Table of Contents

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 March 31, 2017

☐

☐ **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: 001-37449

Nivalis Therapeutics, Inc.
(Exact name of Registrant as specified in its charter)

Delaware	**20-8969493**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
Post Office Box 18387 **Boulder, Colorado**	**80308**
(Address of principal executive offices)	**(Zip Code)**

(720) 600-4740
(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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer" "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐		Accelerated filer	☒
Non-accelerated filer	☐	(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 ☐☒

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of April 30, 2017 was 15,656,251.

NIVALIS THERAPEUTICS, INC.

FORM 10-Q

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Nivalis Therapeutics, Inc.
Balance Sheets
(In thousands, except for share amounts)

	March 31, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 12,929	$ 24,203
Marketable securities	39,745	36,832
Prepaid expenses and other current assets	263	628
Total current assets	52,937	61,663
Property and equipment and other assets, net	72	272
Total assets	$ 53,009	$ 61,935
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,278	$ 1,921
Accrued direct program expenses	87	2,646
Accrued restructuring charges	2,251	—
Accrued employee benefits	119	1,879
Accrued other liabilities	54	53
Total current liabilities	3,789	6,499
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized and no shares issued and outstanding for both periods presented	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized for both periods presented; 15,656,251 and 15,565,973 shares issued and outstanding, respectively	16	16
Additional paid-in capital	238,434	235,737
Accumulated other comprehensive income	(14)	(17)
Accumulated deficit	(189,216)	(180,300)
Total stockholders' equity	49,220	55,436
Total liabilities and stockholders' equity	$ 53,009	$ 61,935

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

Nivalis Therapeutics, Inc.
Statements of Operations and Comprehensive Loss
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2017	2016
Revenue	$ —	$ —
Operating expenses:		
Research and development (1)	2,758	5,567
General and administrative (1)	2,781	2,367
Restructuring charges	3,486	—
Loss from operations	(9,025)	(7,934)
Interest income	109	96
Net loss attributable to common stockholders	$ (8,916)	$ (7,838)
Unrealized gains on marketable securities	3	—
Comprehensive loss	$ (8,913)	$ (7,838)
Weighted average shares outstanding - basic and diluted	15,644	15,462
Net loss per share - basic and diluted	$ (0.57)	$ (0.51)
(1) Includes stock-based compensation expense		
Research and development	$ 1,265	$ 213
General and administrative	1,432	494
Total stock-based compensation expense	$ 2,697	$ 707

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

Nivalis Therapeutics, Inc.
Statement of Stockholders' Equity
(In thousands)
(Unaudited)

	Common Stock		Additional Paid--in	Accumulated Other		Total Stockholders'
	Shares	Amount	Capital	Comprehensive Income	Accumulated Deficit	Equity
Balance as of December 31, 2016	15,566	$ 16	$ 235,737	$ (17)	$ (180,300)	$ 55,436
Employee stock-based compensation expense	—	—	2,697	—	—	2,697
Issuance of common stock under restricted stock unit awards	90	—	—	—	—	—
Unrealized gains on marketable securities	—	—	—	3	—	3
Net loss	—	—	—	—	(8,916)	(8,916)
Balance as of March 31, 2017	15,656	$ 16	$ 238,434	$ (14)	$ (189,216)	$ 49,220

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

Nivalis Therapeutics, Inc.
Statements of Cash Flows
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2017	**2016**
Operating activities		
Net loss	$ (8,916)	$ (7,838)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	57	30
Stock-based compensation expense	2,697	707
Gain on sales of property and equipment	(26)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other	462	(69)
Accounts payable	(643)	202
Accrued direct program expenses	(2,559)	1,054
Accrued restructuring charges	2,251	—
Accrued employee benefits	(1,760)	(963)
Accrued other liabilities	1	(134)
Net cash used in operating activities	(8,436)	(7,011)
Investing activities		
Purchases of property and equipment	—	(31)
Proceeds from sales of property and equipment	72	—
Purchases of marketable securities	(18,982)	(29,469)
Proceeds from sales and maturities of marketable securities	16,072	27,550
Net cash used in investing activities	(2,838)	(1,950)
Net decrease in cash and cash equivalents	(11,274)	(8,961)
Cash and cash equivalents, beginning of period	24,203	24,991
Cash and cash equivalents, end of period	$ 12,929	$ 16,030

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

NIVALIS THERAPEUTICS, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS

1. Organization and Description of Business

Nivalis Therapeutics, Inc. (the "Company" or "Nivalis"), incorporated in Delaware on August 1, 2012, is a pharmaceutical company that has historically focused on the discovery and development of product candidates for patients with cystic fibrosis, or CF. In November 2016, the Company announced that its Phase 2 trial, evaluating the efficacy and safety of cavosonstat in adult patients with CF, had failed to demonstrate a benefit in its primary endpoint. On January 3, 2017, the Company announced that its Board of Directors had initiated a process to explore and review a range of strategic alternatives. At that time, the Company also announced that it had engaged a financial advisor and established a Special Committee of the Board to explore strategic alternatives. As a result of this process, on April 18, 2017, the Company, Nautilus Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company ("Merger Sub"), and Alpine Immune Sciences, Inc., a Delaware corporation ("Alpine"),entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Alpine, with Alpine continuing as a wholly owned subsidiary of Nivalis and the surviving corporation of the merger (the "Merger"). See Note 7 below for more information regarding the Merger.

2. Liquidity Risks

The Company has incurred operating losses and has an accumulated deficit as a result of ongoing research and development spending. As of March 31, 2017, the Company had an accumulated deficit of $189.2 million. For the three months ended March 31, 2017, net loss was $8.9 million and net cash used in operating activities was $8.4 million.

As announced on January 12, 2017, the Company committed to a restructuring plan that consisted primarily of a workforce reduction of 25 positions, to a total of five remaining positions in order to conserve cash while the Company continued to evaluate strategic alternatives. In connection with this restructuring, the Company discontinued a substantial portion of its research and clinical development activities and no longer anticipates expending material resources on any of its drug candidates in order to reduce expenditures. The Company expects to incur significant transaction related expenses relating to the consummation of the Merger. After considering the actions taken by management, the Company has sufficient cash and marketable securities to fund operations for at least the next 12 months.

3. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and include all adjustments necessary for the presentation of the Company's financial position, results of operations and cash flows for the periods presented. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements and accompanying notes, including accrued liabilities and the fair value-based measurement of equity instruments. Actual results could differ materially from those estimates. The Company evaluates its estimates and assumptions as facts and circumstances dictate.

Unaudited Interim Financial Data

The balance sheet at December 31, 2016 was derived from the Company's audited financial statements, but these interim financial statements do not include all the annual disclosures required by GAAP. These financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto for the year ended December 31, 2016. The accompanying interim financial statements as of March 31, 2017 and for the three months ended March 31, 2017 and 2016, are unaudited. The unaudited interim financial statements have been prepared on a basis consistent with the audited financial statements, pursuant to the rules and regulations of the SEC for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in

accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, the financial statements reflect all adjustments (consisting of normal recurring adjustments) considered necessary to fairly state the Company's financial position as of March 31, 2017 and the results of operations and cash flows for the three months ended March 31, 2017 and 2016. The results for the three months ended March 31, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017 or for any future interim period.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of 90 days or less at the time of purchase to be cash equivalents. Cash and cash equivalents consist of deposits with commercial banks in checking, interest-bearing and demand money market accounts.

Marketable Securities

The Company has designated marketable securities as available-for-sale securities and accounts for them at their respective fair values. Marketable securities are classified as short-term or long-term based on the nature of the securities and their availability to meet current operating requirements. Securities that are classified as available-for-sale are carried at fair value, including accrued interest, with temporary unrealized gains and losses reported as a component of stockholders' equity until their disposition. The Company reviews all available-for-sale securities at each period end to determine if they remain available-for-sale based on the Company's then current intent and ability to sell the security if it is required to do so. The cost of securities sold is based on the specific identification method. All marketable securities are subject to a periodic impairment review. The Company will recognize an impairment charge when a decline in the fair value of the investments below the cost basis is judged to be other-than-temporary.

Accrued Direct Program Expenses

Substantial portions of the Company's preclinical studies and clinical trials, including the manufacture and packaging of drug supplies were performed by third-party laboratories, contract manufacturing organizations, medical centers, contract research organizations and other service providers (collectively vendors). These vendors generally bill monthly or quarterly for services performed or upon achieving certain milestones. For preclinical studies and product development and manufacturing, the Company accrues expenses based upon estimated percentage of work completed and the contract milestones remaining. For clinical studies, expenses are accrued based upon patient enrollment and the duration of the study. The Company monitors patient enrollment, the progress of clinical studies and related activities to the extent possible through internal reviews of data reported by these vendors using software tracking systems, or through clinical site visits and vendor correspondence. The Company's estimates depend on the timeliness and accuracy of the data provided by these vendors regarding the status of each program and total program spending. The Company periodically evaluates these estimates to determine if adjustments are necessary or appropriate based on information received.

Accrued Restructuring Charges

In January 2017, the Company committed to a restructuring plan that consisted primarily of a workforce reduction of 25 positions, to a total of five remaining positions in order to conserve cash while the Company continued to evaluate strategic alternatives. The restructuring was substantially completed during the first quarter of 2017. Cash payments in connection with the workforce reduction, comprised principally of monthly or one-time severance payments, retention bonuses and benefit continuation costs, were approximately $3.5 million of which approximately $1.2 million was paid during the first quarter of 2017. As of March 31, 2017, approximately $2.3 million was accrued for remaining restructuring-related payments expected to be paid in the second and third quarters of 2017.

Comprehensive Loss

Comprehensive loss is comprised of net loss and adjustments for the change in unrealized gains and losses on the Company's investments in available-for-sale marketable securities. The Company presents comprehensive loss and its components in the statements of operations and comprehensive loss for the three months ended March 31, 2017.

Net Loss per Share

The Company reports net loss per share in accordance with the standard codification of ASC "Earnings per Share" ("ASC 260"). Under ASC 260, basic earnings per share, which excludes dilution, is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted earnings per share reflects the potential dilution of securities that could be exercised or converted into common shares, and is computed by dividing net loss by the weighted average of common shares outstanding plus the dilutive potential common shares. Diluted earnings per share excludes the impact of options to purchase common stock, restricted stock units and warrants to purchase common stock, as the effect would be anti-dilutive. During a loss period, the assumed exercise of in-the-money stock options and other potentially diluted instruments has an anti-dilutive effect and therefore, these instruments are excluded from the computation of dilutive earnings per share.

Recent Accounting Pronouncements

In March 2016, the FASB issued ASU No. 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The amendments in this update simplify several aspects of the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, statutory tax withholding requirements, as well as classification within the statement of cash flows. The guidance is effective for the annual periods beginning after December 15, 2016, and interim periods within those annual periods. The Company adopted this standard as of January 1, 2017 and it did not have a material effect on its financial statements. As part of the adoption of this standard, the Company elected to recognize forfeiture of awards as they occur rather than estimating the expected forfeiture rate, as was previously required.

For additional discussion of recent accounting pronouncements please refer to Note 3, "Summary of Significant Accounting Policies – Recently Adopted Accounting Pronouncements and Recently Issued Accounting Pronouncements", in the Company's previously filed Annual Report on Form 10-K for the year ended December 31, 2016.

Fair Value of Financial Instruments

The carrying amounts of cash equivalents and marketable securities approximate their fair value based upon quoted market prices. Certain financial instruments are not measured at fair value on a recurring basis, but are recorded at amounts that approximate their fair value due to their liquid or short-term nature, such as cash, accounts payable, accrued direct program expenses, accrued restructuring charges, and accrued employee benefits, and other financial instruments included within current assets or current liabilities.

Fair Value Measurements

In general, asset and liability fair values are determined using the following categories:

Level 1 – inputs utilize quoted prices in active markets for identical assets or liabilities.

Level 2 – inputs include quoted prices for similar assets or liabilities in active markets, and inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly.

Level 3 – inputs are unobservable inputs and include situations where there is little, if any, market activity for the balance sheet items at period end. Pricing inputs are unobservable for the terms and are based on the Company's own estimates about the assumptions that a market participant would use in pricing an asset.

The Company's financial instruments, including money market investments, reverse repurchase agreements, corporate debt securities, U.S. Treasury securities and obligations of U.S. government agencies, are measured at fair value on a recurring basis. There were no transfers between levels for the three months ended March 31, 2017.

Assets and liabilities measured at fair value on a recurring basis consisted of the following types of instruments as of March 31, 2017 and December 31, 2016 (in thousands):

Description	March 31, 2017	Quoted prices in active markets for identical assets (Level 1)	Quoted prices for similar assets observable in the marketplace (Level 2)	December 31, 2016	Quoted prices in active markets for identical assets (Level 1)	Quoted prices for similar assets observable in the marketplace (Level 2)
Assets measured at fair value:						
Money market investments	$ 6,882	$ 6,882	$ —	$ 14,186	$ 14,186	$ —
U.S. Treasury securities, obligations of U.S. government agencies, corporate debt securities and reverse repurchase agreements	42,745	—	42,745	41,832	—	41,832

4. Cash, Cash Equivalents and Marketable Securities

The following is a summary of cash, cash equivalents and marketable securities as of March 31, 2017 and December 31, 2016 (in thousands):

	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Fair market value
March 31, 2017				
Cash	$ 3,047	$ -	$ -	$ 3,047
Money market funds	6,882	-	-	6,882
Reverse repurchase agreement	3,000	-	-	3,000
U.S Treasury securities and obligations of U.S. government agencies	16,535	-	(7)	16,528
Corporate debt securities	23,224	1	(8)	23,217
Total for March 31, 2017	$ 52,688	$ 1	$ (15)	$ 52,674
December 31, 2016				
Cash	$ 5,017	$ –	$ –	$ 5,017
Money market funds	14,186	–	–	14,186
Reverse repurchase agreements	5,000	–	–	5,000
U.S Treasury securities and obligations of U.S. government agencies	16,458	1	(2)	16,457
Corporate debt securities	20,391	1	(17)	20,375
Total for December 31, 2016	$ 61,052	$ 2	$ (19)	$ 61,035

5. Stockholders' Equity

Common Stock

On June 22, 2015, the Company completed its IPO of 6,325,000 shares of its common stock, including 875,000 shares from the exercise of the underwriters' over-allotment option. The Company received proceeds of $78.8 million from its IPO, net of $9.8 million in expenses and underwriters' discounts and commissions relating to the issuance and distribution of the securities.

On April 18, 2016, in connection with the appointment of the Company's new Chief Medical Officer, the Company approved a grant of stock options to purchase 108,333 shares of the Company's common stock (the "Options") and 216,667 restricted stock units ("RSUs"). The Options and RSUs were issued pursuant to a separate Notice of Inducement Stock Option Grant and Inducement Stock Option Agreement and Notice of Restricted Stock Unit Inducement Grant and Inducement Restricted Stock Unit Agreement and are considered inducement grants made in

accordance with NASDAQ Listing Rule 5635(c)(4). In January 15, 2017, Dr. Rodman's employment was terminated as part of our workforce reduction when his position was eliminated. As a result of the termination of Dr. Rodman's employment, all unvested Options were 100% vested and the unvested portion of the RSUs that would have vested in the 12-month period following the termination date vested and the remaining unvested RSUs were forfeited.

On July 5, 2016, the Company filed a registration statement on Form S-3 that was declared effective on July 14, 2016 registering (i) the offering, issuance and sale of up to $125,000,000 in the aggregate of an indeterminate number of shares of common stock and preferred stock, an indeterminate principal amount of debt securities and an indeterminate number of warrants and (ii) the resale of up to 3,732,412 shares of common stock by selling stockholders pursuant to a base prospectus that forms a part of the registration statement. The registration statement also registers the offering, issuance and sale of the Company's common stock having up to a maximum aggregate offering price of $20,000,000 that may be issued and sold in an at-the-market offering under a sales agreement the Company entered into with Cowen and Company, LLC on July 5, 2016 pursuant to a sales agreement prospectus that forms a part of the registration statement. The $20,000,000 of common stock that may be sold under the sales agreement prospectus is included in the $125,000,000 that may be sold by the Company under the base prospectus. As of March 31, 2017, approximately 20,000 shares of common stock have been sold at an average sales price of $8.00 per share under the sales agreement, net of offering costs of approximately $140,000.

At March 31, 2017, shares of common stock have been reserved for issuance as follows:

Options to purchase common stock - issued	3,376,921
Options to purchase common stock - unissued	550,225
Inducement grants - issued	108,333
Employee stock purchase plan - unissued	180,845
Warrants to purchase common stock	18,534
	4,234,858

Stock-Based Compensation

During the three-month period ended March 31, 2017 and 2016, the Company recorded approximately $2.7 million and $707,000, respectively, in stock-based compensation expense for the vesting of stock options and RSUs. During the first quarter of 2017, the Company recorded approximately $2.3 million of stock-based compensation expense specifically related to the accelerated vesting of options and RSUs held by employees affected by the restructuring plan and workforce reduction announced on January 12, 2017.

6. Net Loss per Share

The Company excluded the following common stock equivalents, outstanding as of March 31, 2017 and 2016, from the computation of diluted net loss per share for the applicable quarterly periods because they had an anti-dilutive impact on the computation:

	March 31,	
	2017	2016
Options to purchase common stock - issued	3,376,921	1,807,118
Inducement grants - issued	108,333	—
Warrants to purchase common stock	18,534	18,534
Total	3,503,788	1,825,652

7. Subsequent Events

On April 18, 2017, the Company, Merger Sub and Alpine entered into the Merger Agreement pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Alpine, with Alpine continuing as a wholly owned subsidiary of Nivalis and the surviving corporation of the Merger. The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

Subject to the terms and conditions of the Merger Agreement, at the closing of the Merger, each outstanding share of Alpine capital stock will be converted into the right to receive shares of Nivalis common stock (subject to the payment of cash in lieu of fractional shares and after giving effect to a reverse stock split of Nivalis common stock if determined necessary or appropriate by Nivalis, Alpine and Merger Sub) such that, immediately following the effective time of the Merger, current Nivalis stockholders are expected to own approximately 26% of the outstanding capital stock of Nivalis on a fully diluted basis, and current Alpine stockholders are expected to own approximately 74% of the outstanding capital stock of Nivalis on a fully diluted basis.

Prior to the execution and delivery of the Merger Agreement, and as a condition of the willingness of Nivalis to enter into the Merger Agreement, certain existing stockholders of Alpine have entered into agreements with Alpine pursuant to which such stockholders have agreed, subject to the terms and conditions of such agreements, to purchase prior to the consummation of the Merger shares of Alpine's capital stock for an aggregate purchase price of approximately $17 million. The consummation of the transactions contemplated by such agreements is conditioned upon the satisfaction or waiver of the conditions set forth in the Merger Agreement.

Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by the stockholders of Nivalis and Alpine, and satisfaction of minimum net cash thresholds by each of Nivalis and Alpine. In accordance with the terms of the Merger Agreement, (i) certain executive officers, directors and stockholders of Alpine (solely in their respective capacities as Alpine stockholders) have entered into support agreements with Nivalis to vote all of their shares of Alpine capital stock in favor of adoption of the Merger Agreement (the "Alpine Support Agreements") and (ii) certain executive officers, directors and stockholders of Nivalis (solely in their respective capacities as Nivalis stockholders) have entered into support agreements with Alpine to vote all of their shares of Nivalis common stock in favor of approval of the Merger Agreement (the "Nivalis Support Agreements," together with the Alpine Support Agreements, the "Support Agreements"). The Support Agreements include covenants with respect to the voting of such shares in favor of approving the transactions contemplated by the Merger Agreement and against any competing acquisition proposals and, other than the Nivalis Support Agreement delivered by The Estate of Arnold H. Snider, III, place certain restrictions on the transfer of the shares of Nivalis and Alpine held by the respective signatories thereto. The Support Agreements to be executed by certain stockholders of Nivalis affiliated with Deerfield Management Company, L.P. (the "Deerfield Signatories") contain certain exceptions to the transfer of the shares of Nivalis held by the respective signatories thereto.

The Merger Agreement contains certain termination rights for both Nivalis and Alpine, and further provides that, upon termination of the Merger Agreement under specified circumstances, either party may be required to pay the other party a termination fee of $2,500,000, or in some circumstances reimburse the other party's expenses up to a maximum of $1,000,000.

At the effective time of the Merger, the Board of Directors of Nivalis is expected to consist of seven members, four of whom will be designated by Alpine, two of whom will be designated by Nivalis and one of whom will be an independent director designated by a majority of the other members of the Nivalis Board of Directors.

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

Forward-Looking Information

This Quarterly Report on Form 10-Q and the information incorporated herein by reference includes statements that are, or may be deemed, "forward-looking statements" (including within the meaning of Section 21E of the United States Securities Exchange Act of 1934, as amended, and Section 27A of the United States Securities Act of 1933, as amended). In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Quarterly Report on Form 10-Q and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, expectations regarding our liquidity and financial condition, prospects and strategies, and the timing and our ability to consummation of the Merger.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. These risks and uncertainties include, without limitation, the risk that the conditions to the closing of the Merger are not satisfied, including the failure to timely or at all obtain stockholder approval for the transaction; uncertainties as to the timing of the consummation of the transaction and the ability of each of Nivalis and Alpine to consummate the transaction; risks related to our ability to correctly estimate our operating expenses and our expenses associated with the transaction; risks related to the market price of our common stock relative to the exchange ratio under the Merger Agreement; the ability of Nivalis or Alpine to protect their respective intellectual property rights; competitive responses to the transaction; unexpected costs, charges or expenses resulting from the transaction; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the transaction; and legislative, regulatory, political and economic developments. We caution you that forward-looking statements are not guarantees of future performance or events and that actual performance or events may differ materially from the forward-looking statements contained herein. Any forward-looking statements that we make in this Quarterly Report on Form 10-Q speak only as of the date of this report, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

You should also read carefully the factors described in the "Risk Factors" section of our annual report on Form 10-K filed with the SEC for the year ended December 31, 2016 and in this Quarterly Report on Form 10-Q to better understand the risks and uncertainties we face and underlying any forward-looking statements including statements we make in our other reports filed with the SEC. You may obtain a copy of all reports we file with the SEC on our website at www.nivalis.com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this report.

Overview

We are a pharmaceutical company that has historically been focused on the discovery and development of product candidates for patients with cystic fibrosis, or CF. In November 2016, we announced that a Phase 2 clinical trial of cavosonstat had failed to achieve its primary endpoint of lung function improvement and a key secondary endpoint of sweat chloride reduction. In February 2017, we announced that a second Phase 2 clinical trial of cavosonstat had also failed to achieve its primary endpoint of lung function improvement and a key secondary endpoint of sweat chloride reduction. We currently do not have any drugs that are commercially available and none of our drug candidates have obtained the approval of the U.S. Food and Drug Administration, or FDA, or any similar foreign regulatory authority.

Strategic Process

Following the failure of these Phase 2 clinical trials in CF patients to meet their primary endpoints, we announced on January 3, 2017 the initiation of a process to explore and review a range of strategic alternatives focused on maximizing stockholder value from our clinical assets and cash resources and our intent to streamline our operations in order to conserve capital. We also announced that we had engaged a financial and strategic advisor, Ladenburg

Thalmann & Co., Inc., to advise us on strategic alternatives and appointed a Special Committee of our Board of Directors to investigate and evaluate strategic alternatives. In January, our Board of Directors also approved a workforce reduction that took place between January 15 and March 31, 2017 that affected a total of 25 employees, including our former President and Chief Executive Officer, and our former Chief Medical Officer, whose employment was terminated effective January 15, 2017. As of the date of this filing, we have five full-time employees and all research and development activities have ceased.

Merger Agreement

After conducting a diligent and extensive process, together with our financial advisor, which included the receipt of more than eighty non-binding proposals from interested parties and careful evaluation and consideration of those proposals, and following extensive negotiation with Alpine Immune Sciences, Inc., a Delaware corporation, or "Alpine," on April 18, 2017, we, Nautilus Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Nivalis, or "Merger Sub", and Alpine entered into an Agreement and Plan of Merger and Reorganization, or the "Merger Agreement" pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Alpine, with Alpine continuing as a wholly owned subsidiary of Nivalis and the surviving corporation of the merger, which we refer to as the "Merger".

The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

Subject to the terms and conditions of the Merger Agreement, at the closing of the Merger, each outstanding share of Alpine capital stock will be converted into the right to receive shares of Nivalis common stock (subject to the payment of cash in lieu of fractional shares and after giving effect to a reverse stock split of Nivalis common stock if determined necessary or appropriate by Nivalis, Alpine and Merger Sub) such that, immediately following the effective time of the Merger, preexisting Nivalis stockholders are expected to own approximately 26% of the outstanding capital stock of Nivalis on a fully diluted basis, and preexisting Alpine stockholders are expected to own approximately 74% of the outstanding capital stock of Nivalis on a fully diluted basis.

Prior to the execution and delivery of the Merger Agreement, and as a condition of the willingness of Nivalis to enter into the Merger Agreement, certain existing stockholders of Alpine have entered into agreements with Alpine pursuant to which such stockholders have agreed, subject to the terms and conditions of such agreements, to purchase prior to the consummation of the Merger shares of Alpine's capital stock for an aggregate purchase price of approximately $17 million. The consummation of the transactions contemplated by such agreements is conditioned upon the satisfaction or waiver of the conditions set forth in the Merger Agreement.

Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by the stockholders of Nivalis and Alpine, and satisfaction of minimum net cash thresholds by each of Nivalis and Alpine. In accordance with the terms of the Merger Agreement, (i) certain executive officers, directors and stockholders of Alpine (solely in their respective capacities as Alpine stockholders) have entered into support agreements with Nivalis to vote all of their shares of Alpine capital stock in favor of adoption of the Merger Agreement (the "Alpine Support Agreements") and (ii) certain executive officers, directors and stockholders of Nivalis (solely in their respective capacities as Nivalis stockholders) have entered into support agreements with Alpine to vote all of their shares of Nivalis common stock in favor of approval of the Merger Agreement (the "Nivalis Support Agreements," together with the Alpine Support Agreements, the "Support Agreements"). The Support Agreements include covenants with respect to the voting of such shares in favor of approving the transactions contemplated by the Merger Agreement and against any competing acquisition proposals and, other than the Nivalis Support Agreement delivered by The Estate of Arnold H. Snider, III, place certain restrictions on the transfer of the shares of Nivalis and Alpine held by the respective signatories thereto. The Support Agreements to be executed by certain stockholders of Nivalis affiliated with Deerfield Management Company, L.P. (the "Deerfield Signatories") contain certain exceptions to the transfer of the shares of Nivalis held by the respective signatories thereto.

The Merger Agreement contains certain termination rights for both Nivalis and Alpine, and further provides that, upon termination of the Merger Agreement under specified circumstances, either party may be required to pay the

other party a termination fee of $2,500,000, or in some circumstances reimburse the other party's expenses up to a maximum of $1,000,000.

At the effective time of the Merger, the Board of Directors of Nivalis is expected to consist of seven members, four of whom will be designated by Alpine, two of whom will be designated by Nivalis and one of whom will be an independent director designated by a majority of the other members of the Nivalis Board of Directors.

Despite devoting significant efforts to identify, evaluate and negotiate the Merger Agreement with Alpine, we may not be successful in completing the Merger. Further, even if the Merger is completed, it ultimately may not deliver the anticipated benefits or enhance stockholder value. If the Merger is not completed, we cannot predict whether and to what extent we would be successful in consummating an alternative transaction, the timing of such a transaction or our future cash needs required to complete such a transaction, and we may choose or be forced to dissolve and liquidate our assets.

GSNOR Inhibitor Portfolio

Based on years of focused research in the GSNOR area, and notwithstanding the failure of cavosonstat to achieve the primary endpoint within a Phase 2 trial in CF, we continue to believe that compounds that interact specifically with the enzyme known as S-nitrosoglutathione reductase, which we refer to as GSNOR, may have the potential to achieve positive medical effects by modulating its activity in the body. GSNOR regulates levels of an endogenous protein known as S-nitrosoglutathione or GSNO. Depleted levels of GSNO have been associated with CF, asthma, inflammatory bowel diseases and certain cardiovascular diseases. Cavosonstat and other GSNOR inhibitor drug candidates in our portfolio may have benefit in other clinical indications, such as, inflammatory lung and bowel diseases, and certain cardiovascular diseases. Cavosonstat is the furthest advanced in development of these potential candidates. In addition to the clinical safety profile, chronic toxicology testing for six months in rats and nine months in dogs has also been completed along with a six-month carcinogenicity trial in RASh transgenic mice.

We have built a patent portfolio covering the structure or therapeutic use of small molecules designed to selectively inhibit GSNOR activity. We own exclusive rights to cavosonstat in the United States and all other major markets, including U.S. composition of matter patent protection until at least 2031. We do not have current plans to continue development of any of our GSNOR inhibitor drugs ourselves.

Our lead product candidate, cavosonstat, is a small molecule inhibitor of GSNOR. In patients with CF, decreased CFTR activity is due in part to reduced levels of GSNO, which is regulated by GSNOR. GSNO modifies the function of certain CFTR chaperone proteins, and thereby improves the stability of F508del CFTR. Our preclinical studies have previously shown that cavosonstat is a selective and reversible inhibitor of GSNOR, that GSNOR inhibition increased GSNO levels, and that the stabilizing effect of cavosonstat significantly increased and prolonged CFTR activity when added to other CFTR modulators. The ultimate goal of our CFTR stabilizing therapy was, therefore, to increase and prolong CFTR activity through GSNOR inhibition when cavosonstat was administered along with other CFTR modulators, thereby increasing chloride transport. In other models of inflammatory lung and bowel disease, cavosonstat also demonstrated positive anti-inflammatory effects.

Financial Operations Overview

Revenue

To date, we have not generated any revenue and may never do so. We have determined to cease further development of cavosonstat and our other GSNOR inhibitors while we identify and evaluate strategic alternatives and, therefore, do not anticipate generating revenue ourselves from our potential product candidates.

Research and Development Expense

Research and development expense consists of costs incurred for the development of our product candidates, which include:

- direct program expenses, which are costs incurred for contract research organizations, or CROs, clinical investigators, clinical consultants and clinical sites that will conduct our preclinical studies and clinical trials as well as costs associated with acquiring, developing and manufacturing preclinical and clinical

supplies;

- employee-related expenses, including salaries, benefits, stock-based compensation expense and other compensation costs;
- costs associated with regulatory filings; and
- costs of laboratory supplies, facilities, depreciation, travel and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other operating costs related to research and development.

Research and development costs are expensed as incurred. 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.

Below is a summary of our research and development expenses by categories of costs for the periods presented. The other expenses category includes travel, lab and office supplies, clinical trial management software license fees, business insurance and other miscellaneous expenses.

	Three Months Ended March 31,	
	2017	2016
	(in thousands)	
Direct program expenses		
Cavosonstat for cystic fibrosis	$ 177	$ 3,478
Personnel and other expenses		
Salaries, benefits and stock-based compensation	1,975	1,480
Consulting and outsourced services	169	89
Facilities and depreciation	84	81
Other expenses	353	439
Total research and development expenses	$ 2,758	$ 5,567

All of our research and development expenses for the three months ended March 31, 2017 and 2016 relate to the development of cavosonstat. We have expended an aggregate of approximately $30.4 million for direct program expenses related to cavosonstat from inception through March 31, 2017. We anticipate that overall research and development costs will decrease significantly for the foreseeable future as compared to prior periods due to the near-term conclusion of our currently planned program expenses and our workforce reduction that occurred during the first quarter of 2017 resulting from our determination to cease further development of cavosonstat and our other GSNOR inhibitors and to seek to conserve cash resources while we identify and evaluate strategic alternatives. We have not incurred, nor do we expect to incur, significant cancellation charges with our vendors during the wind-down of research and development activities.

General and Administrative Expense

General and administrative expense consists principally of salaries and related costs not included in research and development expenses, including stock-based compensation for personnel in executive, finance, business development and information technology functions, facility costs and professional fees for legal, patent review, consulting and accounting services.

We anticipate that overall general and administrative costs will decrease during the remainder of 2017 compared with prior periods due to lower personnel-related costs and stock-based compensation due to the workforce reduction. Partially offsetting these decreases will be increased legal and financial advisory costs in connection with pursuing and completing a potential strategic transaction of the company.

Interest Income

Interest income for the three months ended March 31, 2017 and 2016 consists of interest earned on marketable securities and money market funds.

Results of Operations

Comparison of the Three Months Ended March 31, 2017 and 2016.

Research and Development Expenses. Research and development expenses for the three months ended March 31, 2017 and 2016 were as follows:

	Three Months Ended March 31,	
	2017	2016
	(in thousands)	
Research and development expenses	$ 2,758	$ 5,567
Decrease from prior period	$ (2,809)	—
% change from prior period	(50.5)%	—

The decrease in research and development expenses for the three months ended March 31, 2017 compared to the same period in the prior year was the result of winding down all research and development activities during the first quarter of 2017. During the first quarter of the prior year we incurred approximately $2.5 million for cavosonstat Phase 2 clinical trials in CF and approximately $800,000 for clinical drug manufacturing and long-term toxicology studies. Salaries and benefit expenses decreased by approximately $400,000 during the first quarter of 2017 compared to the prior year due to the workforce reduction. Partially offsetting these decreases were increased stock-based compensation expenses of $1.1 million related to the accelerated vesting of options and RSUs held by employees affected by the restructuring plan and workforce reduction.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2017 and 2016 were as follows:

	Three Months Ended March 31,	
	2017	2016
	(in thousands)	
General and administrative expenses	$ 2,781	$ 2,367
Increase from prior period	$ 414	—
% change from prior period	17.5 %	—

The increase in general and administrative expenses for the three months ended March 31, 2017 compared to the same period in the prior year was primarily due to stock-based compensation expense of $1.0 million related to the accelerated vesting of options held by employees affected by the restructuring plan and workforce reduction. During this same period marketing and patent expenses combined decreased by approximately $470,000 due to the wind-down in drug-development activities, while legal expenses increased by approximately $200,000 in support of our pursuing and completing a potential strategic transaction of the company. Salaries and benefit expenses decreased by approximately $135,000 during the first quarter of 2017 compared to the prior year due to the workforce reduction.

Restructuring charges. Restructuring charges were approximately $3.5 million for the three months ended March 31, 2017. We did not have any restructuring charges during the prior year. In November 2016, we announced that our Phase 2 trial, evaluating the efficacy and safety of cavosonstat in adult patients with CF, had failed to demonstrate a benefit in its primary endpoint. On January 3, 2017, we announced that our Board of Directors had initiated a process to explore and review a range of strategic alternatives. At that time, we engaged a financial advisor and established a Special Committee of the Board of Directors to explore strategic alternatives.

In January 2017, we committed to a restructuring plan that consisted primarily of a workforce reduction of 25 positions, to a total of five remaining positions in order to conserve cash while we continued to evaluate strategic alternatives. We entered into severance and release agreements with employees affected by the workforce reduction and retention agreements with key employees if these employees remained with us until terminated by the company without cause prior to such date. All employees affected by the workforce reduction received either a lump-sum severance payment or monthly severance payments per the terms of their employment agreements with us. Certain of these employees also received retention bonus payments that were expensed upon payment and separation from Nivalis during the first quarter of 2017. In accordance with ASC 420, "Exit and Disposal Cost Obligations", we are recognizing the restructuring liabilities related to the five remaining positions over the employees' anticipated service period, which was expected to be the first three quarters of 2017.

Accrued restructuring charges for the three months ended March 31, 2017, in connection with the workforce reduction, comprised principally of monthly or one-time severance payments, retention bonuses and benefits continuation costs, were approximately $3.5 million of which approximately $1.2 million was paid during the first quarter of 2017. As of March 31, 2017, approximately $2.3 million was accrued in remaining restructuring-related payments expected to be paid in the second and third quarters of 2017.

Interest Income. Interest income for the three months ended March 31, 2017 and 2016 were as follows:

	Three Months Ended March 31,	
	2017	2016
	(in thousands)	
Interest income	$ 109	$ 96
Increase from prior period	$ 13	—
% change from prior period	13.5 %	—

The increase in interest income during 2017 over the prior year three-month period was due to higher investment interest rates earned on our cash equivalents and marketable securities.

Liquidity and Capital Resources

Since inception, we have funded our operations primarily through the proceeds from our IPO in June 2015 as well as private placements of equity and convertible debt prior to the IPO. As of March 31, 2017, we had cash, cash equivalents and marketable securities of $52.7 million and no debt.

The following table sets forth the primary uses of cash for the three months ended March 31, 2017 and 2016:

	Three Months Ended March 31,	
	2017	2016
	(in thousands)	
Net cash used in operating activities	$ (8,436)	$ (7,011)
Net cash used in investing activities	(2,838)	(1,950)
Net decrease in cash and cash equivalents	$ (11,274)	$ (8,961)

Operating Activities

During the first three months of fiscal 2017, our net loss of $8.9 million included noncash charges of $2.7 million, primarily associated with stock-based compensation. During this same period, our net operating liabilities, excluding cash, cash equivalents and marketable securities, decreased by $2.2 million and, when combined with the adjustment for noncash charges, decreased our net cash used in operating activities to $8.4 million. Net operating liabilities decreased primarily because of lower accounts payable and accrued direct program expenses of $3.2 million and decreases in accrued employee benefits of $1.8 million. Slightly offsetting these decreases were increases in accrued

restructuring charges of $2.3 million and decreases in prepaid expenses of $462,000. Decreases in accounts payable and accrued direct program expenses were directly related to the wind-down of all research and development operations and related payments of vendor obligations. Accrued employee benefits decreased due to payment of annual employee performance bonuses during January 2017. Accrued restructuring charges increased by $2.3 million specifically related to the accounting for severance payments, retention bonuses and benefit continuation costs for employees affected by the workforce reduction.

During the first quarter of fiscal 2016, our net loss of $7.8 million included noncash charges of $737,000, primarily associated with stock-based compensation. During this same period, our net operating liabilities, excluding cash, cash equivalents and marketable securities, increased by $90,000 and thus decreased our net cash used in operating activities to $7.0 million. Net operating liabilities increased primarily because of higher accounts payable and accrued direct program expenses of $1.3 million, decreases in accrued employee benefits of $963,000, decreases in accrued other liabilities of $134,000 and increases in prepaid expenses of $69,000. Increases in accounts payable and accrued direct program expenses were directly related to research and development costs for our Phase 2 clinical trial that initiated in November 2015. Accrued employee benefit costs decreased due to payment of employee performance bonuses during February 2016.

Investing Activities

The net cash used in investing activities for the three months ended March 31, 2017 and 2016 was primarily related to net purchases of marketable securities.

Funding Requirements

Based on our current operating plan, and expectations regarding significantly lower operating expenses following the discontinuation of almost all of our research and development activities and the subsequent restructurings in the first quarter of 2017, we expect our $52.7 million in cash and cash equivalents as of March 31, 2017 will be sufficient to fund operations for at least the next twelve months. This estimate assumes no additional funding from equity financings or debt and is subject to numerous risks and uncertainties. Our present and future funding requirements will depend on many factors, including but not limited to:

- our ability to identify and successfully consummate the Merger or, if the Merger is not completed, another strategic transaction for the company;
- the timing, complexity and costs required for completion of the Merger, or, if the Merger is not completed, any transaction that may result from a further review of strategic alternatives;
- the timing and resources required for the completion and close-out of the ongoing clinical trials of cavosonstat;
- personnel-related expenses, including salaries, benefits, stock-based compensation expense and other compensation costs related to implementing our restructuring plan;
- the costs associated with archiving company records related to our research and development, and general and administrative activities;
- the costs of storing drug substance and drug product in compliance with cGMP requirements;
- the costs of preparing, filing, and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the extent to which we may elect to resume drug development activities in the future, if at all; and
- costs that may be incurred in responding to disruptive actions by activist shareholders.

For more information as to the risks associated with our future funding requirements see the risk factors under Item 1A. – “Risk Factors” of this Quarterly Report on Form 10-Q and under the heading “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2016 that we have filed with the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses. We base our estimates on historical experience, known trends and events and various other factors that are 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 that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Accrued Restructuring Charges

As described above under "Results of Operations – Restructuring Charges", in January 2017, we committed to a restructuring plan that consisted primarily of a workforce reduction of 25 positions, to a total of five remaining positions in order to conserve cash while the Company continued to evaluate business alternatives. All employees affected by the workforce reduction received either a lump-sum severance payment or monthly severance payments and certain of these employees also received retention bonus payments that were expensed upon payment and separation from the company during the first quarter of 2017. In accordance with ASC 420, "Exit and Disposal Cost Obligations", we are recognizing the restructuring liabilities related to the five remaining positions over the employees' anticipated service period which is expected to be the first three quarters of 2017.

For a description of our other critical accounting policies, please see Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 that we have filed with the SEC. There have not been any material changes to our critical accounting policies since December 31, 2016.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at March 31, 2017:

	Payments due by period (in thousands) (unaudited)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Purchase obligations	$ 107	$ 107	$ —	$ —	$ —
Operating leases	25	25	—	—	—
Total obligations	$ 132	$ 132	$ 0	$ —	$ —

We have historically entered into contracts with third parties to provide future services. We also had an operating lease obligation for office and laboratory space, which originally expired on March 31, 2018. On February 9, 2017, we elected to exercise our right to terminate the lease earlier than its original term, with an effective termination date of April 30, 2017, and paid the required $25,000 termination fee to the landlord.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet activities, as defined in Item 303(a)(4) of Regulation S-K.

Recent Accounting Pronouncements

Refer to our discussion of recently adopted accounting pronouncements and other recent accounting pronouncements in Note 3 – Summary of Significant Accounting Policies to the accompanying financial statements included elsewhere in this Quarterly Report on Form 10-Q.

We qualify as an "emerging growth company" pursuant to the provisions of the JOBS Act, which allows us to delay adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we irrevocably chose to "opt out" of such extended transition period, and as a result, we plan to comply with any new or revised accounting standards on the relevant dates on which non-emerging growth companies must adopt such standards.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of March 31, 2017, we had cash, cash equivalents and marketable securities of $52.7 million, consisting of deposits with commercial banks in checking, interest-bearing and demand money market accounts, reverse repurchase agreements, corporate debt securities, U.S. treasury securities and obligations of U.S. government agencies. The primary objectives of our investment policy are to preserve principal and maintain proper liquidity to meet operating needs.

Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. 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 are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as defined in Rule 13a−15(e) promulgated under the Exchange Act, that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective. In connection with the filing of this Quarterly Report on Form 10-Q, an evaluation was carried out by our management, with the participation of our principal executive and principal financial officer, of the effectiveness of our disclosure controls and procedures. Based upon this evaluation, our principal executive and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2017.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2017, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any legal proceedings.

ITEM 1A. RISK FACTORS

Our business faces significant risks and uncertainties. Certain factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to carefully consider the risk factors described below and under the heading "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and in our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Our strategic transaction with Alpine may not be consummated or may not deliver the anticipated benefits we expect.

In January 2017, we engaged a financial and strategic advisor, Ladenburg Thalmann & Co., Inc., to advise us on strategic alternatives following our announcement that we had suspended further clinical development of cavosonstat and that we were actively pursuing a strategic transaction, including a merger or acquisition of the company. On April 18, 2017, we entered into the Merger Agreement with Alpine pursuant to which the shareholders of Alpine will become the majority shareholders of Nivalis. The Merger Agreement is subject to satisfaction of closing conditions and subject to certain termination rights. We are devoting substantially all of our time and resources to consummating this transaction, however, there can be no assurance that such activities will result in the consummation of this transaction or, if consummated, that such transaction will deliver the anticipated benefits or enhance shareholder value.

If we do not successfully consummate the strategic transaction with Alpine, we may be unsuccessful in completing an alternative transaction on terms that are as favorable as the terms of the proposed transaction with Alpine, or at all, and we may be unable to reestablish an operating business.

To date, we have not generated any revenue from product sales, and our current assets consist primarily of our cash, cash equivalents and marketable securities, our listing on The NASDAQ Global Market and the Merger Agreement with Alpine. While we have entered the Merger Agreement with Alpine, the consummation of the Merger with Alpine may be delayed or may not occur at all. If we are unable to consummate the Merger with Alpine, our Board of Directors may elect to pursue an alternative strategic transaction similar to the proposed Merger with Alpine. Attempting to complete an alternative transaction will be costly and time consuming. If the Merger with Alpine is not completed and our Board of Directors determines to pursue an alternative transaction, the terms of any such alternative transaction may not be as favorable to Nivalis and its stockholders as the terms of the proposed Merger with Alpine, and we can make no assurances that such an alternative transaction would occur at all. Further, if the Merger with Alpine is not completed, given the failure of the Phase 2 trials of cavosonstat to achieve their primary endpoints, the discontinuation of our research and development efforts commencing in January 2017 and the cost to engage in further development activities, it is unlikely that we would be able to obtain the funding required to recommence our drug development activities. As a result, if we are unable to complete the Merger with Alpine or an alternative transaction, our Board of Directors may elect to take the steps necessary to liquidate all remaining assets of the company, and there can be no assurance as to the amount or timing of available cash to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves.

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

Use of Proceeds

Our initial public offering, or IPO, of common stock was effected through a Registration Statement on Form S-1 (File No. 333-204127) declared effective by the SEC on June 16, 2015. On June 22, 2015, we sold 6,325,000 shares of common stock, including 825,000 shares sold to the underwriters pursuant to their option to purchase such shares to cover over allotments, at an initial public offering price of $14.00 per share, for aggregate gross proceeds of $88.6 million and net proceeds of $78.8 million after deducting underwriting discounts and commissions and expenses. The

underwriters of the offering were Cowen & Company, LLC, Stifel, Nicolaus & Company, Incorporated, Robert W. Baird & Co., Incorporated and H.C. Wainwright & Co., LLC. Following the sale of the shares in connection with the closing of the IPO, the offering terminated.

Through March 31, 2017, we had used $26.1 million of our IPO proceeds for working capital and general corporate expenses. The net proceeds from our initial public offering have been invested in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities. Following the close of our Phase 2 clinical trial of cavosonstat in patients with CF, we commenced a process to identify and evaluate strategic alternatives with the goal of enhancing stockholder value, including the possibility of a merger or sale of the company. In connection with this process we have suspended further research and development activities to reduce our operating expenses and preserve our cash resources. We currently expect to primarily use the remaining net proceeds from our initial public offering for working capital and other general corporate purposes, which include our activities to identify, evaluate and pursue potential strategic alternatives and to consummate the Merger or, if the Merger is not completed, an alternative strategic transaction.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not Applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

Not Applicable.

ITEM 6. EXHIBITS

(a) Exhibits

The exhibits listed on the accompanying exhibit index are filed or incorporated by reference (as stated therein) as part of this Quarterly Report on Form 10-Q.

INDEX TO EXHIBITS

2.1	Agreement and Plan of Merger and Reorganization, dated as of April 18, 2017, by and between the Registrant, Nautilus Merger Sub, Inc. and Alpine Immune Sciences, Inc. (1)
2.2	Form of Support Agreement, by and between the Registrant and certain stockholders of Alpine Immune Sciences, Inc. (1)
2.3	Form of Support Agreement, by and between Alpine Immune Sciences, Inc. and certain stockholders of the Registrant (1)
2.4	Form of Support Agreement, by and between Alpine Immune Sciences, Inc. and the Estate of Arnold H. Snider, III (1)
2.5	Form of Support Agreement, by and between Alpine Immune Sciences and the Deerfield Signatories (1)
3.1	Amended and Restated Certificate of Incorporation of the Registrant (2)
3.2	Amended and Restated Bylaws of the Registrant (3)
4.1	Form Common Stock Certificate of the Registrant (3)
4.2	Second Amended and Restated Warrant to Purchase Common Stock, dated February 18, 2011, issued to Horizon Credit I, LLC (3)
4.3	Second Amended and Restated Warrant to Purchase Common Stock, dated February 18, 2011, issued to Horizon Credit I, LLC (3)
4.4	Second Amended and Restated Investor Rights Agreement dated November 18, 2014 (3)
31.1	Certification pursuant to Exchange Act Rules 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

(1) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the U.S. Securities and Exchange Commission on April 18, 2017

(2) Incorporated by reference to the Registrant's Registration Statement on Form S-8 (Registration No. 333-205220) filed on June 25, 2015.

(3) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (Registration No. 333-204127), filed on May 13, 2015.

* Indicates a management contract or a compensatory plan, contract or arrangement.

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.

Date: May 2, 2017

NIVALIS THERAPEUTICS, INC.

By: /s/ R. Michael Carruthers
R. Michael Carruthers
Interim President and Chief Financial Officer
(Principal Executive, Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, R. Michael Carruthers, Interim President and Chief Financial Officer of Nivalis Therapeutics, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Nivalis Therapeutics, Inc. for the quarter ended March 31, 2017;

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. I am 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 my supervision, to ensure that material information relating to the registrant is made known to me by others within this entity, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: May 2, 2017

/s/ R. MICHAEL CARRUTHERS
R. Michael Carruthers
Interim President and Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)

In connection with the Quarterly Report of Nivalis Therapeutics, Inc., a Delaware corporation (the "Company"), on Form 10-Q for the quarter ended March 31, 2017, as filed with the Securities and Exchange Commission (the "Report"), the undersigned, in the capacity and on the date indicated below, hereby certifies, pursuant to § 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350), that to his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: May 2, 2017

/s/ R. MICHAEL CARRUTHERS

R. Michael Carruthers
Interim President and Chief Financial Officer
(Principal Executive and Principal Financial Officer)