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 June 30, 2016**

☐ **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.)** |
| **3122 Sterling Circle, Suite 200 Boulder, Colorado** | **80301** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**(720) 945-7700**
**(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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting 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 | ☐ |

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 July 31, 2016 was 15,503,149.

**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)**

| | June 30, 2016 | December 31, 2015 |
|---|---|---|
| | (unaudited) | |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 15,416 | $ 24,991 |
| Marketable securities | 58,318 | 62,263 |
| Prepaid expenses and other current assets | 480 | 432 |
| Total current assets | 74,214 | 87,686 |
| | | |
| Property and equipment and other assets, net | 351 | 223 |
| Total assets | $ 74,565 | $ 87,909 |
| | | |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,110 | $ 994 |
| Accrued direct program expenses | 2,742 | 1,555 |
| Accrued employee benefits | 985 | 1,675 |
| Accrued other liabilities | 36 | 195 |
| Total current liabilities | 5,873 | 4,419 |
| | | |
| 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; 15,485,094 and 15,462,030 shares issued and outstanding, respectively | 15 | 15 |
| Additional paid-in capital | 233,808 | 232,309 |
| Accumulated other comprehensive income | 23 | 3 |
| Accumulated deficit | (165,154) | (148,837) |
| Total stockholders' equity | 68,692 | 83,490 |
| Total liabilities and stockholders' equity | $ 74,565 | $ 87,909 |

*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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| Revenue | $ — | — | $ — | $ — |
| Operating expenses: | | | | |
| Research and development | 6,424 | 4,465 | 11,991 | 7,482 |
| General and administrative | 2,172 | 1,387 | 4,539 | 2,685 |
| Loss from operations | (8,596) | (5,852) | (16,530) | (10,167) |
| Interest income | 117 | — | 213 | 1 |
| Net loss attributable to common stockholders | $ (8,479) | $ (5,852) | $(16,317) | $(10,166) |
| Unrealized gains on marketable securities | 20 | — | 20 | — |
| Comprehensive loss | $ (8,459) | $ (5,852) | $(16,297) | $(10,166) |
| Weighted average shares outstanding - basic and diluted | 15,462 | 4,159 | 15,462 | 3,189 |
| Net loss per share - basic and diluted | $ (0.55) | $ (1.41) | $ (1.06) | $ (3.19) |

*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 Capital | Accumulated Other Comprehensive Income | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| Balance as of December 31, 2015 | 15,462 | $ 15 | $232,309 | $ 3 | $ (148,837) | $ 83,490 |
| Employee stock-based compensation expense | — | — | 1,407 | — | — | 1,407 |
| Issuance of common stock under the employee stock purchase plan | 20 | — | 76 | — | — | 76 |
| Exercise of incentive stock options | 3 | — | 16 | — | — | 16 |
| Unrealized gains on marketable securities | — | — | — | 20 | — | 20 |
| Net loss | — | — | — | — | (16,317) | (16,317) |
| Balance as of June 30, 2016 | 15,485 | $ 15 | $233,808 | $ 23 | $ (165,154) | $ 68,692 |

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

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

| | Six Months Ended June 30, | |
|---|---|---|
| | **2016** | **2015** |
| **Operating activities** | | |
| Net loss | $ (16,317) | $ (10,166) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 66 | 31 |
| Stock-based compensation expense | 1,407 | 370 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other | (168) | 61 |
| Accounts payable | 1,116 | 419 |
| Accrued direct program expenses | 1,187 | 438 |
| Accrued employee benefits | (690) | 767 |
| Accrued other liabilities | (159) | — |
| Net cash used in operating activities | (13,558) | (8,080) |
| | | |
| **Investing activities** | | |
| Purchases of property and equipment | (74) | (87) |
| Purchases of marketable securities | (52,235) | — |
| Proceeds from sales and maturities of marketable securities | 56,200 | — |
| Net cash provided by (used in) investing activities | 3,891 | (87) |
| | | |
| **Financing activities** | | |
| Proceeds from issuance of common stock, net of offering costs | — | 80,876 |
| Proceeds from employee stock purchases and stock options exercised | 92 | |
| Net cash provided by financing activities | 92 | 80,876 |
| | | |
| Net increase (decrease) in cash and cash equivalents | (9,575) | 72,709 |
| Cash and cash equivalents, beginning of period | 24,991 | 27,812 |
| Cash and cash equivalents, end of period | $ 15,416 | $ 100,521 |
| | | |
| **Supplemental disclosures of cash flow information** | | |
| Conversion of convertible preferred stock to common stock | $ — | $ 41,880 |

*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 clinical stage pharmaceutical company committed to the discovery, development and commercialization of therapeutics for people with cystic fibrosis. In addition to developing innovative solutions intended to extend and improve the lives of people with cystic fibrosis, Nivalis plans to utilize its proprietary S-nitrosoglutathione reductase (GSNOR) inhibitor portfolio to develop therapeutics for other diseases.

**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 June 30, 2016, the Company had an accumulated deficit of $165.2 million. For the six months ended June 30, 2016, net loss was $16.3 million and net cash used in operating activities was $13.6 million. The Company anticipates that operating losses and net cash used in operating activities will continue and substantially increase over the next several years as it expands development activities for its current product candidate cavosonstat (N91115).

The Company has historically financed its operations primarily through the sale of its equity securities and debt offerings. The Company will continue to be dependent upon such sources of funds until it is able to generate positive cash flows from its operations. Management has determined that the Company's existing cash, cash equivalents and marketable securities as of June 30, 2016 will be sufficient to fund operations at least through the next twelve months.

The Company expects to fund future operations through the sale of its equity securities, incurring debt, entering into partnerships, obtaining grants, or seeking other nondilutive sources of financing. There can be no assurance that sufficient funds from these sources will be available to the Company when needed or at all or on terms that are favorable to the Company. If the Company is unable to obtain additional funding from these or other sources when needed, or to the extent needed, it would have a negative impact on the Company's financial condition and its ability to pursue its business strategy. It could force the Company to delay, limit, reduce or terminate research and development programs and commercialization efforts or cause the Company to cease operations in full.

**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, 2015 was derived from the Company's audited financial statements, but does not include all the 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, 2015. The accompanying interim financial statements as of June 30, 2016 and for the three and six months ended June 30, 2016 and 2015, 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 June 30, 2016 and the results of operations and cash flows for the three and six months ended June 30,

2016 and 2015. The results for the three and six months ended June 30, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016 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 are 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. Company 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.

***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 and six months ended June 30, 2016.

***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 will be effective for the annual periods beginning after December 15, 2016, and interim periods within those annual periods. The Company is currently evaluating the impact of the new pronouncement on its financial statements.

For additional discussion of recent accounting pronouncements please refer to Note 3, "Summary of Significant Accounting Policies – Recent Accounting Pronouncements", in the Company's previously filed Annual Report on Form 10-K for the year ended December 31, 2015. The Company did not adopt any new accounting pronouncements during the six months ended June 30, 2016 that had a material effect on its financial statements.

***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, 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 as 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 six months ended June 30, 2016.

Assets and liabilities measured at fair value on a recurring basis consisted of the following types of instruments as of June 30, 2016 and December 31, 2015 (in thousands):

| Description | June 30, 2016 | Quoted prices in active markets for identical assets (Level 1) | Quoted prices for similar assets observable in the marketplace (Level 2) | December 31, 2015 | 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 | $ 7,580 | $ 7,580 | $ — | $ 12,131 | $ 12,131 | $ — |
| U.S. Treasury securities, obligations of U.S. government agencies, corporate debt securities and reverse repurchase agreements | 63,318 | — | 63,318 | 73,261 | — | 73,261 |

**4. Cash, Cash Equivalents and Marketable Securities**

The following is a summary of cash, cash equivalents and marketable securities as of June 30, 2016 and December 31, 2015 (in thousands):

| | Amortized Cost | Gross unrealized gains | Gross unrealized losses | Fair market value |
|---|---|---|---|---|
| June 30, 2016 | | | | |
| Cash | $ 2,836 | $ - | $ - | $ 2,836 |
| Money market funds | 7,580 | - | - | 7,580 |
| Reverse repurchase agreement | 5,000 | - | - | 5,000 |
| U.S Treasury securities and obligations of U.S. government agencies | 24,148 | 19 | - | 24,167 |
| Corporate debt securities | 34,147 | 7 | (3) | 34,151 |
| Total for June 30, 2016 | $ 73,711 | $ 26 | $ (3) | $ 73,734 |
| | | | | |
| December 31, 2015 | | | | |
| Cash | $ 1,862 | $ – | $ – | $ 1,862 |
| Money market funds | 12,131 | – | – | 12,131 |
| Reverse repurchase agreements | 6,000 | – | – | 6,000 |
| U.S Treasury securities and obligations of U.S. government agencies | 28,982 | 4 | (7) | 28,979 |
| Corporate debt securities | 38,276 | 22 | (16) | 38,282 |
| Total for December 31, 2015 | $ 87,251 | $ 26 | $ (23) | $ 87,254 |

**5. Stockholders' Equity**

Concurrent with the Company's initial public offering completed in June 2015 (the "IPO"), the Company increased its authorized number of shares of common stock to 200,000,000 shares, eliminated its authorized shares of convertible preferred stock and authorized 10,000,000 shares of preferred stock for future issuance.

***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).

At June 30, 2016, shares of common stock have been reserved for issuance as follows:

| | |
|---|---|
| Options to purchase common stock - issued | 1,795,920 |
| Options to purchase common stock - unissued | 1,355,128 |
| Inducement grants - issued | 325,000 |
| Employee stock purchase plan | 203,334 |
| Warrants to purchase common stock | 18,534 |
| | 3,697,916 |

**6. Net Loss per Share**

The Company excluded the following common stock equivalents, outstanding as of June 30, 2016 and 2015, from the computation of diluted net loss per share for the applicable quarterly periods because they had an anti-dilutive impact on the computation:

| | June 30, | |
|---|---|---|
| | 2016 | 2015 |
| Options to purchase common stock - issued | 1,795,920 | 1,310,465 |
| Inducement grants - issued | 325,000 | — |
| Unvested restricted common stock | — | 860 |
| Warrants to purchase common stock | 18,534 | 18,534 |
| Total | 2,139,454 | 1,329,859 |

**7. Subsequent Events**

Effective 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 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. To date, no securities have been sold by the Company pursuant to the base prospectus or the sales agreement prospectus.

The Company evaluated events up to the filing date of these interim financial statements and determined that no other subsequent activity required disclosure.

## 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." 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, our ongoing and planned preclinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our liquidity and future funding needs, our results of operations, financial condition, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.*

*By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity and the development of the industry in which we operate 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, 2015 and in this Quarterly Report on Form 10-Q to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements as well as statements we make in our other reports filed with the SEC concerning our business development programs, financial condition and results of operations. 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 clinical stage pharmaceutical company committed to the discovery, development and commercialization of therapeutics for people with cystic fibrosis. In addition to developing innovative solutions intended to extend and improve the lives of people with cystic fibrosis, we plan to utilize our proprietary S-nitrosoglutathione reductase, or GSNOR, inhibitor portfolio to develop therapeutics for other diseases.

Cystic fibrosis, or CF, is a life-shortening genetic disease that affects an estimated 70,000 people worldwide, predominantly in the United States and Europe. CF is characterized by a defect in the chloride channel of human cells known as the "cystic fibrosis transmembrane conductance regulator," or CFTR, which is caused by mutations in the CFTR gene. Our product candidate, cavosonstat (N91115), works through a novel mechanism of action called GSNOR inhibition to modulate the unstable and defective CFTR protein responsible for CF. GSNOR inhibition restores GSNO levels thereby modifying the chaperones responsible for CFTR protein degradation. This stabilizing effect increases the amount of CFTR protein at the cell surface and the function of the CFTR chloride channel which, in turn, leads to an increase in net chloride secretion.

Nivalis discovered and owns 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. On July 7, 2016, we announced that the United States Adopted Names (USAN) Council had approved "cavosonstat" as the unique non-proprietary or generic name for N91115, which we will use going forward to refer to this product candidate.

We completed a Phase 1b clinical trial of cavosonstat in people with CF with two copies of the *F508del-CFTR* mutation in September 2015. The randomized, double-blind, placebo-controlled, parallel group study of orally administered cavosonstat demonstrated favorable safety, tolerability and pharmacokinetics of various doses of cavosonstat (50, 100 and 200 mg twice daily) in a total of 51 people with CF. Furthermore, a trend toward a modest reduction in sweat chloride, a marker of CFTR activity, was observed in the highest dose tested. This reduction in sweat chloride was statistically significant within group but not when compared with placebo.

During November 2015, we initiated a Phase 2, 12-week, double-blind, randomized, placebo-controlled, parallel group study to investigate the efficacy and safety of cavosonstat in 135 adult patients with CF who have two copies of the *F508del-CFTR* mutation and are being treated with Orkambi™ (lumacaftor/ivacaftor). In early July 2016, we announced completion of enrollment in 138 adult patients for this clinical trial, defined as the last patient enrolled receiving their first study dose. We currently expect to present topline results from this trial by the end of 2016.

During May 2016, we began dosing patients in a Phase 2, proof-of-concept study to further evaluate the effect of cavosonstat in patients who have one copy of the *F508del-CFTR* mutation and a second mutation that results in a gating defect in the CFTR protein. The study is designed to evaluate the efficacy and safety of cavosonstat in adult patients who have these mutations and who are being treated with Kalydeco™ (ivacaftor). We currently expect to present topline results from this trial by the first half of 2017.

Our operations to date have focused on discovery and development of our portfolio of GSNOR inhibitors, including cavosonstat and N6022. N6022 was the first product candidate to emerge from our GSNOR inhibitor portfolio and was optimized for inhaled delivery with low oral bioavailability. In order to provide translational evidence of GSNOR's role in lung disease, we initially explored the effects of N6022 in patients with mild asthma using an intravenous formulation. N6022 demonstrated a significant, beneficial effect on the airways in these patients, thus confirming the beneficial effects of N6022 observed in our preclinical studies of asthma. N6022 paved the way for cavosonstat by establishing initial safety of the class in healthy subjects and patients with CF. Because an oral dosage form is preferable in CF, a systemic disease that is not confined to the lungs, we elected to discontinue further development of N6022 in the chronic management of CF, but we may pursue development of N6022 in an inhaled dosage form for other potential indications.

During June 2015, we completed our initial public offering, or IPO, of an aggregate 6,325,000 shares of common stock at a price to the public of $14.00 per share for aggregate gross proceeds of $88.6 million, before $9.8 million in underwriting commissions and discounts and offering expenses. Our common stock is listed on the NASDAQ Global Market under the symbol "NVLS".

Since inception, we have financed our operations primarily through the proceeds from our IPO, as well as private placements of equity and convertible debt. From our inception in July 2003 to June 30, 2016, we raised $220.0 million in net proceeds from these sources. As of June 30, 2016, we had cash, cash equivalents and marketable securities of $73.7 million and no debt.

We have incurred losses from operations in each year since our inception. Our net losses were $8.5 million and $16.3 million for the three and six months ended June 30, 2016, respectively. As of June 30, 2016, we had an accumulated deficit of $165.2 million. We expect to continue incurring losses for the foreseeable future as we advance our lead product candidate, cavosonstat, through clinical development, regulatory approval and, if approved, commercialization. We expect that research and development expenses will increase as we continue to develop our product candidates, and general and administrative costs will increase as we operate as a public company. We anticipate that we will need to raise additional capital, in addition to the IPO proceeds raised in June 2015, prior to the commercialization of cavosonstat or any other potential product candidate. Until such time that we can generate revenue from product sales, which, based on our current development plans, we do not expect to occur until 2018 at the earliest, we expect to finance our operating activities primarily through selling equity, incurring debt, entering into partnerships, and obtaining grants or seeking other nondilutive sources of financing. However, we may be unable to raise additional funds or enter into such arrangements when needed on favorable terms, if at all. Our failure to raise capital when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. It could force us

to delay, limit, reduce or terminate our research and development programs and commercialization efforts or cause us to cease operations in full.

**Financial Operations Overview**

***Revenue***

To date, we have not generated any revenue. In the future, we may generate revenue from sales or licensing of cavosonstat or other potential product candidates. Based on our current development plans, however, we do not expect to generate product revenue until 2018 at the earliest. If we fail to complete the clinical development of a cavosonstat-based therapy, our ability to generate future revenue, and our results of operations and financial position, will be adversely affected.

***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. Thus, we expect our research and development expenses to increase for the foreseeable future as we seek to advance clinical development of our lead product candidate, cavosonstat.

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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| | (in thousands) | | | |
| **Direct program expenses** | | | | |
| Cavosonstat for cystic fibrosis | $ 4,108 | $ 2,848 | $ 7,586 | $ 4,435 |
| **Personnel and other expenses** | | | | |
| Salaries, benefits and stock-based compensation | 1,660 | 1,240 | 3,140 | 2,338 |
| Consulting and outsourced services | 132 | 80 | 221 | 138 |
| Facilities and depreciation | 86 | 67 | 167 | 134 |
| Other expenses | 438 | 230 | 877 | 437 |
| Total research and development expenses | $ 6,424 | $ 4,465 | $ 11,991 | $ 7,482 |

All of our research and development expenses for the six months ended June 30, 2016 and 2015 relate to the development of cavosonstat. We have expended an aggregate of approximately $24.3 million for direct program expenses related to cavosonstat from inception through June 30, 2016. The successful development of cavosonstat or any other potential product candidate is uncertain. 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 the period in which we receive

material net cash inflows may commence, from cavosonstat or any other potential product candidate. 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 differences arising during clinical development, including:

- the number and results of our clinical trials;
- the number of clinical sites included in the trials;
- the number of patients who ultimately participate in the trials;
- the length of time required to enroll suitable patients and complete the trials; and
- the ability to obtain a drug supply for our trials.

Our expenditures are subject to additional uncertainties, including the commercial uptake of Orkambi, our preclinical study and clinical trial expenses, our costs to acquire, develop and manufacture preclinical study and clinical trial materials, the timing of regulatory approval for cavosonstat and post-commercialization and other incremental research and development costs for cavosonstat or any other potential product candidate. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. Changes in 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 U.S. Food and Drug Administration, or FDA, or other regulatory authorities were to require us to conduct preclinical studies or clinical trials beyond those which we 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 clinical development of our product candidates and we may not obtain results from trials that are delayed when anticipated.

***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 our general and administrative expense will increase during the next two fiscal years, primarily due to increased costs to support further clinical development of cavosonstat, maintain our patent portfolio and operate as a publicly traded company.

***Interest Income***

Interest income for the three and six months ended June 30, 2016 and 2015 consists of interest earned on marketable securities and money market funds.

**Results of Operations**

***Comparison of the Three and Six Months Ended June 30, 2016 and 2015.***

***Research and Development Expenses.*** Research and development expenses for the three and six months ended June 30, 2016 and 2015 were as follows:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| | (in thousands) | | | |
| Research and development expenses | $ 6,424 | $ 4,465 | $ 11,991 | $ 7,482 |
| Increase from prior period | $ 1,959 | — | $ 4,509 | — |
| % change from prior period | 43.9 % | — | 60.3 % | — |

The increase in research and development expenses for the three months ended June 30, 2016 compared to the same period in the prior year was primarily due to $2.4 million of cavosonstat clinical trial expenses for the Phase 2 trial that was initiated in November 2015 and reached 100% patient enrollment as planned in early July 2016. A second Phase 2 trial initiated in March 2016, added $468,000 of expense for the three months ended June 30, 2016. During the second quarter of the prior year our Phase 1b trial incurred $1.6 million of clinical trial expenses. This study was completed in September 2015 and therefore slightly offset the increases in direct program expenses in 2016. Personnel and other expenses increased by $700,000 during the three months ended June 30, 2016 compared to the same period of the prior year. These increases were primarily the result of increased salaries, benefits and stock-based compensation expense of $420,000 which were directly related to additional Research and Development staffing.

The increase in research and development expenses for the six months ended June 30, 2016 compared to the same period in the prior year was primarily due to $4.7 million of cavosonstat clinical trial expenses for the Phase 2 trial that was initiated in November 2015. A second Phase 2 trial initiated in March 2016, added $717,000 of expense for the six months ended June 30, 2016. During the first half of the prior year our Phase 1b trial incurred $2.3 million of clinical trial expenses. This study was completed in September 2015 and therefore slightly offset the increases in direct program expenses in 2016. Personnel and other expenses increased by $1.4 million during the six months ended June 30, 2016 compared to the same period of the prior year. These increases were primarily the result of increased salaries, benefits and stock-based compensation expense of $802,000 which were directly related to additional Research and Development staffing.

***General and Administrative Expenses.*** General and administrative expenses for the three and six months ended June 30, 2016 and 2015 were as follows:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| | (in thousands) | | | |
| General and administrative expenses | $ 2,172 | $ 1,387 | $ 4,539 | $ 2,685 |
| Increase from prior period | $ 785 | — | $ 1,854 | — |
| % change from prior period | 56.6 % | — | 69.1 % | — |

The increase in general and administrative expenses for the three and six months ended June 30, 2016 compared to the same period in the prior year was primarily due to increased expenses related to operating as a publicly-traded company, including increased investor relations and various marketing expenses, audit fees and patent expenses. These expense categories on a combined basis increased by approximately $634,000 and $1.2 million during the three and six months ended June 30, 2016, respectively, compared with the same periods in the prior year. Additionally, stock-based compensation expense increased by approximately $253,000 and $634,000 during the three and six months ended June 30, 2016, respectively, compared with the same periods in the prior year, due to stock options granted during September 2015.

***Interest Income.*** Interest income for the three and six months ended June 30, 2016 and 2015 were as follows:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| | (in thousands) | | | |
| Interest income | $ 117 | $ — | $ 213 | $ 1 |

The increase in interest income during 2016 over the prior year was due to higher investment interest rates earned on a higher average cash and marketable securities balance following the completion of our IPO during June 2015.

**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 in prior years. As of June 30, 2016, we had cash, cash equivalents and marketable securities of $73.7 million and no debt.

The following table sets forth the primary sources and uses of cash for the six months ended June 30, 2016 and 2015:

| | Six Months Ended June 30, | |
|---|---|---|
| | 2016 | 2015 |
| | (in thousands) | |
| Net cash used in operating activities | $ (13,558) | $ (8,080) |
| Net cash provided by (used in) investing activities | 3,891 | (87) |
| Net cash provided by financing activities | 92 | 80,876 |
| Net increase (decrease) in cash and cash equivalents | $ (9,575) | $ 72,709 |

***Operating Activities***

During the first half of fiscal 2016, our net loss of $16.3 million included noncash charges of $1.5 million, primarily associated with stock-based compensation. During this same period, our net operating liabilities, excluding cash, cash equivalents and marketable securities, increased by $1.3 million and thus decreased our net cash used in operating activities to $13.6 million. The increase in net operating liabilities is primarily related to higher accounts payable and accrued direct program expenses of $2.3 million, slightly offset by decreases in accrued employee benefits of $690,000, decreases in accrued other liabilities of $159,000 and increases in prepaid expenses of $168,000. Increases in accounts payable and accrued direct program expenses were directly related to research and development costs for our two Phase 2 clinical trials. Accrued employee benefit costs decreased due to payment of 2015 employee performance bonuses during February 2016, slightly offset by accrued bonus expense for the 2016 period.

During the first half of fiscal 2015, our net loss of $10.2 million included noncash charges of $401,000, primarily associated with stock-based compensation. During this same period, our net operating liabilities, excluding cash and cash equivalents, increased by $1.7 million and thus decreased our net cash used in operating activities to $8.1 million. This was primarily the result of increases in accrued employee benefits by $767,000, accrued direct program expenses by $438,000 and accounts payable by $419,000 (excluding $2.1 million of unpaid IPO related costs). Accrued employee benefit costs increased due to the 2015 employee incentive plan that was initiated at the beginning of the year. Increases in accounts payable and accrued direct program expenses were directly related to research and development costs for our Phase 1b clinical trial which ran from March to September of 2015.

***Investing Activities***

The net cash provided by investing activities of $3.9 million for the six months ended June 30, 2016 was primarily related to proceeds from maturities and sales of marketable securities outweighing our purchases of replacement securities during the period.

***Financing Activities***

The cash provided by financing activities for the first half of fiscal 2015 resulted from $80.9 million of net proceeds for the sale of common stock in our IPO that closed during June 2015. There were $2.1 million of unpaid IPO related costs at June 30, 2015, which after payment in the third quarter of 2015 reduced the net proceeds from the sale of common stock in our IPO to $78.8 million.

***Funding Requirements***

We believe our existing cash, cash equivalents and marketable securities will provide resources to complete our two ongoing Phase 2 clinical trials and to fund our operating expenses and capital expenditure requirements beyond mid-2017 when, with successful clinical outcomes, we expect to be enrolling patients in our Phase 3 clinical program for cavosonstat. We have based these estimates on assumptions that may prove to be incorrect, and given the risks and uncertainties associated with drug development and commercialization, we could require greater or additional capital resources sooner than expected. Our present and future funding requirements will depend on many factors, including but not limited to:

- the scope, progress, results and costs of preclinical development and clinical trials of cavosonstat and any other product candidate;
- our ability to advance the clinical development program for our lead product candidate, cavosonstat;
- personnel-related expenses, including salaries, benefits, stock-based compensation expense and other compensation costs;
- the costs, timing and outcome of regulatory review of cavosonstat or any other potential product candidate;
- the revenue, if any, received from commercial sales of cavosonstat or any other potential product candidate for which we, or any future partner, may receive marketing approval;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for cavosonstat or any other potential product candidate for which we receive marketing approval and do not partner for commercialization; and
- the extent to which we acquire, in-license or out-license other products and technologies.

Existing cash, cash equivalents and marketable securities will not be sufficient to fund our operations through successful development and commercialization of cavosonstat or any other potential product candidate. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of our planned development and commercialization activities, which could harm our business. 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, 2015 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.

For a description of our 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, 2015 that we have filed with the SEC. There have not been any material changes to our critical accounting policies since December 31, 2015.

**Contractual Obligations and Commitments**

The following table summarizes our contractual obligations at June 30, 2016:

| | Payments due by period (in thousands) (unaudited) | | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 year | 1-3 years | 3-5 years | More than 5 years |
| Purchase obligations | $ 8,659 | $ 7,564 | $ 1,095 | $ — | $ — |
| Operating leases | 523 | 296 | 227 | — | — |
| Total obligations | $ 9,182 | $ 7,860 | $ 1,322 | $ — | $ — |

We have entered into contracts with third parties to provide future services, which include research and development, clinical development support and testing services. These purchase obligations indicated above include both cancellable and non-cancellable amounts. We also have an operating lease obligation for office and laboratory space, which will expire on March 31, 2018. We have the option to renew the lease for an additional three-year term and the option to terminate the lease at any time after March 31, 2017, for a termination fee of $25,000.

**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**

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 will be effective for the annual periods beginning after December 15, 2016, and interim periods within those annual periods. We are currently evaluating the impact of the new pronouncement on our financial statements.

For additional discussion of recent accounting pronouncements please refer to Note 3, "Summary of Significant Accounting Policies – Recent Accounting Pronouncements", in our previously filed Annual Report on Form 10-K for the year ended December 31, 2015. There were no new accounting pronouncements adopted during the six months ended June 30, 2016 that had a material effect on our financial statements.

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 June 30, 2016, we had cash, cash equivalents and marketable securities of $73.7 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 Chief Executive Officer and Chief 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 Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2016.

### Changes in Internal Control over Financial Reporting

This Quarterly Report on Form 10-Q does not include a report on changes in our internal controls over financial reporting that occurred during our most recent fiscal quarter due to a transition period established by the Exchange Act for newly public companies.

## 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 under the heading "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 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.*

There have been no material changes to the risk factors included in our previously filed Annual Report on Form 10-K for the year ended December 31, 2015. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial also may negatively impact our business.

### 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 June 30, 2016, we had used $5.1 million of our IPO proceeds for working capital and general corporate expenses. There has been no material change in our planned use of the net proceeds from the IPO as described in the final prospectus for the offering filed with the SEC pursuant to Rule 424(b).

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

### ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

### ITEM 5. OTHER INFORMATION

None.

### 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**

| | |
|---|---|
| 3.1 | Amended and Restated Certificate of Incorporation of the Registrant (1) |
| 3.2 | Amended and Restated Bylaws of the Registrant (2) |
| 4.1 | Form Common Stock Certificate of the Registrant (2) |
| 4.2 | Second Amended and Restated Warrant to Purchase Common Stock, dated February 18, 2011, issued to Horizon Credit I, LLC (2) |
| 4.3 | Second Amended and Restated Warrant to Purchase Common Stock, dated February 18, 2011, issued to Horizon Credit I, LLC (2) |
| 4.4 | Second Amended and Restated Investor Rights Agreement dated November 18, 2014 (2) |
| 10.1 | Employment Agreement, dated as of April 18, 2016, by and between the Registrant and David M. Rodman, M.D. (3)* |
| 10.2 | Notice of Inducement Stock Option Grant and Inducement Stock Option Agreement, each dated April 18, 2016 by and between the Registrant and David M. Rodman, M.D. (3)* |
| 10.3 | Notice of Restricted Stock Unit Inducement Grant and Inducement Restricted Stock Unit Agreement, each dated April 18, 2016 by and between the Registrant and David M. Rodman, M.D. (3)* |
| 31.1 | Certification of the Registrant's Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2 | Certification of the Registrant's Chief Financial Officer 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 of the Registrant's Chief Executive Officer and Chief Financial Officer 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 Registration Statement on Form S-8 (Registration No. 333-205220) filed on June 25, 2015.

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

(3) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (File No.001-37449), filed on May 3, 2016.

* 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: August 2, 2016

**NIVALIS THERAPEUTICS, INC.**

By: /s/ Jon Congleton
Jon Congleton
President and Chief Executive Officer; Director
(Principal Executive Officer)

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

**Exhibit 31.1**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**
**UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jon Congleton, President and Chief Executive 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 June 30, 2016;

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 2, 2016

/s/ JON CONGLETON
Jon Congleton
President and Chief Executive Officer

**Exhibit 31.2**

**CERTIFICATION OF CHIEF FINANCIAL OFFICER**
**UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, R. Michael Carruthers, 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 June 30, 2016;

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 2, 2016

/s/ R. MICHAEL CARRUTHERS
R. Michael Carruthers
Chief Financial Officer

**Exhibit 32.1**

**CERTIFICATIONS 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 June 30, 2016, as filed with the Securities and Exchange Commission (the "Report"), each of the undersigned, in the capacities 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; 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: August 2, 2016

/s/ JON CONGLETON
Jon Congleton
President and Chief Executive Officer

/s/ R. MICHAEL CARRUTHERS
R. Michael Carruthers
Chief Financial Officer