements are met to qualify the product for pediatric exclusivity, including the receipt of a written request from the FDA that we conduct certain pediatric studies, the submission of study reports from such studies to the FDA after receipt of the written request and satisfaction of the conditions specified in the written request. We believe that cantharidin constitutes an NCE, such that VP-102 should, if approved, be eligible for NCE exclusivity and that our planned clinical trials will qualify VP-102 for pediatric exclusivity if a written request from the FDA is received. However, there can be no guarantee that we will successfully obtain such exclusivity, and if any of our competitors obtains FDA approval of an NDA for a cantharidin drug product before we do, they, and not us, may be eligible for NCE exclusivity. If we do not obtain NCE exclusivity for VP-102, or if a competitor obtains NCE exclusivity for a cantharidin product before we submit and receive approval of an NDA for VP-102, our ability to commence sales and generate revenue would be adversely affected.

Moreover, even if we obtain NCE exclusivity and/or pediatric exclusivity for VP-102, such exclusivity would not block the sale of compounded cantharidin products in those situations where compounding would be permitted under Sections 503A or 503B of the FDCA.

The success of VP-102 for the treatment of molluscum and common warts will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these procedures.

We believe our success depends on continued coverage and adequate reimbursement for procedures using VP-102 for the treatment of molluscum and/or common warts or, in the absence of coverage and adequate reimbursement, on the extent to which patients will be willing to pay out of pocket for such procedures. Obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. Even if the procedure using our product is covered, third-party payors may package the cost of the drug into the procedure payment and not separately reimburse the physician for the costs associated with our product. A decision by a third-party payor not to cover or separately reimburse for our products could reduce physician utilization of our products once approved. Additionally, in the United States, there is no uniform policy of coverage and reimbursement among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided is made on a payor-by-payor basis. One payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage, and adequate reimbursement.

Third-party payors determine which medical procedures they will cover and establish reimbursement levels. Even if a third-party payor covers a particular procedure, the resulting reimbursement payment rates may not be adequate. Patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with the procedure and may be unwilling to undergo such procedures for the treatment of molluscum and/or common warts in the absence of such coverage and adequate reimbursement. Physicians may be unlikely to offer procedures for such treatment if they are not covered by insurance and may be unlikely to purchase and use our product candidates, if approved, for molluscum and/or common warts unless coverage is provided, and reimbursement is adequate.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a procedure is safe, effective and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental, nor investigational.

Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payors. Such updates could impact the demand for our product candidates, to the extent that patients who are prescribed our product candidates, if approved, are not separately reimbursed for the cost of the product candidates. An example of payment updates is the Medicare program updates to physician payments, which is done on an annual basis. In the past, when the application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, ended the use of the statutory formula and provided for a 0.5% annual increase in payment rates under the Medicare Physician Fee Schedule through 2019, but no annual update from 2020 through 2025. MACRA also introduced a merit-based incentive bonus program for Medicare physicians beginning in 2019. At this time, it is unclear how the introduction of the merit-based incentive program will impact overall physician reimbursement under the Medicare program. Any resulting decrease in payment under the merit-based reimbursement system may adversely affect our revenue and results of operations. In addition, the Medicare physician fee schedule has been adapted by some private payors into their plan-specific physician payment schedule. We cannot predict how pending and future healthcare legislation will impact our business, and any changes in coverage and reimbursement that further restricts coverage of our product candidates or lowers reimbursement for procedures using our products could harm our business.

Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that coverage and adequate reimbursement will be made available with respect to the treatments in which our products are used under any foreign reimbursement system.

There can be no assurance that VP-102 for the treatment of molluscum and/or common warts, if approved for sale in the United States or in other countries, will be considered medically reasonable and necessary, that they will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available, or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if they are approved for sale.

The market for VP-102 and any other product candidates may not be as large as we expect.

Our lead indications for VP-102 are for molluscum and common warts, both of which are skin diseases that are currently undertreated with no standard of care. If VP-102 is approved for either indication, individuals may continue to decline treatment for molluscum and/or common warts as, if left untreated, these skin diseases will eventually be resolved by the body's immune system.

In addition, our estimates of the potential market opportunity for VP-102 and any other product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research reports and surveys of dermatologists commissioned by us. These assumptions include the prevalence of molluscum, common warts and other skin diseases as well as the estimated reimbursement levels for VP-102, if approved. However, there can be no assurance that any of these assumptions are, or will remain, accurate. Furthermore, even if our estimates relating to the prevalence of molluscum, common warts and other skin diseases as well as the estimated reimbursement levels for VP-102, if approved, are accurate, the degree of market acceptance by the medical community and those infected by such skin diseases following regulatory approval, if any, could impact our assumptions and reduce the market size for VP-102 in molluscum, common warts or any other indication. For example, if VP-102 is approved for either molluscum or common warts, there can be no assurance that the medical community will prescribe VP-102 for patients over current forms of available alternative therapies. Furthermore, the market research study we commissioned surveying payor organizations has no bearing on the payors, and any assumptions or interpretations based on the results of this study, may ultimately be inaccurate. If the actual market for VP-102 in molluscum, common warts or any other indication we may pursue for VP-102 or for any other product candidate we may develop is smaller than we expect, our revenues, if any, may be limited and it may be more difficult for us to achieve or maintain profitability.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or drugs caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

We currently hold $20 million in product liability insurance coverage in the aggregate, with a per incident limit of $20 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Our business activities involve the use of hazardous materials, which require compliance with environmental and occupational safety laws regulating the use of such materials. If we or our vendors violate these laws, we could be subject to significant fines, liabilities or other adverse consequences.

Our business activities involve the controlled use of hazardous materials, including corrosive, explosive and flammable chemicals and other hazardous compounds in addition to certain biological hazardous waste. Ultimately, the activities of our third party product manufacturers when a product candidate reaches commercialization will also require the use of hazardous materials. Accordingly, we are subject to federal, state and local laws governing the use, handling and disposal of these materials. For example, cantharidin is classified as an extremely hazardous substance in the United States and is subject to strict reporting requirements. Furthermore, the excipients in our product candidate are combustible and flammable. If not handled properly, there is a risk of explosion which could carry liability risk and affect the availability or capacity of the affected vendor. Although we believe that our and our vendors' safety procedures for handling and disposing of these materials comply in all material respects with the standards prescribed by local, state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In addition, our collaborators may not comply with these laws. In the event of an accident or failure to comply with environmental laws, we could be held liable for damages that result, and any such liability could exceed our assets and resources or we could be subject to limitations or stoppages related to our use of these materials which may lead to an interruption of our business operations or those of our third party contractors. While we believe that our existing insurance coverage is generally adequate for our normal handling of these hazardous materials, it may not be sufficient to cover pollution conditions or other extraordinary or unanticipated events. Furthermore, an accident could damage or force us to shut down our operations or one of our vendors. Changes in environmental laws may impose costly compliance requirements on us or otherwise subject us to future liabilities and additional laws relating to the management, handling, generation, manufacture, transportation, storage, use and disposal of materials used in or generated by the manufacture of our products or related to our clinical trials. In addition, we cannot predict the effect that these potential requirements may have on us, our suppliers and contractors or our customers.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or a deficiency in our cyber-security.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and the further development of our product candidates could be delayed.

Risks Related to Our Dependence on Third Parties

We will rely on third parties to conduct our future clinical trials for product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We have engaged a CRO to conduct our Phase 2 and Phase 3 clinical trials of VP-102 for the treatment of molluscum, our Phase 2 clinical trial of VP-102 for the treatment of common warts and expect to engage a CRO for future clinical trials for VP-102 or other product candidates that we may progress to clinical development. We expect to continue to rely on third parties, such as clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on these parties for execution of our preclinical studies and clinical trials, and generally do not control their activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If we or any of our CROs or other third parties, including trial sites, fails to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of VP-102 and any other product candidates.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue.

We currently rely on a third party to supply our raw material used in VP-102, and if we encounter any difficulties in procuring, or creating an alternative for, our raw material in VP-102 or any of our other product candidates we may develop, our business operations would be impaired.

To date, we have obtained naturally-sourced cantharidin, which is the raw material used to manufacture the API for VP-102 and is obtained from blister beetles, directly or indirectly from suppliers based in the People's Republic of China, or the PRC. We are exposed to a number of environmental risks, including:

- risk of contamination being introduced in the beetle population through environmental factors that we cannot control, which would result in unexpected anomalies or new impurities in the cantharidin;
- loss of the beetle's habitat and other similar environmental risks to the beetle population whether due to climate change, over-development, or otherwise; and
- risk of disease in the beetles.

In addition, any business or economic challenges our existing supplier faces, whether in the ordinary course or not, could impair its ability to meet our cantharidin supply needs. Accordingly, there is a risk that supplies of our product may be significantly delayed by or may become unavailable as a result of any issues affecting our supplier's supply and production of naturally-sourced cantharidin.

Furthermore, our supplier's operations may be curtailed or delayed in the event the regulators in the PRC determine that our supplier is not acting in accordance with laws or under appropriate permits or licenses. We may also face additional supply chain risks due to the regulatory and political structure of the PRC, or as a result of the international relationship between the PRC and the United States or any of the other countries in which our products are marketed. For example, any deterioration in the trade relationship between the U.S. and China, which imposes any restrictions, tariffs or limitations on the export of cantharidin from China would impact our ability to meet our raw material needs. We are also exposed to foreign exchange risks, and fluctuations in exchange rates between the U.S. dollar and the Renminbi could negatively impact the commercial viability of importing cantharidin from the PRC.

While we are working to develop a process for manufacturing cantharidin synthetically, there is risk that we will be unable to do so or that we will be unable to produce a sufficient quantity of synthetically derived cantharidin to meet our needs and, even if we are ultimately able to produce synthetically derived cantharidin in quantities that are sufficient to meet our needs, we cannot predict when we will be able to do so. If we are unable to develop a process for manufacturing cantharidin synthetically and on a commercial scale, we will be forced to continue to rely on naturally sourced cantharidin.

Any difficulties we face in maintaining our supply of cantharidin, or limitations we face in increasing our supply to meet commercial needs for VP-102 or any of our other product candidates, whether such cantharidin is naturally sourced or synthetically derived, would impair our business operations.

We contract with third parties for the manufacture of VP-102 for preclinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of VP-102 or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacture of VP-102, or any other product candidates which we may pursue, for preclinical and clinical testing as well as for commercial manufacture if VP-102 or any other product candidate which we may pursue receives marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of VP-102 or be able to obtain quantities at an acceptable cost or quality, which could delay, prevent or impair our ability to timely conduct our clinical trials or our other development or commercialization efforts.

We also expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of VP-102 or any other product candidates for which we obtain marketing approval. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other regulatory authorities pursuant to inspections that will be conducted after we submit our NDA or comparable marketing application to the FDA or other regulatory authority. We do not have control over a supplier's or manufacturer's compliance with laws, regulations and applicable cGMP standards and other laws and regulations, such as those related to environmental health and safety matters. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a

comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We may be unable to establish any agreements with future third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, qualifying and validating such manufacturers may take a significant period of time and reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible increase in costs for the applicator components, raw materials or API in VP-102; and
- the possible termination or nonrenewal of any agreement by any third party at a time that is costly or inconvenient for us.

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

Our product candidates and any drugs that we may develop may compete with other product candidates and drugs for access to manufacturing facilities. There are no assurances we would be able to enter into similar commercial arrangements with other manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

To date, all manufacturing and assembly of our single-use precision applicator has been done using a manual process. In order to manufacture our applicator on a commercial scale, we will need to develop an automated process successfully and on a timely basis. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any such replacement. We expect to continue to depend on third-party contract manufacturers for the foreseeable future. Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis. If there is any disruption in our supply chain, it could take a significant period of time to qualify and validate a replacement on terms acceptable to us, if we are able to at all.

We may seek collaborations with third parties for the development or commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may seek third-party collaborators for the development and commercialization of our product candidates, including for the commercialization of any of our product candidates that are approved for marketing outside the United States. Our likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. If we do enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

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

Our product development programs and the potential commercialization of our product candidates will require substantial additional capital. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

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

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

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market.

We plan to rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our product candidates. The issuance, scope, validity, enforceability, strength, and commercial value of patents in the pharmaceutical field involves complex legal and scientific questions and can be uncertain. We currently do not own any issued patents, and the patent applications that we own may fail to result in issued patents with claims that cover the product candidates in the United States or in foreign jurisdictions. If this were to occur, early generic competition could be expected against our product candidates in development. There may be relevant prior art relating to our future patents and patent applications which could

invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the API in many of our product candidates has been available and used for many years, it is possible that these products have previously been used in such a manner that such prior usage would affect our ability to obtain patents based on our patent applications. Moreover, because numerous parties have developed and/or commercialized, or are developing, a wide variety of applicator devices for use with topical dermatological medications, it is possible that prior art related to applicator devices could affect our ability to obtain patent protection for our planned product applicator device or that disputes may arise related to whether third-party applicator devices infringe patents we have applied for.

The patent prosecution process is expensive and time-consuming. We may not be able to prepare, file, and prosecute all necessary or desirable patent applications for a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

In addition to the protection we hope to receive from patents we have applied for, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development and reformulation processes that involve proprietary know-how, information, or technology that is not covered by patents. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, or that our trade secrets and other confidential proprietary information will not be disclosed. Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. Also, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA is considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as that in the United States or Europe. These products may compete with our product candidates, and our future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before grant. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property rights, which could make it difficult for us to stop the infringement of our future patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our future patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that require the USPTO to issue new regulations for their implementation, and it may take the courts years to interpret the provisions of the new statute. It is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents. Further, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have owned or licensed or that we might obtain in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Similarly, changes in patent laws and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims, or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and/or applications and any patent rights we may obtain in the future. We rely on our outside counsel to pay these fees. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market, and this circumstance could harm our business.

The patent applications that we have covering our product candidates are limited to specific formulations, preparations and devices, and methods of use and manufacturing processes, and our market opportunity for our product candidates may be limited by the lack of patent protection for the active ingredient itself and by competition from other formulations and manufacturing processes, as well as administration methods that may be developed by competitors.

Cantharidin is a naturally occurring compound found in many species of blister beetles and has been used since ancient times for medicinal purposes. Therefore, the composition of matter for the chemical structure of cantharidin itself, which is the API used in our product candidates, is not eligible for patent protection. We seek to obtain patent protection for our manufacturing technology, drug administering technology and our product candidates, including specific formulations, preparations and devices, and methods of use and manufacturing processes. Although the protection afforded by our patent applications may be significant with respect to VP-102, when looking at the ability of the patents we have applied for to block competition, the protection offered by the patents we have applied for may be, to some extent, more limited than the protection provided by a patent claiming the composition of matter of an entirely new chemical structure previously unknown. As a result, generic products that do not infringe the claims of our future patents covering formulations, preparations, devices, methods of use, and manufacturing processes may be available while we are marketing our products. In general, method of use patents are more difficult to enforce than composition of matter patents because, for example, of the risks that the FDA may approve alternative uses of the subject compound not covered by method of use patents, and others may engage in off-label sale or use of the subject compound. Physicians are permitted to prescribe an approved product for uses that are not described in the product's labeling. Although off-label prescriptions may infringe the method of use patents we have applied for, the practice is common across medical specialties and such infringement is difficult to prevent or prosecute. In addition, competitors who obtain the requisite regulatory approval will be able to commercialize products with the same active ingredient as our product candidates so long as the competitors do not infringe any process, use, formulation, preparation or device patents that we have applied for to protect our product candidates, subject to any regulatory exclusivity we may be able to obtain for our product candidates.

The number of patents and patent applications covering products containing the same active ingredient as our product candidates indicates that competitors have sought to develop and may seek to commercialize competing formulations that may not be covered by our patents and patent applications. The commercial opportunity for our product candidates could be significantly harmed if competitors are able to develop and commercialize alternative formulations of our product candidates that are different from ours and do not infringe our issued patents covering our product candidates, our device, or uses of our product candidates.

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

Competitors may infringe the patents we have applied for. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review (IPR), and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could have a material adverse impact on our business.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to

license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

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

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain.

As our current and future product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. There can be no assurance that our current and future product candidates do not infringe other parties' patents or other proprietary rights, and competitors or other parties may assert that we infringe their proprietary rights in any event. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and future product candidates, including interference or derivation proceedings before the USPTO. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize VP-102 and any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Because numerous parties have developed and/or commercialized, or are developing, a wide variety of applicator devices for use with topical dermatological medications, it is possible that third parties may assert that our applicator device infringes patents they own or have applied for. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes our drug or product candidate infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or product candidate that is the subject of the actual or threatened suit.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court orders, to cease commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

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

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

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

We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patent applications, our future patents, or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

If we rely on third parties to manufacture or commercialize VP-102 or any future product candidates, or if we collaborate with additional third parties for the development of VP-102 or any future product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third-party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of our future patents;

- we or future collaborators might not have been the first to make the inventions covered by our future issued patents or our pending patent applications;
- we or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may be held invalid or unenforceable as a result of legal challenges by our competitors;
- issued patents that we own may not provide coverage for all aspects of our product candidates in all countries;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Legal and Regulatory Compliance Matters

Our relationships with customers, physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. The term “remuneration” has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act and the civil monetary penalties statute;
- the federal civil and criminal false claims laws, including, without limitation, the False Claims Act, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of products for unapproved, and thus non-reimbursable, uses;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes which prohibit, among other things, a person from knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization on certain health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates, independent contractors that perform certain services involving the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal transparency laws, including 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: (i) payments or other "transfers of value'' made to physicians teaching hospitals and applicable manufacturers; and (ii) ownership and investment interests held by physicians and their immediate family members; and
- state and foreign law equivalents of each of the above federal laws; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; 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, or that otherwise restrict payments that may be made to healthcare providers; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws that govern 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.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If VP-102 or other product candidates that we may identify are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Even if we obtain regulatory approval for VP-102 or any future product candidates, they will remain subject to ongoing regulatory oversight.

Even if we obtain any regulatory approval for VP-102 or any future product candidates, such product candidates, once approved, will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record-keeping and submitting of safety and other post-market information among other things. Any regulatory approvals that we receive for VP-102 or any future product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 trials, and surveillance to monitor the quality, safety and efficacy of the drug. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval. We will further be required to immediately report any serious and unexpected adverse events and certain quality or production problems with our products to regulatory authorities along with other periodic reports.

Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. We will also have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drug products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we will not be allowed to promote our products for indications or uses for which they do not have approval. The holder of an approved NDA must submit new or supplemental applications and obtain prior approval for certain changes to the approved product, product labeling, or manufacturing process.

In addition, drug manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of VP-102 or any future product candidates, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize VP-102 or any future product candidates and harm our business, financial condition, results of operations and prospects.

Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things: (i) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to

individuals enrolled in Medicaid managed care organizations; (ii) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs; (iii) expanded the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; (iv) increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP; (v) expanded the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (vi) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and (vii) established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug.

Some of the provisions of the ACA have yet to be implemented, and 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. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, 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 ACA-mandated fees, 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. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." We continue to evaluate the potential impact of the ACA and its possible repeal or replacement on our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further 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.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. The Trump administration has also taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these requirements will be interpreted and implemented and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. Any new

regulations or guidance, including implementation of or new guidance regarding the frameworks for compounding under Sections 503A and 503B of the FDCA, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for VP-102 or any future product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of VP-102 or other product candidates by authorizing competition in the form of compounded cantharidin products, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations.

Our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Risks Related to Employee Matters and Managing Our Growth

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

We are highly dependent on the management, development, clinical, financial and business development expertise of Ted White, our President and Chief Executive Officer, Linda Palczuk, our Chief Operating Officer, Joe Bonaccorso, our Chief Commercial Officer, Chris Degnan, our Chief Financial Officer, Patrick Burnett, our Chief Medical Officer, and the other members of our scientific and clinical teams. While we have entered into employment agreements with our executive officers, each of them may currently terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our product pipeline toward scaling up for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of June 30, 2018, we had 11 full-time employees. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of product development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

Risks Related to Ownership of Our Common Stock and Our Status as a Public Company

An active trading market for our common stock may not continue to be developed or be sustained.

Prior to our initial public offering, there was no public market for our common stock, and we cannot assure you that an active trading market for our shares will continue to develop or be sustained. As a result, it may be difficult for you to sell shares at an attractive price or at all.

The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price may be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- the commencement, enrollment or results of our clinical trials of VP-102 for the treatment of molluscum and common warts and any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for VP-102 for the treatment of molluscum and common warts or any other product candidate we may develop, including VP-103, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results from, delays in or termination of clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;

- unanticipated serious safety concerns related to the use of VP-102 or any other product candidate;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. As a newly public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to initiate or continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. Even if we continue to have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

As of August 7, 2018, we had 25,696,371 outstanding shares of common stock. Of these shares, approximately 5.8 million shares are freely tradable and substantially all of the remaining shares of common stock will be available for sale in the public market beginning in December 2018 following the scheduled expiration of lock-up agreements between our stockholders and certain of the underwriters entered into in connection with our initial public offering. Merrill Lynch, Pierce, Fenner & Smith Incorporated and Jefferies LLC may release these stockholders from their lock-up agreements with the underwriters at any time and without notice, which would allow for earlier sales of shares in the public market.

In addition, we have filed a registration statement on Form S-8 under the Securities Act registering the issuance of 4,981,761 shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under this registration statement on Form S-8 are available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and the restrictions of Rule 144 in the case of our affiliates.

Additionally, the holders of approximately 19 million shares of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration

statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors are elected each year;
- stockholders are not entitled to remove directors other than by a 66 $^{2}/_{3}$% vote and only for cause;
- stockholders are not permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent our other stockholders from influencing significant corporate decisions.

Our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates, including entities affiliated with Paul B. Manning, in the aggregate, beneficially own a majority of our outstanding common stock. As a result, these persons, acting together, can significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

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

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;

- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) ending December 31, 2023, which is the end of the fiscal year following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, the Sarbanes-Oxley Act and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting.

Commencing with our fiscal year ending December 31, 2019, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to our initial public offering, we were not required to test our internal control within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the Securities and Exchange Commission, or SEC, or other regulatory authorities.

We have broad discretion in the use of proceeds from our initial public offering.

We will have broad discretion over the use of proceeds from our recent initial public offering. We expect to use the net proceeds to us from our initial public offering, together with our existing cash and cash equivalents, to complete our planned clinical trials, seek regulatory approval and fund the commercial launch, if approved, of VP-102 for the treatment of molluscum, to advance the clinical development of VP-102 for the treatment of common warts, as well as for working capital and other general corporate purposes, including to develop VP-103 and VP-102 for additional indications and to pursue our strategy to develop, in-license or acquire additional product candidates. In addition, we may use a portion of the proceeds from our initial public offering to pursue our strategy to in-license or acquire additional product candidates. Our failure to apply the net proceeds from our initial public offering effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds.

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), effective for net operating losses incurred in taxable years beginning after December 31, 2017, 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 how various states will respond 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 you to consult with your legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in more than one tax jurisdiction. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income tax law, changes in the mix of our profitability from jurisdiction to jurisdiction, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

We might not be able to utilize a significant portion of our net operating loss carryforwards.

As of December 31, 2017, we had federal and state net operating loss carryforwards of $7.0 million. The federal and state net operating loss carryforwards will begin to expire, if not utilized, by 2036. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain how various states will respond to the newly enacted federal tax law. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future.

We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any existing or future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

We will incur increased costs and demands upon management as a result of being a public company.

As a newly public company listed in the United States, we will incur significant additional legal, accounting and other costs, which we anticipate could be between $1.0 million and $2.0 million annually. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the Nasdaq Stock Market, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management’s time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. For example, stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery and federal district courts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Some companies that adopted a similar federal district court forum selection provision are currently subject to a suit in the Chancery Court of Delaware by stockholders who assert that the provision is not enforceable. If a court were to find either choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

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

(a) Recent Sales of Unregistered Equity Securities

Common Stock Issued upon Conversion of Preferred Stock

On June 18, 2018, upon the closing of our IPO, all shares of our then-outstanding convertible preferred stock were automatically converted into 16,246,872 shares of common stock. The issuance of such shares of common stock was exempt from registration under Section 3(a)(9) of the Securities Act.

(b) Use of Proceeds

There has been no material change in the planned use of proceeds from our IPO from those disclosed in the final prospectus for our IPO dated as of June 14, 2018 and filed with the SEC on June 15, 2018 pursuant to Rule 424(b)(4).

(c) Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

The exhibits listed on the Exhibit Index are either filed or furnished with this report or incorporated herein by reference.

EXHIBIT INDEX

Exhibit No.	Description
3.1(1)	Amended and Restated Certificate of Incorporation
3.2(2)	Amended and Restated Bylaws
10.1+ (3)	Form of 2018 Equity Incentive Plan
10.2+ (4)	Form of Stock Option Grant Notice, Stock Option Agreement, Restricted Stock Unit Grant Notice, and Restricted Stock Unit Award Agreement under 2018 Equity Incentive Plan
10.3+ (5)	Form of Indemnification Agreement with Executive Officers and Directors
10.4(6)	Sublease Agreement, by and between Therakos, Inc. and the Registrant, dated April 9, 2018
10.5(7)	Non-Employee Director Compensation Policy
10.6+ (8)	Transition Agreement, by and between the Registrant and Matt Davidson, effective as of May 31, 2018
31.1#	Certification of Chief Executive Officer and President (Principal Executive Officer), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2#	Certification of Chief Financial Officer (Principal Financial Officer), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1#*	Certifications of Chief Executive Officer and President (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer), pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).
101#	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Balance Sheets, (ii) the Condensed Statements of Operations, (iii) the Condensed Statement of Stockholders' Equity (Deficit), (iv) the Condensed Statements of Cash Flows, and (v) Notes to the Condensed Financial Statements (filed herewith).

(1) Previously filed as Exhibit 3.3 to the Company's Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on May 22, 2018, and incorporated herein by reference

(2) Previously filed as Exhibit 3.4 to the Company's Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on May 22, 2018, and incorporated herein by reference

(3) Previously filed as Exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on May 22, 2018, and incorporated herein by reference

(4) Previously filed as Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on May 22, 2018, and incorporated herein by reference

(5) Previously filed as Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on May 22, 2018, and incorporated herein by reference

(6) Previously filed as Exhibit 10.17 to the Company's Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on May 22, 2018, and incorporated herein by reference

(7) Previously filed as Exhibit 10.18 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on June 5, 2018, and incorporated herein by reference

(8) Previously filed as Exhibit 10.19 to Amendment No. 1 the Company's Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on June 5, 2018, and incorporated herein by reference

\+ Indicates management contract or compensatory plan.

\# Filed herewith.

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Signatures

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

VERRICA PHARMACEUTICALS INC.

August 7, 2018

By: /s/ Ted White
Ted White
Chief Executive Officer and President
(Principal Executive Officer)

By: /s/ Chris Degnan
Chris Degnan
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

VERRICA PHARMACEUTICALS INC.
CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ted White, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2018 of Verrica Pharmaceuticals Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2018

/s/ Ted White
Ted White
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

VERRICA PHARMACEUTICALS INC.
CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Chris Degnan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2018 of Verrica Pharmaceuticals Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2018

/s/ Chris Degnan
Chris Degnan
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

VERRICA PHARMACEUTICALS INC.
PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350),Ted White, President and Chief Executive Officer of Verrica Pharmaceuticals Inc. (the "Company"), and Chris Degnan, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2018, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 7th day of August, 2018.

/s/ Ted White	/s/ Chris Degnan
Ted White President and Chief Executive Officer (principal executive officer)	Chris Degnan Chief Financial Officer (principal financial officer)

* This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.