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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 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)

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

Title of each class	**Name of each exchange on which registered**
Common Stock par value $0.001 per share	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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 ☐ 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 aggregate market value of the Registrant's common stock, par value $0.001 per share, held by non-affiliates of the Registrant on June 30, 2016, the last business day of the registrant's most recently completed second quarter, was $54,062,337 based on the closing price of the registrant's common stock on the NASDAQ Global Market on that date of $4.60 per share.

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of January 31, 2017 was 15,656,251.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2017 Annual Meeting of Stockholders, which is to be filed within 120 days after the end of the registrant's fiscal year ended December 31, 2016, are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated therein.

NIVALIS THERAPEUTICS, INC.

FORM 10-K

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PART I.

This Annual Report on Form 10-K 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 Annual Report on Form 10-K and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things:

- *The plans, strategies and objectives of management and the board of directors with respect to the exploration and review of strategic alternatives for the company;*
- *The benefits that may be derived from any of our product candidates or the commercial opportunity in any target indication;*
- *The progress, scope or the duration of the development of cavosonstat or any of our potential product candidates, such as the target indication (s) for development, the size, design, population, location, conduct, objective, duration or endpoints of any clinical trial, or the timing for completion of or availability of results from any clinical trial, for submission or approval of any regulatory filing, for interactions with regulatory authorities;*
- *Our operations, financial position, revenues, costs or expenses; or*
- *Our strategies, prospects, plans, expectations or objectives*

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change and depend on economic, financial, regulatory or other factors 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. You should also read carefully the factors described in the "Risk Factors" section of this Annual Report on Form 10-K to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements.

Any forward-looking statements that we make in this Annual Report on Form 10-K 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 Annual Report on Form 10-K or to reflect the occurrence of unanticipated events.

ITEM 1. BUSINESS

Overview

Nivalis Therapeutics, Inc. is a pharmaceutical company that has historically been focused on the discovery and development of product candidates for patients with cystic fibrosis, or CF. Our GSNOR inhibitors selectively target an enzyme known as S-nitrosoglutathione reductase, which we refer to as GSNOR. 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. Our lead product candidate, cavosonstat (N91115), is a small molecule inhibitor of GSNOR being evaluated in patients with CF. However, in light of recent results from a clinical trial of cavosonstat in CF patients, we determined to discontinue the development of this compound in CF and we have shifted our strategic emphasis to focus on identifying and evaluating strategic alternatives not related to GSNOR inhibition or specific to CF. 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.

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. This clinical trial was conducted in 138 adult CF patients with two copies of the F508del-CFTR mutation who were being treated with lumacaftor/ivacaftor or Orkambi™ and was designed to assess the efficacy and safety of cavosonstat in a triple therapy with lumacaftor/ivacaftor, or Orkambi. We are also evaluating the efficacy and safety of cavosonstat in a separate Phase 2 trial of 19 adult CF patients with one copy of the F508del-CFTR mutation and a second gating mutation who are being treated with ivacaftor or Kalydeco™. Enrollment in this trial was completed in November 2016 and results are expected in the first quarter of 2017. After completion of this trial, we do not expect to expend material resources on the development of cavosonstat or any other drug candidates in our portfolio.

Following the failure of the Phase 2 clinical trial in CF patients with two copies of the F508del mutation in November 2016, 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. As part of this process, we engaged a financial and strategic advisor, Ladenburg Thalmann & Co., Inc., to advise us on strategic alternatives in January 2017. Our board of directors also approved a reduction in force that is taking place between January 15 and March 31, 2017 that will affect 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. We expect to have approximately five employees after completion of the reduction in force on March 31, 2017. As described above, we continue to conduct limited activities related to completion of our in-process clinical trials. All other research and development activities have ceased.

We expect to devote substantial time and resources to exploring strategic alternatives that our board of directors believes will maximize stockholder value. Our consideration of strategic alternatives includes, but is not limited to, the potential for an acquisition, merger, business combination, licensing and/or other strategic transaction involving the company. Despite devoting significant efforts to identify and evaluate potential strategic transactions, we may not be successful in completing a transaction. Further, even if a strategic transaction is completed, it ultimately may not deliver the anticipated benefits or enhance stockholder value.

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 GSNOR may have the potential to achieve positive medical effects by modulating its activity in the body. 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.

Our Business Strategy

Our strategy is currently focused on identifying and evaluating strategic alternatives focused on maximizing stockholder value from our GSNOR inhibitor portfolio and cash resources. These alternatives may include, but are not

limited to, the potential for an acquisition, merger, business combination, licensing and/or other strategic transaction involving the company. We have engaged Ladenburg Thalman & Co., Inc. to act as our strategic financial advisor for this process. We have ceased all further research activities and plan to complete activity related to our ongoing clinical trials in CF during the first quarter of 2017. Whether or not we are successful in concluding a strategic transaction, we currently have no plans to pursue any further GSNOR inhibitor development ourselves.

Clinical Development of Cavosonstat to Date

We filed an investigational new drug application, or IND, for the commencement of clinical trials of cavosonstat with the U.S. Food and Drug Administration, or the FDA, on December 30, 2013. To date, we have completed dose escalation and drug-drug interaction trials in healthy subjects, a pharmacokinetic trial in CF patients, a Phase 1b clinical trial that assessed safety and tolerability in CF patients who were homozygous for F508del, and a Phase 2 clinical trial to assess efficacy and safety in that same patient population. Cavosonstat was well-tolerated in those trials with no dose-limiting safety findings when administered up to 800 mg twice daily in healthy subjects and 400 mg twice daily in CF patients. Including the Phase 2 clinical trial in CF patients that is concluding in the first quarter of 2017, we have completed two Phase 2 and five Phase 1 studies of cavosonstat as further described below. Cavosonstat has exhibited linear plasma level exposures with increases in dose resulting in proportional increases in both maximum plasma levels, or C_{max}, and area under the curve, or AUC, for plasma concentration versus time in healthy subjects and CF patients. There has been no significant systemic drug accumulation detected up to 12 weeks of administration. To date, there have been no significant human safety issues detected nor have there been any dose limiting toxicities observed, and the accumulated preclinical and clinical safety data provide support for the continued study of cavosonstat in other potential indications.

In 2015, we completed a Phase 1b clinical trial to evaluate the safety and tolerability of cavosonstat in adult CF patients homozygous for F508del. This trial met its stated objectives by demonstrating no dose-limiting toxicities of cavosonstat and informing dose selection for our Phase 2 clinical trial. The Phase 1b trial was a randomized, double-blind, placebo-controlled, parallel group trial with three doses of cavosonstat, at 50 mg, 100 mg and 200 mg, administered twice daily. These doses and a placebo were administered over 28 days in a total of 51 patients. The independent data safety monitoring board, or DSMB, concluded that there were no dose limiting toxicities observed with cavosonstat. We reported the top line results from this trial in September 2015 and presented the results at the North American Cystic Fibrosis Conference in October 2015. The data showed a trend toward a reduction in sweat chloride at the highest dose tested which was statistically significant using a within group comparison. The lack of dose limiting toxicity and a potential sweat chloride signal supported the inclusion of a higher dose in the Phase 2 trials.

Our first clinical trial of cavosonstat was a Phase 1, multiple ascending dose, safety and pharmacokinetic trial in healthy subjects. Cavosonstat was well tolerated with no dose-limiting toxicities noted up to 500 mg per day. In this trial, four cohorts each with six healthy subjects received 14-day dosing at 10 mg, 50 mg, 250 mg and 500 mg per day and two cohorts each with six healthy subjects received single doses of 50 mg and 250 mg.

Our second Phase 1 trial of cavosonstat was an open-label trial in CF patients homozygous for the F508del mutation. Six CF patients were dosed with 50 mg of cavosonstat twice daily for 14 days. The AUC in the CF patients was 97% of that in healthy subjects from our first Phase 1 trial. This trial showed that no dosing adjustments would be required for CF patients.

Our third Phase 1 trial was the trial described above in F508del homozygous patients.

Our fourth Phase 1 trial was a drug-drug interaction study using Rifampin as a surrogate for lumacaftor/ivacaftor because of its similar drug metabolizing properties. The drug-drug interaction trial was conducted in preparation for dose selection for Phase 2 and no adjustment of the cavosonstat dose was required on the basis of the results of this trial.

Our fifth Phase 1 trial was designed to assess the maximum tolerated dose of cavosonstat in order to provide dosing flexibility should the Phase 2 trial have suggested that a higher dose was warranted. A total of 32 healthy subjects were included and the maximum dose tested was 800mg twice daily. Final analysis of the trial data is pending and expected during the first quarter of 2017.

In late 2016 we completed the Phase 2 clinical trial of cavosonstat in 138 CF patients who had two copies of the F508del mutation and were receiving treatment with Orkambi. This three arm, double-blind, randomized, placebo-controlled, parallel group study evaluated the efficacy and safety of two doses of cavosonstat administered with Orkambi, compared to placebo administered with Orkambi. The primary endpoint of the study was the change from baseline to week 12 in absolute percent predicted forced expiratory volume in one second or $ppFEV_1$ from baseline to week 12. Statistical significance between each active dose and placebo (Orkambi) was not achieved for the primary and key secondary endpoints.

In the first quarter of 2017, we expect to complete 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.

Preclinical Safety Studies

We had previously conducted repeat oral-dose, 28 and 90-day toxicity studies in mice, rats and dogs in support of up to 12 weeks of treatment in Phase 2 clinical trials. In 2016 we also completed chronic toxicity studies of six months duration in rats and nine months duration in dogs. These species are routinely selected for toxicology testing and were deemed appropriate for small molecule inhibitors of GSNOR. All three species exhibited toxicities that were generally mild and occurred at higher exposures than intended in humans. The toxicology data generated thus far suggest the kidney, liver and possibly bone marrow may be target organs. Completion of the chronic toxicity studies provides support for human clinical trials of long-term duration. Additionally, a carcinogenicity study of six months duration was completed in transgenic mice and cavosonstat showed no carcinogenic effects.

Other GSNOR Inhibitors

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. We advanced N6022 into the clinic in an intravenous formulation to explore safety, tolerability and pharmacological attributes of this novel class of compounds. N6022 paved the way for cavosonstat by establishing initial safety of the class in healthy subjects and patients with CF. 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. N6022 demonstrated a significant effect on the airways, as measured by airway hyper-reactivity thus confirming the beneficial effects of N6022 observed in our preclinical studies of asthma. Because an oral dosage form is preferable in CF, a systemic disease that is not confined to the lung, we elected to discontinue further development of N6022 in the chronic management of CF. Currently, we do not plan to pursue development of N6022 in an inhaled or intravenous dosage form for other potential indications.

Our GSNOR inhibitor portfolio includes other compounds with differing chemical structures and properties suitable for oral, inhaled, injectable and topical administration. Although we are not pursuing further development ourselves, preclinical evidence supports a potential role for these compounds in indications such as inflammatory lung and bowel diseases and certain cardiovascular disorders.

Manufacturing and Supply

We do not currently own or operate manufacturing facilities for the production of drug substance or drug product. We have terminated our existing contracts for the production of cavosonstat and are currently establishing contracts for the storage of existing supplies of drug substance and drug product, and for destruction of those supplies should that be required.

The manufacturing process for cavosonstat and N6022 is relatively straightforward and generally in line with other small molecule pharmaceutical compounds in terms of cost and complexity. The process is robust and reproducible within our current specifications, does not require dedicated reactors or specialized equipment, uses common synthetic

chemistry and readily available materials, including off-the-shelf and made-to-order starting materials, and is readily transferable.

Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements that govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. The contract manufacturers that we used to manufacture our drug substance and drug product did so under current Good Manufacturing Practices, or cGMP, a regulatory standard for the production of pharmaceuticals. All contract manufacturers used in production had been inspected by the FDA for compliance to cGMP and maintained FDA establishment licenses.

Competition

We have no current plans to further develop or commercialize our portfolio of GSNOR inhibitors. However, to the extent a potential strategic transaction results in the further development of these candidates, potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. The pharmaceutical industry is highly competitive and subject to rapid and significant technological change. Key competitive factors are likely to be efficacy, safety and tolerability profile, convenience of dosing, price and reimbursement. Many of these potential competitors have substantial financial, technical and human resources and significant experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Further, mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a small number of competitors. Accordingly, competitors may be more successful in obtaining FDA approval for therapies and achieving widespread market acceptance. Competitors' products may also be more effective, or more effectively marketed and sold, than any product candidate that may be commercialized and may render our therapies obsolete or non-competitive before development and commercialization expenses can be recovered.

Intellectual Property

We believe that we have a strong patent portfolio and substantial know-how relating to cavosonstat (N91115) and our other product candidates. Our patent portfolio, described more fully below, includes claims directed to CFTR modulator compounds, pharmaceutical compositions comprising such compounds and methods of making and using the same. As of December 31, 2016, we are the owner of record of 32 issued U.S. patents and 213 issued non-U.S. patents. We continue to pursue an additional 10 U.S. patent applications including three provisional U.S. applications, four international patent applications, and 32 non-U.S. patent applications in over ten foreign countries. We are the licensee of five issued U.S. patents and seven issued non-U.S. patents.

We strive to protect the proprietary technology that we believe is important to our business, including our product candidates and our processes, and will continue to devote resources to do so while we identify and evaluate potential strategic opportunities. We seek patent protection in the United States and internationally for our products, their methods of use and processes of manufacture and any other technology to which we have rights, where available and when appropriate. We also rely on trade secrets that may be important to the development of our business.

We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may own or license in the future, nor can we be sure that any of our existing patents will be useful in protecting our technology. For this and more comprehensive risks related to our intellectual property, please see "Risk Factors—Risks Relating to Our Intellectual Property."

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing the non-provisional priority application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent.

The term of a U.S. patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug.

The patent portfolios for our proprietary technology portfolio and our two most advanced product candidates are summarized below.

Cavosonstat (N91115)

The patent portfolio for cavosonstat includes wholly owned patents and patent applications directed to GSNOR inhibitors, including cavosonstat and other compounds, pharmaceutical compositions comprising such compounds, methods of making such pharmaceutical compositions and methods of using such compounds and pharmaceutical compositions. Specific for our cavosonstat product candidate, we have six issued U.S. patents, pending U.S. patent applications, and corresponding foreign national or regional counterpart issued patents and/or patent applications pending in Europe, Japan and other countries. Our U.S. patents are expected to expire in 2031, excluding any additional term that may be available due to a patent term extension. Patents, if issued, based on these pending U.S. and foreign patent applications are expected to expire in 2031, excluding any additional term that may be available due to patent term adjustments or patent term extensions. We also have a pending international application directed to combination therapies. Patents, if issued, based on this pending international patent application, are expected to expire in 2035, excluding any additional term that may be available due to patent term adjustments or patent term extensions. We have three additional pending international patent applications directed to various cavosonstat related inventions. Patents, if issued, based on these pending international patent applications, are expected to expire in 2036, excluding any additional term that may be available due to patent term adjustments or patent term extensions. We also have three pending U.S. provisional patent applications directed to various cavosonstat related inventions. Patents, if issued, based on future patent applications filed claiming priority to these pending U.S. provisional patent applications, are expected to expire in 2037, excluding any additional term that may be available due to patent term adjustments or patent term extensions.

N6022

The patent portfolio for N6022 includes wholly owned patents and patent applications directed to GSNOR inhibitors, including N6022 and other compounds, pharmaceutical compositions comprising such compounds, methods of making such pharmaceutical compositions and methods of using such compounds and pharmaceutical compositions. Specific for our N6022 product candidate, we have six issued U.S. patents, pending U.S. patent applications and corresponding foreign national or regional counterpart issued patents and/or patent applications pending in Europe, Japan, and other foreign countries. The six issued U.S. patents are expected to expire in 2029, excluding any additional term that may be available due to patent term extension. Patents, if issued, based on pending U.S. and foreign patent applications are expected to expire in 2029 excluding any additional term that may be available due to patent term adjustments or extensions.

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to protect our proprietary technology and processes. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade

secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Regulatory Matters

Government authorities in the United States at the federal, state and local levels, and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of new drugs.

A number of different regulatory agencies may be involved, depending on the product at issue, and the type and stage of activity. These include the FDA, the Drug Enforcement Administration, or DEA, the Centers for Medicare and Medicaid Services, or CMS, other federal agencies, state boards of pharmacy, state controlled substance agencies and more.

U.S. Government Regulation

Drug Development Process

In the United States, the FDA is a primary regulator of drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and implementing regulations. The process of obtaining regulatory approvals and other compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with applicable requirements at any time during the drug development process, approval process, or after approval, may subject us to adverse consequences and administrative or judicial sanctions, any of which could have a material adverse effect on us. These sanctions could include refusal to approve pending applications; withdrawal or restriction of an approval; imposition of a clinical hold or other limitation on research; Warning Letters; product seizures; total or partial suspension of development, production, or distribution; or injunctions, fines, disgorgement, or civil or criminal payments or penalties.

The process required before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal trials and formulation trials conducted according to Good Laboratory Practices, or GLP, animal welfare laws and other applicable regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials, meaning trials in human subjects, in the United States may begin, obtaining similar authorizations in other jurisdictions where clinical research will be conducted and maintaining these authorizations on a continuing basis throughout the time that trials are performed and new data are collected;
- performance of adequate and well-controlled clinical trials according to Good Clinical Practices, or GCP, to demonstrate whether a proposed drug is safe and effective for its intended use;
- preparation and submission to the FDA of a marketing authorization application, such as a new drug application, or NDA, and submitting similar marketing authorization applications in other jurisdictions where commercialization will be pursued;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product will be produced to assess compliance with current good manufacturing practices, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity; and

- FDA review and approval of the NDA or other marketing authorization application.

The development, testing and approval process requires substantial time, effort and financial resources, as well as bearing inherent risk that individual products will not exhibit relevant safety, effectiveness, or quality characteristics. We cannot be certain that any approvals for our product candidates will be granted on a timely basis, or with the specific terms that we desire, if at all.

Clinical trials typically are conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The drug initially is introduced into a small number of healthy human volunteers and is tested for safety, dosage tolerance, absorption, metabolism, distribution and elimination.

- *Phase 2.* Clinical trials are initiated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug candidate for specific targeted diseases, and to determine dosage tolerance and optimal dosage.

- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall benefit-risk profile of the drug candidate and provide an adequate basis for regulatory approval and product labeling.

Progress reports related to clinical trials must be submitted at least annually to the FDA and participating IRBs, and more frequent safety reports must be submitted to the FDA and to investigators for serious and unexpected suspected adverse events, and certain other purposes. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within a specified period, if at all. The FDA or the sponsor may suspend a clinical trial at any time for a variety of reasons, including a finding that the healthy volunteers or patients are being exposed to an unacceptable health risk or that the investigational product apparently lacks efficacy. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with applicable requirements or if the drug candidate has been associated with unexpected serious harm to healthy volunteers or patients.

We estimate that it generally takes 10 to 15 years, or possibly longer, to discover, develop and bring to market a new pharmaceutical product in the United States. Several years may be needed to complete each phase, including discovery, preclinical, Phase 1, 2 or 3, or marketing authorization.

At times during the development of a new drug product, sponsors are given opportunities to meet with the FDA. This commonly occurs prior to submission of an IND, at the end of Phase 2 testing, and before an NDA is submitted. Meetings at other times may also be requested. These meetings provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. A plan for pediatric assessment also must be discussed at the end of Phase 2 meeting.

Concurrent with clinical trials, companies usually complete additional animal trials and develop additional information about the chemistry and physical characteristics of the drug candidate and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate, and the manufacturer must develop methods for confirming the identity, quality, purity, and potency of the final products. Additionally, appropriate packaging must be selected and tested and stability trials must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf-life and distribution pathway.

Disclosure of Clinical Trial Information

Sponsors of clinical trials (other than Phase 1 trials) of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, comparator, patient

population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of certain trials may be delayed until the new product or new indication being studied has been approved. However, there are evolving rules and increasing requirements for publication of trial related information, and it is possible that data and other information from trials involving drugs that never garner approval could in the future be required to be disclosed. In addition, publication policies of major medical journals mandate certain registration and disclosures as a pre-condition for potential publication, even when this is not currently mandated as a matter of law. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

New Drug Application Review and Approval Processes

The results of drug candidate development, preclinical trials and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug candidate, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the drug candidate. The submission of an NDA is subject to the payment of a substantial user fee, and the sponsor of an approved NDA is also subject to annual product and establishment user fees; a waiver of fees may be obtained under limited circumstances.

The FDA reviews each NDA to ensure that it is sufficiently complete for substantive review before it accepts it for filing. Once the submission is accepted for filing, the FDA begins an in depth review. The FDA reviews an NDA to determine, among other things, whether a drug candidate is safe and effective for its intended use and indication for use and whether its manufacturing is cGMP-compliant to assure and preserve the drug candidate's identity, strength, quality and purity. The FDA may refer the NDA to an advisory committee consisting of a panel of external experts for review and recommendation as to whether the NDA should be approved and under what conditions. Before approving an NDA, the FDA will typically inspect the facility or facilities where the active ingredient and the formulated drug candidate are manufactured and tested.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable criteria are not satisfied, or it may require additional clinical or other data. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a Complete Response Letter if the agency decides not to approve the NDA in its present form. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the Complete Response Letter may include recommended actions that the applicant might take to place the application in a condition for approval.

If a product receives regulatory approval, the approval may be limited to specific diseases, dosages, or indications for use, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval trials, including Phase 4 clinical trials, to further assess a drug's safety and effectiveness after NDA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Expedited Development and Review Programs

The FDA has various programs, including fast track, priority review, accelerated approval, and breakthrough therapy designation, that are intended to increase agency interactions, expedite or facilitate the process for reviewing drug candidates, and/or provide for initial approval on the basis of surrogate endpoints. Generally, drug candidates that may be eligible for these programs are those for serious or life-threatening conditions, have the potential to address unmet medical needs and offer meaningful benefits over existing treatments. The FDA has granted orphan drug and fast track designations for cavosonstat in CF. Based on the clinical trial results with cavosonstat, however, the FDA may decide that it no longer meets the conditions for qualification. Moreover, the time period for FDA review may not actually be shortened even if a drug candidate has qualified for an expedited development program.

If a drug candidate is approved under certain expedited programs, for example, the FDA's accelerated approval regulations, the approval may be conditioned upon post marketing requirements, including the completion of post-approval clinical trials, sometimes referred to as Phase 4 trials, to confirm the effect on the desired clinical endpoint. Failure to conduct required post-approval trials, or the inability to confirm a clinical benefit during post marketing trials, may allow the FDA to withdraw the drug from the market on an expedited basis. In addition, all promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Post-approval Requirements

Any products that receive FDA approval are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting and analysis of adverse experiences with the product, providing the FDA with updated safety, efficacy and quality information, product sampling and distribution requirements, maintaining up-to-date labels, warnings, and contraindications, and complying with promotion and advertising requirements. Products may be promoted only for the approved indications and in accordance with the approved label; products cannot be promoted for unapproved, or off-label, uses, although physicians may prescribe drugs for off-label uses in accordance with the practice of medicine. Manufacturers must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to manufacturing processes often require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Manufacturers and other entities involved in the manufacturing and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic inspections for compliance with cGMP and other laws. FDA and state inspections may identify compliance issues at manufacturing that may disrupt production or distribution or may require substantial resources to correct.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market such as adverse events the existence or severity of which was unknown when the product was approved. Later discovery of previously unknown problems with a product may result in restrictions on the product or complete withdrawal from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, warning letters, holds on clinical trials, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal payments or penalties.

From time to time, new legislation is enacted that changes the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA. In addition, FDA regulations and guidance may be revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative or regulatory or policy changes will occur or be implemented and what the impact of such changes, if any, may be.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drug candidates intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that costs of research and development of the drug for the indication can be recovered by sales of the drug in the United States. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Although there may be some increased communication opportunities, orphan drug designation does *not* convey any advantage in or shorten the duration of the regulatory review and approval process.

If a drug candidate that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in very limited circumstances, such as if the second applicant demonstrates the clinical superiority of its product. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

Orphan drug exclusivity could block the approval of our drug candidates for seven years if a competitor obtains approval of the same product as defined by the FDA or if our drug candidate is determined to be contained within the competitor's product for the same indication or disease.

As in the United States, designation of a drug candidate as an orphan drug for the treatment of a specific indication is available in the European Union if applied for before the application for marketing authorization is made. Orphan drugs in Europe enjoy economic and marketing benefits, including up to 10 years of market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan designated product.

The FDA and foreign regulators expect holders of exclusivity for orphan drugs to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients. Failure to do so could result in the withdrawal of marketing exclusivity for the orphan drug.

Pharmaceutical Coverage, Pricing, and Reimbursement

United States

Even if the FDA approves NDAs for our drug candidates, sales of our products will depend, in part, on the availability of coverage and reimbursement by third party payers, such as government health programs, commercial or private insurance, and managed care organizations. The process for determining whether a payer will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payer will pay for the drug product. Third party payers may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Moreover, a payer's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third party payers fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on cost containment measures in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

European Union

In Europe and many other foreign countries, the success of our drug candidates we may develop, depends largely on obtaining and maintaining government reimbursement, because in many foreign countries patients are unlikely to use prescription pharmaceutical products that are not reimbursed by their governments. Negotiating reimbursement rates in foreign countries can delay the commercialization of a pharmaceutical product and generally results in a reimbursement rate that is lower than the net price that companies can obtain for the same product in the United States.

In some countries, such as Germany, commercial sales of a product can begin while the reimbursement rate that a company will receive in future periods is under discussion. In other countries, a company must complete the reimbursement discussions prior to the commencement of commercial sales of the pharmaceutical product. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides

options for its member states to restrict the range of drugs for which their national health insurance systems provide reimbursement and to control the prices of drugs for human use. A member state may approve a specific price for the drug or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug on the market. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries.

Other U.S. Healthcare Laws and Compliance Requirements

Pharmaceutical companies also are subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and false claims laws, and the reporting of payments to physicians and teaching hospitals. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business.

Anti-kickback Laws

U.S. federal laws, including the federal Anti-Kickback Statute, prohibit fraud and abuse involving state and federal healthcare programs, such as Medicare and Medicaid. These laws are interpreted broadly and enforced aggressively by various state and federal agencies, including CMS, the Department of Justice, the Office of Inspector General for HHS, and various state agencies. These anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal healthcare program. Remuneration is broadly defined to include anything of value, such as cash payments, gifts or gift certificates, discounts, or the furnishing of services, supplies, or equipment. The anti-kickback laws are broad and prohibit many arrangements and practices that are lawful in businesses outside of the healthcare industry. A person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation.

The penalties for violating the anti-kickback laws can be severe. The sanctions include criminal and civil penalties, and possible exclusion from the federal healthcare programs. Many states have adopted laws similar to the federal anti-kickback laws, and some apply to items and services reimbursable by any payer, including third party payers.

Federal and State Prohibitions on False Claims

The federal False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment under federal programs (including Medicare and Medicaid). Under the False Claims Act, a person acts knowingly if he has actual knowledge of the information or acts in deliberate ignorance or in reckless disregard of the truth or falsity of the information. Although we would not submit claims directly to government payers, manufacturers can be held liable under the False Claims Act if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law.

Provisions of the False Claims Act allow a private individual to bring an action on behalf of the federal government and to share in any amounts paid by the defendant to the government in connection with the action. The number of filings under these provisions has increased significantly in recent years. Conduct that violates the False Claims Act may also lead to exclusion from the federal healthcare programs. In addition, various states have enacted similar laws modeled after the False Claims Act that apply to items and services reimbursed under Medicaid and other state healthcare programs, and, in several states, such laws apply to claims submitted to all payers.

Federal Prohibitions on Healthcare Fraud and False Statements Related to Healthcare Matters

There are numerous federal and state laws protecting the privacy and security of protected health information. Additionally, a number of related crimes can be prosecuted related to healthcare fraud, false statements relating to healthcare matters, theft or embezzlement in connection with a health benefit program, and obstruction of criminal investigation of healthcare offenses. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including a private insurer. Violation of any of these laws is a felony and may result in fines or exclusion from the federal healthcare programs.

Physician Payment Sunshine Act

The Physician Payment Sunshine Act requires most pharmaceutical manufacturers to report annually to the Secretary of HHS financial arrangements, payments, or other transfers of value made by that entity to physicians and teaching hospitals. The payment information is made publicly available in a searchable format on a CMS website. Failure to comply with the reporting requirements can result in significant civil monetary penalties. Similar laws have been enacted or are under consideration in foreign jurisdictions, including France, which has adopted the *Loi Bertrand*, or French Sunshine Act, which became effective in 2013.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act prohibits U.S. companies and their representatives from offering, promising, authorizing, or making payments to foreign officials for the purpose of obtaining or retaining business abroad. In many countries, the healthcare professionals we regularly interact with may meet the definition of a foreign government official for purposes of the Foreign Corrupt Practices Act.

Other Regulations

In addition to the statutes and regulations described above, we also are subject to regulation in the United States under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other federal, state, local and foreign statutes and regulations, now or hereafter in effect.

Foreign Regulation

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials, and governing any future distribution and commercial sales, if any, of our products. Whether or not FDA approval is obtained for a drug candidate, the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, must approve commencement of clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders, or diabetes and optional for those medicines that are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for approval by one or more “concerned” member states based on an assessment of an application performed by one-member state, known as the “reference” member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state’s assessment report, each concerned member state must decide whether or not to approve the assessment report and related materials. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

Employees

As of the date of this filing, we have 15 full-time employees. Ten of these employees have been notified that their employment with the company will terminate at the end of February or March 2017. None of our employees is represented by a labor union or covered by a collective bargaining agreements.

Research and Development

We incurred approximately $23.3 million, $16.1 million and $12.2 million in research and development in the years ended December 31, 2016, 2015 and 2014, respectively.

About Nivalis

We were incorporated under the laws of the State of Delaware in August 2012 and completed our initial public offering of our common stock in June 2015. Our common stock is listed on the NASDAQ Global Market under the symbol "NVLS". Our principal executive offices are located at 3122 Sterling Circle, Suite 200, Boulder, Colorado 80301, and our telephone number is (720) 945-7700. Our website address is *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.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) December 31, 2020; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission. We refer to the Jumpstart Our Business Startups Act of 2012 herein as the "JOBS Act," and references herein to "emerging growth company" shall have the meaning associated with it in the JOBS Act.

Available Information

As a public company, we file reports and proxy statements with the Securities and Exchange Commission, or the SEC. These filings include our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and proxy statements on Schedule 14A, as well as any amendments to those reports and proxy statements, and are available free of charge through our website as soon as reasonably practicable after we file them with, or furnish them to, the SEC. Once at *www.nivalis.com*, go to the *Investors/SEC Filings* section of our website to locate copies of such reports. You may also read and copy materials that we file with SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website at *www.sec.gov* that contains reports, proxy statements and other information regarding us and other issuers that file electronically with the SEC.

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 consider the following discussion of risk factors, in its entirety, in addition to other information contained in or incorporated by reference into this Annual Report on Form 10-K and 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.

Risks Relating to Our Evaluation of Strategic Alternatives and Our Business

Our exploration and pursuit of strategic alternatives may not be successful.

Following the failure of cavosonstat to achieve the primary endpoint in a Phase 2 trial of patients with CF, we determined to cease all further development of cavosonstat and our other product candidates and implemented operating cost reductions and organizational restructurings, including a recent reduction in our workforce, to preserve our cash resources and better align our organization with our current operating plan. Our strategic focus has shifted to the identification and evaluation of a range of potential strategic alternatives designed to maximize stockholder value. Potential strategic alternatives that may be explored or evaluated as part of this process include the potential for an acquisition, merger, business combination, licensing and/or other strategic transaction involving the Company. Despite devoting significant efforts to identify and evaluate potential strategic transactions, the process may not result in any definitive offer to consummate a strategic transaction, or, if we receive such a definitive offer, the terms may not be as favorable as anticipated or may not result in the execution or approval of a definitive agreement. Even if we enter into a definitive agreement, we may not be successful in completing a transaction or, if we complete such a transaction, it may not enhance stockholder value or deliver expected benefits.

If we do not successfully consummate a strategic transaction, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that the process to identify a strategic transaction will result in a successfully consummated transaction. If no transaction is completed, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations while we evaluate our strategic alternatives. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include (i) regulatory and clinical obligations remaining under our Phase 2 trial for cavosonstat; (ii) obligations under our employment and related agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of our company; and (iii) potential investigations or litigation against us, and other various claims and legal actions arising in the ordinary course of business. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our company. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of our company.

If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.

Although there can be no assurance that a strategic transaction will result from the process we have undertaken to identify and evaluate strategic alternatives, the negotiation and consummation of any such transaction will require significant time on the part of our management, and the diversion of management's attention may disrupt our business.

The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected acquisition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership; and
- inability to retain key employees of our company or any acquired business.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

We may not realize any additional value in a strategic transaction for our portfolio of GSNOR inhibitors.

The market capitalization of our company is significantly below the value of our cash, cash equivalents and marketable securities. Although our most advanced product candidate, cavosonstat, failed to meet its primary endpoint and a key secondary endpoint in CF, we believe that data from preclinical studies of cavosonstat and the other GSNOR inhibitors in our portfolio support potential further investigation of these candidates in other therapeutic indications, which may include inflammatory lung and bowel diseases, and certain cardiovascular diseases. Potential counterparties in a strategic transaction involving our company may place minimal or no value on these assets, however, given the limited data regarding their potential application in these diseases. Further, the development and any potential commercialization of our product candidates will require substantial additional cash to fund the costs associated with conducting the necessary preclinical and clinical testing and obtaining regulatory approval. Consequently, any potential counterparty in a strategic transaction involving our company may choose not to spend additional resources and continue development of our product candidates and may attribute little or no value, in such a transaction, to those product candidates.

We may become involved in securities class action litigation that could divert management's attention and harm the company's business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in investigations by the Securities and Exchange Commission. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our recently announced corporate restructuring plans, and our restructuring activities may adversely affect our ability to consummate a strategic transaction that enhances stockholder value.

Following the failure of our Phase 2 trial of cavosonstat to meet its primary endpoint in patients with CF in November 2016, we implemented a plan in January 2017 to reduce our workforce by approximately 84%, leaving approximately five employees remaining after March 31, 2017 in order to better align our resources with our operational needs going forward. As part of this corporate restructuring and our focus on the identification and evaluation of strategic alternatives, we also discontinued all of our research activities and focused on the completion and close-out of

any ongoing clinical trial activities. These reductions in force resulted in or will result in the loss of numerous long-term employees, the loss of institutional knowledge and expertise, and the reallocation of certain job responsibilities, all of which could negatively affect operational efficiencies and increase our operating expenses such that we may not fully realize anticipated savings from the restructuring, and could significantly impair our ability to successfully complete a potential strategic transaction on terms that are favorable to our stockholders, or at all.

We are substantially dependent on our remaining employees to facilitate the consummation of a strategic transaction.

Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining personnel, particularly R. Michael Carruthers, our Interim President and Chief Financial Officer, and Janice Troha, our Chief Operating Officer. Despite our efforts to retain these employees, one or more may terminate their employment with us on short notice. The loss of the services of any of these employees could potentially harm our ability to evaluate and pursue strategic alternatives, as well as fulfill our reporting obligations as a public company.

Risks Associated with Our Limited Operating History, Financial Position and Capital Requirements

We have incurred significant losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future.

We have incurred significant net losses in each year since our inception, including net losses of $31.5 million, $22.8 million, and $15.0 million for the years ended December 31, 2016, 2015, and 2014, respectively. As of December 31, 2016, we had an accumulated deficit of $180.3 million. We expect to continue to incur operating expenses and anticipate that we will continue to have losses in the foreseeable future as we evaluate and potentially act on strategic alternatives. Moreover, even if our Board of Directors determines to pursue a specific strategic alternative, we expect that significant expenses will be involved in completing any resulting transaction or transactions, which will further reduce our existing capital.

Our future funding requirements will depend on many factors, including but not limited to:

- our ability to identify and successfully consummate a strategic transaction involving our company;
- the timing, complexity and costs required for completion of any transaction that may result from our review of strategic alternatives;
- the timing and resources required for completion and close-out of our cavosonstat clinical trials;
- 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 research and development activities in the future, if at all; and
- costs that may be incurred in responding to disruptive actions by activist stockholders.

Our losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Further, because of uncertainties relating to the outcome of the process we have undertaken to identify and evaluate strategic alternatives and the risks and uncertainties inherent in the biotechnology industry, we are unable to predict the extent of any future losses or whether we will become profitable.

Our recurring losses from operations may raise substantial doubt regarding our ability to continue as a going concern.

We have had recurring losses from operations since inception and will likely not generate revenue for the foreseeable future. We believe that our existing cash, cash equivalents and marketable securities and interest thereon will be sufficient to fund our projected operating requirements under our current operating plan. However, if our operating

plans change and our projected operating requirements increase, we may be unable to continue as a going concern. In this event, the perception that we may not be able to continue as a going concern may have an adverse impact on our business due to concerns about our ability to meet our contractual obligations. Further, if we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation and dissolution could be significantly lower than the values reflected in our financial statements and an investor could lose all or part of their investment in our company.

Although we have ceased all further development of cavosonstat and our other potential product candidates, if we were to resume research and development activities, we would require substantial additional funding. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or to a product candidate.

We currently do not have any committed external source of funds and do not expect to generate any revenue in the foreseeable future. We believe that our existing cash, cash equivalents and marketable securities and interest thereon will be sufficient to fund our projected operating requirements under our current operating plan. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect if our operating plans change. If our current operating plans change and we determine to pursue further research and development activities, we will require substantial additional funding to operate, and would expect to finance these cash needs through a combination of equity offerings, debt financings, government or other third-party funding and licensing or collaboration arrangements.

To the extent that we raise additional capital through the sale of equity or convertible debt, the ownership interests of our stockholders will be diluted. In addition, the terms of any equity or convertible debt we agree to issue may include liquidation or other preferences that adversely affect the rights of our stockholders. Convertible debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, and declaring dividends, and may impose limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to curtail or cease our operations or we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us.

Our inability to utilize our net operating loss carryforwards before they expire may adversely affect our results of operations and financial condition.

As of December 31, 2016 we had federal and state net operating loss carryforwards of approximately $75.7 million and $83.0 million, respectively, which may be utilized against future federal and state income taxes. In general, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating loss carryforwards, or NOLs, to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders, generally stockholders beneficially owning five percent or more of our common stock, applying certain look-through and aggregation rules, increases by more than 50% over such stockholders’ lowest percentage ownership during the testing period, generally three years. Purchases of our common stock in amounts greater than specified levels, which will be beyond our control, could create a limitation on our ability to utilize our NOLs for tax purposes in the future. In addition, the closing of a strategic transaction may result in the limitation of our NOLs, which may affect the value we receive in such a strategic transaction. Limitations imposed on our ability to utilize NOLs could cause us to pay U.S. federal and state income taxes earlier than we would otherwise be required if such limitations were not in effect and could cause such NOLs to expire unused. Furthermore, we may not be able to generate sufficient taxable income to utilize our NOLs before they expire beginning in 2032. In addition, at the state level there may be periods during which the use of NOLs is suspended or otherwise limited, which would accelerate or may permanently increase state taxes owed. If any of these events occur, we may not derive some or all of the expected benefits from our NOLs, and our results of operations and financial condition may be adversely affected as a result. As of December 31, 2016, we have not performed a formal study to determine whether limitations to our NOLs have occurred or whether such limitations could result from the sale of shares in our initial public offering in June 2015. Such limitations could be significant.

Risks Relating to Development and Regulatory Approval

Cavosonstat did not achieve its primary endpoint in a Phase 2 trial with CF patients, and our previous findings from preclinical studies in other potential disease areas may not be predictive of a benefit for cavosonstat or any other of our GSNOR inhibitors.

We have ceased all research and development activities for cavosonstat and all of our GSNOR inhibitors and we currently have no plans to pursue such development ourselves as we identify and evaluate potential strategic alternatives for the company. If our operating plans change, however, and we are successful in completing a transaction following which further development of cavosonstat or our other GSNOR inhibitors is resumed, these development activities may not result in drugs that are approved by regulatory authorities. Regulatory agencies, including the FDA, ultimately must approve any product candidate before it can be promoted, marketed or commercially distributed. Cavosonstat and any other potential product candidate we may develop will be subject to extensive and rigorous review and regulation by governmental authorities. We have never obtained approval for or commercialized a product candidate, and our portfolio of GSNOR inhibitors outside of CF is at an early stage of development and unproven. The timing of the drug development process is lengthy and can be unpredictable and may include post-marketing studies and surveillance. Any such development of our GSNOR inhibitors would require the expenditure of additional resources beyond our existing cash, cash equivalents or marketable securities. Of the large number of drugs in development for approval in the United States, only a small percentage successfully complete the regulatory approval process and are commercialized. The success of any of our potential product candidates depends on, among other things:

- our ability to complete clinical trials and other product research and development activities;
- whether clinical trials demonstrate statistically significant and clinically meaningful efficacy not outweighed by safety issues;
- meeting FDA and other regulatory agencies' requirements to obtain approval for a product candidate; and
- ensuring that the manufacturing processes and facilities of the third parties with which we contract to manufacture a product candidate are in compliance with all relevant regulatory requirements, including those of the FDA.

If we are not successful with respect to one or more of these factors either in a timely manner or at all, significant delays in obtaining regulatory approval, including, but not limited to, denial of a new drug application, or NDA, could result. We have never applied for, and have never received, regulatory approval for a drug. If we are unable to successfully complete the clinical development of a product candidate and meet other related regulatory requirements, we will be unable to obtain approval of an NDA from the FDA. It is possible that, even if we successfully complete clinical development, the FDA may refuse to accept our NDA for substantive review or may conclude after review of our data that our application is insufficient. If the FDA does not accept or approve our NDA, it may require that we conduct additional clinical, nonclinical or manufacturing studies or analyses and submit that data to it before it will reconsider our application. Depending on the extent of these or any other FDA requirements, approval of any NDA or application that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDA.

In addition, the regulatory agencies may not complete their review processes in a timely manner, or additional delays may result if a potential drug candidate is brought before an FDA advisory committee, which could recommend restrictions on approval or recommend non-approval of the product candidate. In addition, delays or rejections could result based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical studies and the review process. As a result, we cannot predict when, if at all, we will receive regulatory approval of any product candidate.

Any delay in obtaining, or an inability to obtain, regulatory approvals would prevent us from commercializing a product candidate, generating revenue and achieving and sustaining profitability. If any of these outcomes occur, it would have a material adverse effect on our business and could potentially cause us to cease operations. These factors could materially harm our business, and the value of our common stock would likely decline.

The regulatory approval processes of the FDA, the European Medicines Agency, or EMA, and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable.

We are not permitted to market any of our potential product candidates in the United States or outside the United States until we receive approval of an NDA from the FDA or approval of a marketing application from the comparable regulatory authority in other countries. Should we determine to resume development of any of our GSNOR inhibitors, prior to submitting an NDA to the FDA for approval, we will need to complete our preclinical studies in the applicable indication, as well as all necessary clinical trials. Successfully initiating and completing clinical programs and obtaining approval of an NDA is a complex, lengthy, expensive and uncertain process, and FDA and other comparable foreign regulatory authorities may delay, limit or deny approval of a potential product candidate for many reasons, including, among others:

- the results of our clinical trials may not meet the level of statistically significant and clinically meaningful efficacy with an acceptable safety profile as required by FDA, or other comparable regulatory authorities in other countries, for marketing approval;
- the FDA or other comparable regulatory authorities in other countries may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA or other comparable regulatory authorities may find the data from preclinical studies and clinical trials insufficient to demonstrate that the potential clinical and other benefits outweigh its safety risks;
- the FDA or other comparable regulatory authorities in other countries may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the FDA or other comparable regulatory authorities in other countries may not accept data generated at one or more of our clinical trial sites;
- if our NDAs or similar applications, if and when submitted, are reviewed by FDA or other comparable regulatory authorities, as applicable, the regulatory authorities may have difficulties scheduling the necessary review meetings in a timely manner, may recommend against approval of our application or may recommend that the FDA or other comparable regulatory authorities, as applicable, require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and restrictions on use;
- the FDA may determine that our NDAs, if and when submitted, must follow a different regulatory pathway than we have attempted, and there may be potentially extended standards, timelines, and/or costs in order to pursue approval;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy as a condition of approval or post-approval, and other comparable regulatory authorities may grant only conditional approval or impose specific obligations as a condition for marketing authorization, or may require us to conduct post-authorization safety studies;
- the FDA or other comparable regulatory authorities may determine that the manufacturing processes or facilities of third party manufacturers with which we contract are not in compliance with all relevant regulatory requirements, including current good manufacturing practice, or cGMP, requirements; or
- the FDA or other comparable regulatory authorities may change their approval policies or adopt new regulations.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market any of our potential product candidates, which would have a material adverse effect on our business and prospects.

If we were to resume research and development activities on our potential product candidates, we would depend on the successful completion of clinical trials for any potential product candidate. The positive clinical results, if any, obtained by us in future clinical trials may not be repeated in later-stage clinical trials.

Before obtaining regulatory approval for the sale of a potential product candidate, extensive clinical trials are required to demonstrate safety and efficacy in humans. We have not completed the clinical trials necessary to support an application for approval to market cavosonstat or any other potential product candidate. Successful completion of such clinical trials is a prerequisite to submitting an NDA to the FDA and, consequently, the ultimate approval and commercial marketing of any of our potential product candidates. A failure of one or more clinical trials can occur at any stage of testing. Further, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later preclinical testing or clinical trials, and interim results of a clinical trial do not necessarily predict final results. For example, despite positive preclinical and early stage clinical results, cavosonstat did not achieve the primary endpoint in a recently completed Phase 2 clinical trial in CF that was announced in November 2016. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

Should we choose to resume development of any of our potential candidates, we may experience a number of unforeseen events during, or as a result of, any future clinical trials of that may be conducted on any of our potential product candidates that could adversely affect the completion of those clinical trials, including:

- regulators, and/or institutional review boards or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- clinical trials of a potential product candidate may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects required for clinical trials of a potential product candidate may be larger than anticipated, enrollment in these clinical trials may be insufficient or slower than anticipated or subjects may drop out of these clinical trials at a higher rate than anticipated;
- third party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- clinical trials of a potential product candidate may be suspended or terminated for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- regulators, institutional review boards or data monitoring committees may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical trials of a potential product candidate may be greater than anticipated;
- the supply or quality of a potential product candidate or other materials necessary to conduct clinical trials of a product candidate may be insufficient or inadequate; and
- a potential product candidate may have undesirable side effects or other unexpected characteristics.

Negative or inconclusive results of any future clinical trials of our potential product candidates could mandate repeated or additional clinical studies. Despite the safety results reported in earlier clinical trials for cavosonstat, we do not know whether any other clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market cavosonstat in any other indications or any other potential product candidate. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for a potential product candidate may be adversely impacted.

Should we resume research and development activities, delays in clinical trials are common and have many causes, and any delay could have a material adverse effect on our business, such as increased costs and delays in our ability to obtain regulatory approval and commence product sales. In this event, we may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Clinical trials must be conducted in accordance with FDA regulations or other applicable foreign government regulations, and are subject to oversight by the FDA or other foreign regulatory authorities and institutional review boards at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced under current Good Manufacturing Practices, or cGMP, and may require large numbers of test subjects.

If we resume research and development activities relating to our GSNOR inhibitors, we may experience delays in clinical trials at any stage of development and testing of any such potential product candidate.

Events which may result in a delay or unsuccessful completion of clinical trials for any of our GSNOR inhibitors include:

- inability to secure a collaborative partner to undertake future development of any of our GSNOR inhibitors raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with FDA or regulatory authorities in other countries on final trial design;
- imposition of a clinical hold based on the submission of results of clinical and preclinical studies or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required institutional review board approval at each site;
- delays in recruiting and retaining suitable subjects to participate in a trial;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- delays caused by subjects dropping out of a trial due to side effects or otherwise;
- clinical sites dropping out of a trial to the detriment of enrollment;
- study personnel may administer the wrong version of a potential product candidate or assign study therapy to the wrong treatment group, resulting in disqualification of subjects from data analysis;
- study personnel may not perform in accordance with good clinical practices;
- a potential product candidate may have unforeseen adverse side effects;
- time required to add new clinical sites; and
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

If initiation or completion of any of our clinical trials are delayed for any of the above reasons, our development may be arrested, development costs may increase, our approval process could be delayed, any periods during which we may have the exclusive right to commercialize a potential product candidate may be reduced and our competitors may have more time to bring products to market before we do or otherwise delay us. Any of these events could impair our ability to generate revenue from product sales and impair our ability to generate regulatory and commercialization milestones and royalties, all of which could have a material adverse effect on our business.

Our potential product candidates may cause adverse events or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

If we were to resume research and development activities relating to our GSNOR inhibitors, undesirable adverse events caused by our potential product candidates could cause us or regulatory authorities to interrupt, delay, halt or terminate clinical trials and could result in the denial of regulatory approval by the FDA or other comparable foreign regulatory authorities for any or all targeted indications. It is possible that during the course of the clinical development of a potential product candidate, results of our clinical trials could reveal an unacceptable severity and prevalence of adverse events. In addition, our remaining preclinical testing may produce inconclusive or negative safety results, which may require us to conduct additional preclinical testing or to abandon a potential product candidate. Also, a potential product candidate may have unfavorable pharmacology or toxicity characteristics, or cause undesirable side effects.

Undesirable adverse events caused by a potential product candidate could affect patient recruitment or the ability of enrolled patients to complete a clinical trial or result in potential product liability claims. In addition, adverse events that occur in our trials as a consequence of the serious disease that is being studied may negatively affect the profile of the potential product candidate. The FDA or other regulatory authorities may determine that additional safety testing is required for a potential product candidate, which would cause a delay in our clinical development of such product candidate.

Additionally, if any potential product candidate receives marketing approval, and we or others later identify undesirable adverse events caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approval of the potential product candidate or impose restrictions on their distribution in the form of a modified risk evaluation and mitigation strategy;
- regulatory authorities may require additional labeling, such as warnings or contraindications;
- we may be required to change the way the product is administered or to conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects. Any such events would increase our costs and could delay or prevent our ability to commercialize our product candidates should we resume development activities, which could adversely impact our business, financial condition and results of operations.

Cavosonstat and any other potential product candidate based on our GSNOR inhibitor portfolio are based on a novel technology, which may raise development issues we may not anticipate or be able to resolve, and regulatory issues that could delay or prevent approval.

Cavosonstat and any other potential product candidate based on our GSNOR inhibitor technology platform are based on a novel technology, and there can be no assurance that unforeseen development problems related to our novel technology will not arise in the future and cause significant delays should we determine to resume research and development activities relating to our GSNOR inhibitors. We may be unable to resolve any such unforeseen problems.

Regulatory approval of novel product candidates can be more expensive and take longer than other, more well-known or extensively studied pharmaceutical product candidates due to our and regulatory agencies' lack of experience with them. There are no GSNOR inhibitors that we know of in clinical development and none have been approved to date. Should we resume research and development activities relating to our GSNOR inhibitors, the novelty of our platform may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of cavosonstat or any other potential product candidate based on our GSNOR inhibitor technology platform or lead to significant post-approval limitations or restrictions. For example, the FDA could require additional studies or characterization that may be difficult or impossible to perform.

Even if we obtain regulatory approval for a potential product candidate, we will still face extensive ongoing regulatory requirements.

Even if we obtain regulatory approval in the United States, the FDA may still impose significant future restrictions on the indicated uses or marketing of a potential product candidate, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance, including Phase 4 clinical trials. Should we obtain regulatory approval, we will be subject to ongoing FDA requirements governing the labeling, manufacturing, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs, and adherence to commitments made in the NDA. If we, or a regulatory agency, discover previously unknown problems with a product, such as quality issues or adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including necessitating recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable ongoing regulatory requirements following approval of a product candidate, a regulatory agency may:

- issue an untitled or warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us; or
- demand recall and/or seize product.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit the commercialization of any potential product candidate and inhibit our ability to generate revenue.

The approval of a potential product candidate in any given market does not ensure approval in any other market.

In order to market any product candidate, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval in the United States by the FDA or by a regulatory agency in another country does not ensure approval by the regulatory authorities in other countries or jurisdictions or ensure approval for the same conditions of use. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our product candidates will be unrealized.

Risks Related to Our Dependence on Third Parties

If we attempt to form strategic alliances or collaborations in the future with third parties for the development and commercialization of any of our product candidates, we may not be successful in establishing these alliances or collaborations.

We may seek to form strategic alliances or collaborations for the development and potential commercialization of our product candidates. We may not be successful in entering into any such transaction on favorable terms or at all. Our potential product candidates may be considered to be too early in development for a collaborative effort or may be perceived as being too risky or without sufficient market potential or otherwise as insufficient for clinical, market or other reasons. If we were successful in entering into a strategic alliance or collaboration, our ability to generate revenue from the alliance or collaboration will depend on our collaborators' abilities to establish the safety and efficacy of our product candidates, to obtain regulatory approvals and to achieve market acceptance. Strategic alliances and collaborations involving our product candidates pose many risks to us, including:

- strategic alliances and collaborations may not lead to development of product candidates or commercialization of products in the most efficient manner or at all;
- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these alliances
- collaborators may interpret clinical trial or non-clinical study results differently than we do, may pursue further development and commercialization of our product candidates for indications that we do not believe are optimal, may not pursue further development and commercialization of our product candidates at all or may elect not to continue or renew research and development programs based on nonclinical or clinical trial results, changes in their strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive;
- collaborators with marketing and distribution rights to one or more products may not commit enough resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- disputes may arise between us and collaborators that result in the delay or termination of the research, development or commercialization of our product candidates, that result in costly litigation or arbitration that diverts management attention and resources or that, if resolved unfavorably to us, result in adverse financial consequences for us under the terms of the applicable agreements; and
- strategic alliances and collaborations may be terminated, either in their entirety or as to particular product candidates or programs, which may result in a need for a reallocation of internal funds or additional capital to pursue further development of the applicable product candidates.

Our employees, consultants or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of fraud or other misconduct by our employees, consultants and other third parties, such as principal investigators, CROs and vendors, if any. Misconduct by these parties could include intentional, reckless or negligent conduct, and/or failures to comply with FDA regulations, provide accurate information to the FDA, comply

with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent misconduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Risks Relating to Protecting Our Intellectual Property

It is difficult and expensive to protect our intellectual property rights and we cannot ensure that they will prevent third parties from competing against us.

Our success will depend, in part, on our ability to obtain and maintain intellectual property rights, both in the United States and other countries, successfully defend this intellectual property against third party challenges and successfully enforce this intellectual property to prevent third party infringement. We rely upon a combination of patents, trade secret protection and confidentiality agreements.

Our ability to protect any of our product candidates and technologies from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents in both the United States and other countries. Patent matters in the biotechnology and pharmaceutical industries can be highly uncertain and involve complex legal and factual questions. Changes in either the patent laws, implementing regulations or in interpretations of patent laws may diminish the value of our patent rights.

There can be no assurance that we will discover or develop patentable products or processes or that patents will issue from any pending patent applications owned or licensed by us or any patent applications we may own or license in the future, or if issued, that the breadth of such patent coverage will be sufficient. We cannot guarantee that claims of issued patents owned or licensed to us, either now or in the future, are or will be held valid or enforceable by the courts or, even if unchallenged, will provide us with exclusivity or commercial value for our product candidates or technology or any significant protection against competitive products or prevent others from designing around our claims. Further, if we encounter delays in regulatory approvals, the period of time during which we could market our product candidates under patent protection could be reduced. Our patent rights also depend on our compliance with technology and patent licenses upon which our patent rights are based and upon the validity of assignments of patent rights from consultants and other inventors that were, or are, not employed by us.

Patent applications are generally maintained in confidence until publication. In the United States, for example, patent applications are maintained in secrecy for up to 18 months after their filing. Similarly, publication of discoveries in scientific or patent literature often lag behind actual discoveries. Consequently, we cannot be certain that we were the first to invent, or the first to file patent applications on our product candidates. There is also no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which could be used by a third party to challenge validity of our patents or prevent a patent from issuing from a pending patent application.

In addition, even if patents do successfully issue, third parties may challenge any patent we own or license through adversarial proceedings in the issuing offices, which could result in the invalidation or unenforceability of some or all of the relevant patent claims. If a third party asserts a substantial new question of patentability against any claim of a United States patent we own or license, the USPTO may grant a request for reexamination, which may result in a loss of scope of some claims or a loss of the entire patent. The adoption of the America Invents Act has established additional opportunities for third parties to invalidate United States patent claims, including *inter partes* review and post-grant review, on the basis of a lower legal standards than reexamination and additional grounds.

We will incur significant ongoing expenses in maintaining our patent portfolio. Should we lack the funds to maintain our patent portfolio or to enforce our rights against infringers, we could be adversely impacted. Even if claims of infringement are without merit, any such action could divert the time and attention of management and impair our ability to access additional capital and/or cost us significant funds to defend.

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

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may manufacture and sell our potential products in those foreign countries where we have not filed for patent protection or where patent protection may be unavailable, not obtainable or ultimately not enforceable. Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets and, further, may be able to export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Our patent portfolio includes patents and patent applications in countries outside of the United States, including Europe, Canada, Japan and Australia. The scope of coverage provided by these patents varies from country to country. Moreover, the laws of some foreign jurisdictions do not provide intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in obtaining such rights in foreign jurisdictions. Outside of the United States, patents we own or license may become subject to patent opposition in the European Patent Office or similar proceedings, which may result in loss of scope of some claims or loss of the entire patent. Participation in adversarial proceedings is very complex, expensive, and may divert our management's attention from our core business and may result in unfavorable outcomes that could adversely affect our ability to prevent third parties from competing with us.

Many companies have also encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, an April 2014 report from the Office of the United States Trade Representative identified a number of countries, including India and China, where challenges to the procurement and enforcement of patent rights have been reported. Several countries, including India and China, have been listed in the report every year since 1989. If we encounter difficulties in protecting our intellectual property rights in foreign jurisdictions, the value of our proprietary technology could be substantially harmed. Proceedings to enforce our patent rights in certain foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

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

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

- Others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- We or our licensors or strategic collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- We or our licensors or strategic collaborators might not have been the first to file patent applications covering certain of our inventions;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- It is possible that our pending patent applications will not lead to issued patents;

- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- We may not develop additional proprietary technologies that are patentable; and
- The patents of others may have an adverse effect on our business.

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

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

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business, our current and pending patent portfolio and future intellectual property strategy. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

Periodic maintenance fees on any issued patent are due to be paid to the U.S. Patent and Trademark Office, or USPTO, the European Patent Office, or EPO, and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Some of our intellectual property is licensed to us by a third party. If we fail to comply with our obligations in the agreement under which we license intellectual property rights from that third party, or otherwise experience disruptions to our business relationships with our licensor, we could lose license rights that are important to our business.

We have a license under certain patents and/or know-how to develop and commercialize certain of our potential product candidates. Our existing license agreements impose, and we expect that any future license agreements will impose on us, various obligations. If we fail to comply with our obligations under these agreements, the licensor may have the right to terminate the license. If any of our licenses are terminated and we are not able to negotiate other agreements for use of the intellectual property protections underlying these product candidates, we would not be able to manufacture and market these potential products, which would adversely affect our business prospects and financial condition.

The patent protection and patent prosecution for some of our potential product candidates is dependent or may be dependent in the future on third parties.

While we normally seek and gain the right to fully prosecute the patents relating to our potential product candidates, there may be times when platform technology patents or product-specific patents that relate to our potential

product candidates are controlled by our licensors. In addition, our licensors and/or licensees may have back-up rights to prosecute patent applications in the event that we do not do so or choose not to do so, and our licensees may have the right to assume patent prosecution rights after certain milestones are reached. If any of our licensing partners fail to appropriately prosecute and maintain patent protection for patents covering any of our potential product candidates, our ability to develop and commercialize those potential product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

We may be subject to litigation alleging that we are infringing the intellectual property rights of third parties or litigation or other adversarial proceedings seeking to invalidate our patents or other proprietary rights, and we may need to resort to litigation to protect or enforce our patents or other proprietary rights, all of which will be costly to defend or pursue and uncertain in its outcome and may prevent or delay any future development and commercialization efforts or otherwise affect our business.

Our success also will depend, in part, on our refraining from infringing patents or otherwise violating intellectual property owned or controlled by others. Numerous patents and pending applications are owned by third parties in the fields in which we are or may develop product candidates, both in the United States and elsewhere. It is difficult for industry participants, including us, to identify all third party patent rights that may be relevant to any of our potential product candidates because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Moreover, because some patent applications are maintained in secrecy until the patents publish, we cannot be certain that third parties have not filed patent applications that cover our potential product candidates and technologies. Pharmaceutical companies, biotechnology companies, universities, research institutions and others may have filed patent applications or have received, or may obtain, issued patents in the United States or elsewhere relating to aspects of our technology, including our potential product candidates, processes for manufacture or methods of use, including combination therapy. It is uncertain whether the issuance of any third party patents will require us to alter our potential product candidates or processes, obtain licenses, or cease certain activities.

If patents issued to third parties contain blocking, dominating or conflicting claims and such claims are ultimately determined to be valid, we may be required to obtain licenses to these patents or to develop or obtain alternative non-infringing technology and cease practicing those activities, including potentially manufacturing or selling any products deemed to infringe those patents. If any licenses are required, there can be no assurance that we will be able to obtain any such licenses on commercially favorable terms, if at all, and if these licenses are not obtained, we might be prevented from pursuing the development and commercialization of certain of our potential product candidates. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. Our failure to obtain a license to any technology that we may require to commercialize our potential product candidates on favorable terms may have a material adverse impact on our business, financial condition and results of operations.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our technologies, including our potential product candidates, processes for manufacture or methods of use, including combination therapy, or other proprietary technologies infringe their intellectual property rights. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our potential product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Parties making successful claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our potential product candidates. We cannot provide any assurances that third party patents do not exist which might be enforced against our products or potential product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

Litigation, which could result in substantial costs to us (even if determined in our favor), may also be necessary to enforce any patents issued or licensed to us. The cost to us in initiating any litigation or other proceeding relating to

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

If we were to initiate legal proceedings against a third party to enforce a patent covering one of our potential product candidates or our technology, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and in most European countries, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our platform technology. Such a loss of patent protection could have a material adverse impact on our business. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without legally infringing our patents or other intellectual property rights.

In addition, if a third party has filed patent applications in the United States prior to March 16, 2013 that claim technology also claimed by us, we may have to participate in interference proceedings in the USPTO to determine priority of invention. Such proceedings can be lengthy, are costly to defend and involve complex questions of law and fact the outcomes of which are difficult to predict. Moreover, we may have to participate in adversarial proceedings in the USPTO or foreign patent offices. An adverse decision relating to our patent rights could require us to cease using such technology, any of which could have a material adverse effect on our business, financial condition and results of operations. If initiated, adversarial proceedings could result in substantial costs to us, even if the eventual outcome is favorable to us.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.

We also rely on trade secrets to protect technology, especially where patent protection is not believed to be appropriate or obtainable or where patents have not issued. We attempt to protect our proprietary technology and processes, in part, with confidentiality agreements and assignment of invention agreements with our employees and confidentiality agreements with our consultants and certain contractors. There can be no assurance that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors. We may fail in certain circumstances to obtain the necessary confidentiality agreements, or their scope or term may not be sufficiently broad to protect our interests.

If our trade secrets or other intellectual property become known to our competitors, it could result in a material adverse effect on our business, financial condition and results of operations. To the extent that we or our consultants or research collaborators use intellectual property owned by others in work for us, disputes may also arise as to the rights to related or resulting know-how and inventions.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.

Many of our current or former employees were previously employed at universities or biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could compromise our ability to commercialize, or prevent us from commercializing, our product candidates, which could severely harm our

business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Relating to Our Business Operations and Industry

Following our recent reduction in force, we will not have resources or the required expertise to develop any of our potential product candidates, which may impair their value.

Because of the specialized scientific nature of our business and the unique properties of our GSNOR inhibitor platform, our ability to develop and commercialize any of our potential product candidates is highly dependent upon our ability to attract and retain qualified scientific and technical personnel, consultants and advisors. Our recent reduction in force resulted in the departure of Mr. Jon Congleton, our CEO, Dr. David Rodman, our CMO, and Dr. Sherif Gabriel, our VP of Research and Discovery. Additionally, the reduction in force resulted in, or soon will result in, the elimination of all of our research and development staff. The loss of their services will significantly delay or prevent any resumption of the research and development of our GSNOR inhibitors should we choose to resume those activities in the future.

Should we need to recruit additional personnel in order to resume research and development activities, we will need to hire additional qualified scientific personnel to perform research and development, as well as personnel with expertise in clinical testing, government regulation, manufacturing, marketing and sales, which may strain our existing managerial, operational, regulatory compliance, financial and other resources. We also rely on consultants and advisors to assist in formulating our research and development strategy and adhering to complex regulatory requirements. We face competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities and other research institutions. There can be no assurance that we will be able to attract and retain such individuals in the future, on acceptable terms, if at all. Additionally, our facilities are located in Colorado, which may make attracting and retaining qualified scientific and technical personnel from outside of Colorado difficult. The failure to attract and retain qualified personnel, consultants and advisors could delay or prevent our ability to commercialize any of our potential product candidates based on our GSNOR inhibitor portfolio, which could have a material adverse effect on our business, financial condition and results of operations.

If our research and development activities resume, we are exposed to potential product liability or similar claims, and insurance against these claims may not be available to us at a reasonable rate in the future or at all.

Drug development involves potential liability risks that are inherent in the testing, manufacturing and marketing of human therapeutic products. Clinical trials involve the testing of product candidates on human subjects or volunteers under a research plan, and carry a risk of liability for personal injury or death to patients due to unforeseen adverse side effects, improper administration of the product candidate, or other factors. Many of these patients are already seriously ill and are therefore particularly vulnerable to further illness or death.

We currently carry clinical trial liability insurance in the amount of $10.0 million in the aggregate, but there can be no assurance that we will be able to maintain such insurance or that the amount of such insurance will be adequate to cover claims. We could be materially and adversely affected if we were required to pay damages or incur defense costs in connection with a claim outside the scope of indemnity or insurance coverage, if the indemnity is not performed or enforced in accordance with its terms, or if our liability exceeds the amount of applicable insurance. In addition, there can be no assurance that insurance will continue to be available on terms acceptable to us, if at all, or that if obtained, the insurance coverage will be sufficient to cover any potential claims or liabilities. Similar risks would exist upon the commercialization or marketing of any products by us or our collaborators.

Regardless of their merit or eventual outcome, product liability claims may result in:

- decreased demand for any products that may eventually be approved;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- costs of litigation;
- distraction of management; and
- substantial monetary awards to plaintiffs.

Should any of these events occur, it could have a material adverse effect on our business and financial condition.

We may become involved in securities class action litigation that could divert management's attention and adversely affect our business and could subject us to significant liabilities.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations as well a broad range of other factors, including the realization of any of the risks described in this "Risk Factors" section of this Annual Report and the consummation of any transaction resulting from our review of various strategic alternatives, may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies generally experience significant stock price volatility. We may become involved in this type of litigation in the future. Litigation typically is expensive and diverts management's attention and resources, which could adversely affect our business. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

Risks Related to Ownership of Our Common Stock

Our stock price is likely to be volatile and an active, liquid and orderly trading market may not develop for our common stock. As a result, stockholders may not be able to resell shares at or above their purchase price.

Prior to our initial public offering, which was completed in June 2015, there was no public market for shares of our common stock. Although our common stock is listed on The NASDAQ Global Market, an active trading market for our common stock may not develop or, if it develops, may not be sustained. The lack of an active market may impair the ability of our stockholders to sell their shares at the time they wish to sell them or at a price that they consider reasonable, which may reduce the fair market value of their shares. Further, an inactive market may also impair our ability to raise capital by selling our common stock should we determine additional funding is required and may impair our ability to enter into strategic transaction.

The market price of our common stock may fluctuate substantially as a result of many factors, some of which are beyond our control. For example, shares of our common stock have traded as high as $20.43 and as low as $2.04 in the eighteen-month period following the effective date of our IPO. These fluctuations could cause an investor to lose all or part of the value of his, her or its investment in our common stock. Factors that could cause fluctuations in the market price of our common stock include the following:

- the announcement of a strategic transaction, including the acquisition or our company or its assets;
- the development status of our potential product candidates;
- the results of preclinical studies and clinical trials;
- results of operations that vary from those of our competitors and the expectations of securities analysts and investors;
- changes in expectations as to our future financial performance, including financial estimates by securities analysts and investors;
- our announcement of significant contracts, acquisitions, or capital commitments;
- announcements by our competitors of competing products or other initiatives;
- announcements by third parties of significant claims or proceedings against us;
- regulatory and reimbursement developments in the United States and abroad;
- lack of an active, liquid or orderly market in our common stock;
- future sales of our common stock or of debt securities;
- additions or departures of key personnel; and

- general domestic and international economic conditions unrelated to our performance.

In addition, the stock market in general has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to operating performance of individual companies. These broad market factors may adversely affect the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A securities class action suit against us could result in significant liabilities and, regardless of the outcome, could result in substantial costs and the diversion of our management's attention and resources.

Our common stock may be delisted from the NASDAQ Global Market if we are unable to maintain compliance with NASDAQ's continued listing standards.

NASDAQ imposes, among other requirements, continued listing standards including minimum bid and public float requirements. The price of our common stock must trade at or above $1.00 to comply with NASDAQ's minimum bid requirement for continued listing on the NASDAQ. If our stock trades at bid prices of less than $1.00 for a period in excess of 30 consecutive business days, the NASDAQ could send a deficiency notice to us for not remaining in compliance with the minimum bid listing standards. Our common stock has never traded below $1.00. However, if the closing bid price of our common stock fails to meet NASDAQ's minimum closing bid price requirement, or if we otherwise fail to meet any other applicable requirements of the NASDAQ and we are unable to regain compliance, NASDAQ may make a determination to delist our common stock. Any delisting of our common stock could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease. Furthermore, if our common stock were delisted it could adversely affect our ability to obtain financing for the continuation of our operations and/or result in the loss of confidence by investors, customers, suppliers and employees.

Our principal stockholders will have a controlling influence over our business affairs and may make business decisions with which stockholders disagree and which may adversely affect the value of their investment.

Our principal stockholders, which consist of entities affiliated with Deerfield Management Company, L.P., Wellington Management Company LLP, the Estate of Arnold H. Snider, III, and BVF Partners L.P., and certain of their affiliates, beneficially own or control, directly or indirectly, approximately 55% of the outstanding shares of our common stock. As a result, if some of these persons or entities act together, they will have the ability to exercise significant influence over matters submitted to our stockholders for approval, including the election and removal of directors, amendments to our certificate of incorporation and bylaws and the approval of any strategic transaction requiring the approval of our stockholders. These actions may be taken even if they are opposed by other stockholders. This concentration of ownership may also have the effect of delaying or preventing a change of control of our company or discouraging others from making tender offers for our shares, which could prevent our stockholders from receiving a premium for their shares. Some of these persons or entities who make up our principal stockholders may have interests different from other stockholders.

Future sales, or the perception of future sales, of a substantial amount of our common shares could depress the trading price of our common stock.

As of February 13, 2017, we have 200,000,000 shares of common stock authorized and 15,656,251 shares of common stock outstanding. Of these shares, the 6,325,000 shares sold during our IPO are freely tradable and, without giving effect to the purchase of shares by entities affiliated with certain of our existing stockholders, approximately 5.6 million shares are freely tradable under Rule 144 under the Securities Act by non-affiliates, and approximately 3.7 million shares are eligible for resale pursuant to Rule 144 under the Securities Act, subject to the volume, manner of sale, holding period and other limitations of Rule 144. In addition, we have registered on a registration statement on Form S-3 that has been declared effective, (i) the 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 that are freely tradable by selling stockholders pursuant to a base prospectus that forms a part. The registration statement also registers the offering, issuance and sale of common stock having up to a maximum aggregate offering price of $20,000,000 that we may issue and sell in an at-the-market offering under a sales agreement we 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. As of December 31, 2016, approximately $19.8 million in shares of common stock remain for sale under the sales agreement.

If we or our stockholders sell substantial amounts of our shares of common stock in the public market or if the market perceives that these sales could occur, the market price of shares of our common stock could decline. These sales may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate, or to use equity as consideration for future acquisitions.

The JOBS Act allows us to postpone the date by which we must comply with certain laws and regulations intended to protect investors and to reduce the amount of information we provide in our reports filed with the SEC. We cannot be certain if this reduced disclosure will make our common stock less attractive to investors.

The JOBS Act is intended to reduce the regulatory burden on "emerging growth companies." As defined in the JOBS Act, we qualify as an "emerging growth company" and could remain an "emerging growth company" until as late as December 31, 2020. For so long as we are an "emerging growth company," we will, among other things:

- not be required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley;
- not be required to hold a nonbinding advisory stockholder vote on executive compensation pursuant to Section 14A(a) of the Exchange Act;
- not be required to seek stockholder approval of any golden parachute payments not previously approved pursuant to Section 14A(b) of the Exchange Act;
- be exempt from any rule adopted by the Public Company Accounting Oversight Board, requiring mandatory audit firm rotation or a supplemental auditor discussion and analysis; and
- be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We have irrevocably elected not to avail ourselves of an extended transition period under the JOBS Act that permits an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. As a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other companies.

Furthermore, if we take advantage of some or all of the reduced disclosure requirements above, investors may find our common stock less attractive, which may result in a less active trading market for our common stock and greater stock price volatility.

We first became subject to rules and regulations established by the SEC and the Public Company Accounting Oversight Board, or PCAOB, regarding our internal control over financial reporting in the fiscal year ended December 31, 2016. If our internal controls are not determined to be effective, it may adversely affect investor confidence in our company and, as a result, the market price of our common stock and a stockholder's investment in our stock.

As a public reporting company, we are subject to the rules and regulations established from time to time by the SEC and the PCAOB. These rules and regulations require, among other things, that we establish and periodically evaluate procedures with respect to our internal controls over financial reporting. Reporting obligations as a public company place a considerable strain on our financial and management systems, processes and controls, as well as on our personnel, particularly following our reduction in force, which will result in approximately five employees remaining with the company after March 31, 2017.

In addition, as a public company we are required to document and test our internal control over financial reporting pursuant to Section 404 of Sarbanes-Oxley so that our management can certify as to the effectiveness of our internal control over financial reporting. Maintaining and monitoring these internal controls may be more difficult with fewer resources available to perform the necessary documentation and testing, and our internal controls may be found to be deficient. Likewise, our independent registered public accounting firm will be required to provide an attestation report on the effectiveness of our internal control over financial reporting at such time as we cease to be an "emerging growth company," as defined in the JOBS Act, although, as described in the preceding risk factor, we could potentially qualify as an "emerging growth company" until December 31, 2020. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating.

If our senior management is unable to conclude that we have effective internal control over financial reporting, or to certify the effectiveness of such controls, or if our independent registered public accounting firm cannot render an unqualified opinion on management's assessment and the effectiveness of our internal control over financial reporting, or if material weaknesses in our internal controls are identified, we could be subject to regulatory scrutiny and a loss of public confidence, which could have a material adverse effect on our business and our stock price. In addition, if we do not maintain adequate financial and management personnel, processes and controls, we may not be able to manage our business effectively or accurately report our financial performance on a timely basis, which could cause a decline in our common stock price and adversely affect our results of operations and financial condition.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Our disclosure controls and procedures are designed to reasonably ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures as well as internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are and will be met. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We expect to continue to incur significant costs as a result of operating as a public company, and our remaining management team will be required to devote substantial time to compliance efforts.

We will continue to incur significant legal, accounting, insurance and other expenses as a result of being a public company. The Dodd-Frank Act and Sarbanes-Oxley as well as related rules implemented by the SEC and The NASDAQ Global Market, have imposed corporate governance requirements on public companies. In addition, rules that the SEC is implementing or is required to implement pursuant to the Dodd-Frank Act are expected to require additional changes. We expect that compliance with these and other similar laws, rules and regulations, including compliance with Section 404 of Sarbanes-Oxley, will substantially increase our expenses, including our legal and accounting costs, and make some activities more time-consuming and costly. Although the JOBS Act may for a limited period of time somewhat lessen the cost of complying with these additional regulatory and other requirements, we nonetheless expect to incur significant legal, accounting, insurance and certain other expenses in the future, which will negatively impact our business, results of operations and financial condition.

Anti-takeover provisions in our charter documents could discourage, delay or prevent a change in control of our company and may affect the trading price of our common stock.

Our corporate documents and the Delaware General Corporation Law, or DGCL, contain provisions that may enable our Board of Directors to resist a change in control of our company even if a change in control were to be considered favorable by our stockholders. These provisions:

- stagger the terms of our Board of Directors and require 66 2/3% stockholder voting to remove directors, who may only be removed for cause;
- authorize our Board of Directors to issue "blank check" preferred stock and to determine the rights and preferences of those shares, which may be senior to our common stock, without prior stockholder approval;
- establish advance notice requirements for nominating directors and proposing matters to be voted on by stockholders at stockholders meetings;
- prohibit our stockholders from calling a special meeting and prohibit stockholders from acting by written consent;
- require 66 2/3% stockholder voting to effect certain amendments to our certificate of incorporation and bylaws; and
- prohibit cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates.

These provisions could discourage, delay or prevent a transaction involving a change in control of our company. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors of their choosing and cause us to take other corporate actions our stockholders desire.

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

Our amended and restated certificate of incorporation provides that we will indemnify our directors to the fullest extent permitted by Delaware law.

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

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

- We may, in our discretion, indemnify other employees and agents in those circumstances where indemnification is permitted by applicable law.

- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

- We will not be obligated pursuant to our amended and restated bylaws to indemnify any director or officer in connection with any proceeding (or part thereof) initiated by such person unless the proceeding was authorized in the specific case by our Board of Directors or such indemnification is required to be made pursuant to our amended and restated bylaws.

- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to our directors or officers.

As a result, if we are required to indemnify one or more of our directors or officers, it may reduce our available funds to satisfy successful third party claims against us, may reduce the amount of our available cash and may have a material adverse effect on our business and financial condition.

Our amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, any action asserting a claim arising pursuant to any provision of the DGCL our amended and restated certificate of incorporation or our amended and restated bylaws or any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein and the claim not being one which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery or for which the Court of Chancery does not have subject matter jurisdiction. Any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to this provision of our amended and restated certificate of incorporation. This choice of forum provision may limit our stockholders' ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and our directors, officers, employees and agents even though an action, if

successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find this provision of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition or results of operations.

We do not expect to pay any dividends on our common stock for the foreseeable future.

We currently expect to retain all future earnings, if any, for future operations and expansion, and have no current plans to pay any cash dividends to holders of our common stock for the foreseeable future. Any decision to declare and pay dividends in the future will be made at the discretion of our Board of Directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our Board of Directors may deem relevant. As a result, stockholders may not receive any return on an investment in our common stock unless stockholders sell our common stock for a price greater than that which they paid for it.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our corporate headquarters are located in Boulder, Colorado, where we lease approximately 15,000 square feet of office and laboratory space pursuant to a lease that expires in March 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. In order to preserve our cash resources as a result of our shift in strategic focus to identify and evaluate strategic alternatives, we have notified the landlord that we are exercising our right to terminate this lease effective April 30, 2017 and have paid the required termination fee.

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II.

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Holders

As of June 17, 2015, our common stock began trading on the NASDAQ Global Market under the symbol "NVLS." The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported on the NASDAQ Global Market:

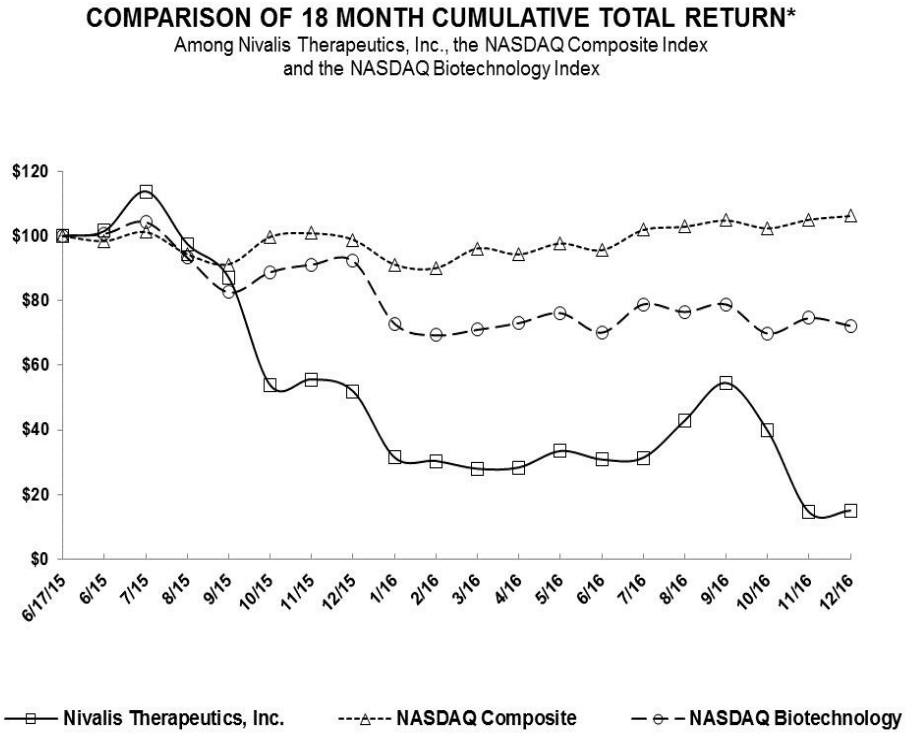
	HIGH	LOW
Year Ended December 31, 2016		
First Quarter	$ 7.68	$ 3.68
Second Quarter	$ 5.25	$ 3.79
Third Quarter	$ 9.35	$ 4.21
Fourth Quarter	$ 8.11	$ 2.00
Year Ended December 31, 2015		
Second Quarter	$ 17.84	$ 14.07
Third Quarter	$ 20.43	$ 12.11
Fourth Quarter	$ 13.62	$ 7.05

Stockholders

As of January 31, 2017, we have approximately 24 stockholders of record of our common stock, which excludes stockholders whose shares were held in nominee or street name by brokers.

Performance Graph (1)

The following graph illustrates a quarterly comparison of the total cumulative stockholder return for our common stock since June 17, 2015, which is the date our common stock began trading on the NASDAQ Global Market, to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes an initial investment of $100 on June 17, 2015 in our common stock, or in the stocks comprising the NASDAQ Composite Index, and the stocks comprising the NASDAQ Biotechnology Index. Historical stockholder return is not necessarily indicative of the performance to be expected for any future periods.



(1) This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that Section, and shall not be deemed incorporated by reference into any filing of Nivalis Therapeutics, Inc. under the Securities Act of 1933, as amended.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

Information relating to our equity compensation plans as of December 31, 2016, under which equity securities were authorized for issuance, is included in Item 12 of Part III of this Annual Report.

Unregistered Sales of Equity Securities

Not applicable.

Use of Proceeds from Initial Public Offering

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 December 31, 2016, we had used $17.8 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.

Issuer Purchases of Equity Securities

Not applicable.

ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth certain of our selected historical financial data at the dates and for the periods indicated. The selected historical statement of operations data presented below for the years ended December 31, 2016, 2015, and 2014 and the historical balance sheet data as of December 31, 2016 and 2015 have been derived from our audited financial statements, which are included elsewhere in this Annual Report on Form 10-K. The historical statement of operations data presented below for the year ended December 31, 2013 and 2012 and the historical balance sheet data as of December 31, 2014, 2013 and 2012 have been derived from our audited financial statements that do not appear in this report.

Our historical results are not necessarily indicative of results expected in any future period.

The selected historical financial data presented below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes thereto, which are included elsewhere in this Annual Report on Form 10-K. The selected historical financial information in this section is not intended to replace our financial statements and the related notes thereto.

Statement of Operations Data:

	Years Ended December 31,				
	2016	2015 (1)	2014	2013	2012
	(in thousands, except per share data)				
Revenue	$ —	$ —	$ —	$ —	$ —
Operating expenses:					
Research and development	23,316	16,054	12,200	13,136	7,100
General and administrative	8,586	6,844	2,287	2,141	1,930
Loss from operations	(31,902)	(22,898)	(14,487)	(15,277)	(9,030)
Interest and other income, net	439	80	296	10	151
Interest expense	—	—	(845)	(931)	(694)
Net loss	(31,463)	(22,818)	(15,036)	(16,198)	(9,573)
Gain on extinguishment of convertible debt as a capital transaction	—	—	378	—	—
Net loss attributable to common shareholders	$ (31,463)	$ (22,818)	$ (14,658)	$ (16,198)	$ (9,573)
Weighted average shares outstanding—basic and diluted	15,492	9,371	723	155	137
Net loss per share attributable to common stockholders—basic and diluted	$ (2.03)	$ (2.43)	$ (20.27)	$ (104.50)	$ (69.88)

Balance Sheet Data:

	As of December 31,				
	2016	2015 (1)	2014	2013	2012
	(in thousands)				
Cash, cash equivalents and marketable securities	$ 61,035	$ 87,254	$ 27,812	$ 1,098	$ 4,705
Restricted cash	–	–	–	2,500	2,500
Working capital	55,164	83,267	26,027	(2,209)	5,050
Total assets	61,935	87,909	28,543	4,134	8,012
Total liabilities	6,499	4,419	2,415	17,629	5,406
Convertible preferred stock	–	–	41,880	77,793	77,793
Accumulated deficit	(180,300)	(148,837)	(126,019)	(110,983)	(94,785)
Total stockholders' equity (deficit)	55,436	83,490	(15,752)	(91,288)	(75,188)

(1) In June 2015, we completed an initial public offering of our common stock with the sale and issuance of 6,325,000 shares of common stock at a price to the public of $14.00 per share.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing at the end of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and expected financial results, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

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. Our GSNOR inhibitors selectively target an enzyme known as S-nitrosoglutathione reductase, which we refer to as GSNOR. 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. Our lead product candidate, cavosonstat (N91115), is a small molecule inhibitor of GSNOR being evaluated in patients with CF. However, in light of recent results from a clinical trial of cavosonstat in CF patients, we determined to discontinue the development of this compound in CF and we have shifted our strategic emphasis to focus on identifying and evaluating strategic alternatives not related to GSNOR inhibition or specific to CF. 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.

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. This clinical trial was conducted in 138 adult CF patients with two copies of the F508del-CFTR mutation who were being treated with lumacaftor/ivacaftor or Orkambi and was designed to assess the efficacy and safety of cavosonstat in a triple therapy with lumacaftor/ivacaftor, or Orkambi. We are also evaluating the efficacy and safety of cavosonstat in a separate Phase 2 trial of 19 adult CF patients with one copy of the F508del-CFTR mutation and a second gating mutation who are being treated with ivacaftor or Kalydeco. Enrollment in this trial was completed in November 2016 and results are expected in the first quarter of 2017. After completion of this trial, we do not expect to expend material resources on the development of cavosonstat or any other drug candidates in our portfolio.

Following the failure of the Phase 2 clinical trial in CF patients with two copies of the F508del mutation in November 2016, 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. As part of this process, we engaged a financial and strategic advisor, Ladenburg Thalmann & Co., Inc., to advise us on strategic alternatives in January 2017. Our board of directors also approved a reduction in force that is taking place between January 15 and March 31, 2017 that will affect 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. We expect to have approximately five employees after completion of the reduction in force on March 31, 2017. As described above, we continue to conduct limited activities related to completion of our in-process clinical trials. All other research and development activities have ceased.

We expect to devote substantial time and resources to exploring strategic alternatives that our board of directors believes will maximize stockholder value. Our consideration of strategic alternatives includes, but is not limited to, the potential for an acquisition, merger, business combination, licensing and/or other strategic transaction involving the company. Despite devoting significant efforts to identify and evaluate potential strategic transactions, we may not be successful in completing a transaction. Further, even if a strategic transaction is completed, it ultimately may not deliver the anticipated benefits or enhance stockholder value.

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 GSNOR may have the potential to achieve positive medical effects by modulating its activity in the body. 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 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 compensations 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.

	Year Ended December 31,		
	2016	2015	2014
Direct program expenses:			
Cavosonstat for cystic fibrosis	$ 13,498	$ 9,254	$ 4,248
N6022 for cystic fibrosis	—	—	1,622
Total direct program expenses	13,498	9,254	5,870
Personnel and other expenses			
Salaries, benefits and stock-based compensation	6,834	4,931	4,973
Consulting and outsourced services	1,026	352	418
Facilities and depreciation	340	266	284
Other expenses	1,618	1,251	655
Total research and development expenses	$ 23,316	$ 16,054	$ 12,200

All of our research and development expenses for the years ended December 31, 2016, 2015 and 2014 relate to the development of cavosonstat and, to a lesser extent, N6022. We have expended an aggregate of approximately $30.2 million for direct program expenses related to cavosonstat from inception through December 31, 2016. 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 reduction in force that occurred in 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. Partially offsetting these decreases are expected increases from recognition of stock-based compensation expense related to accelerated vesting of stock options and payment of severance benefits that were provided to all affected employees as part of the January 2017 restructuring program. We have not incurred, nor do we expect to incur, significant cancellation charges with our vendors as a result of winding down 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 increase during the first quarter of 2017 compared with prior periods due to recognition of stock-based compensation expense related to accelerated vesting of stock options and payment of severance benefits that were provided to all affected employees as part of the January 2017 restructuring program. We expect that general and administrative expense will also increase during the first quarter of 2017 as compared to prior periods due to the re-allocation of property and liability insurance expenses as well as facilities and information technology overhead costs that would otherwise be allocated to research and development expense. We further expect to incur additional general and administrative expenses in connection with pursuing and completing a potential strategic transaction of the company. We expect these increases will be partially offset by lower personnel-related costs due to the restructuring activities.

Interest and Other Income, Net

Interest and other income, net for the years ended December 31, 2016 and 2015 consists of interest earned on marketable securities and money market funds. For the year ended December 31, 2014, interest and other income, net consists of the gain on the change in the fair value of preferred stock warrant liabilities. On September 23, 2014, all outstanding shares of preferred stock converted into shares of common stock in connection with a recapitalization of the company; when this conversion occurred, warrants exercisable for shares of our preferred stock automatically adjusted to

become exercisable for shares of common stock, and therefore changes in the fair value of preferred stock warrant liabilities no longer impacted interest and other income, net.

Interest Expense

We had no interest expense for the years ended December 31, 2016 and 2015. Interest expense for the year ended December 31, 2014, consists primarily of interest accrued on our previously outstanding convertible debt and interest paid on our previously outstanding Loan and Security Agreement with Horizon Technology Finance dated February 18, 2011, or the Horizon Loan. We repaid all outstanding principal and interest under the Horizon Loan in full in July 2014 and all principal and accrued interest under our convertible debt converted into equity in September 2014. Also included in interest expense is the amortization of the discount on the Horizon Loan and convertible debt during 2014.

Results of Operations

Comparison of the Years Ended December 31, 2016, 2015 and 2014.

Research and Development Expenses. Research and development expenses for the years ended December 31, 2016, 2015 and 2014 were as follows:

	Year Ended December 31,		
	2016	2015	2014
	(in thousands)		
Research and development expenses	$ 23,316	$ 16,054	$ 12,200
Increase (decrease) from prior period	$ 7,262	$ 3,854	—
% change from prior period	45.2 %	31.6 %	—

Fiscal 2016 as compared to Fiscal 2015 – The increase in research and development expenses for the year ended December 31, 2016 compared to prior year was primarily due to $5.7 million of cavosonstat clinical trial expenses for the Phase 2 trial in patients with CF that was initiated in November 2015 and reached 100% patient enrollment as planned in early July 2016. A second Phase 2 trial in patients with CF initiated in March 2016 added $1.7 million of clinical trial expenses for the year, while $1.2 million was expended on a Phase 1 Multiple Ascending Dose trial initiated and completed in the fourth quarter of 2016. By comparison, during the prior year, we incurred $3.5 million of clinical trial expenses for our Phase 1b trial that was completed in September 2015. Personnel and other expenses increased by $3 million during the year ended December 31, 2016 compared to the same period of the prior year. These increases were primarily the result of increased staff and related salaries, benefits and stock-based compensation expense.

Fiscal 2015 as compared to Fiscal 2014 – The increase in research and development expenses for the year ended December 31, 2015 compared to prior year was primarily due to an increase in direct program expenses of $3.4 million and increased personnel and other expenses of $470,000, combined. The increase in direct program expenses for cavosonstat was largely driven by clinical trial expenses increasing by $3.0 million during the comparable periods due to the Phase 1b trial that was initiated during the first quarter of fiscal 2015 and completed in September 2015, the Phase 1a drug-drug interaction trial completed during the third quarter of fiscal 2015 and the Phase 2 triple therapy trial that was initiated during the fourth quarter of fiscal 2015. During fiscal 2014, two smaller Phase 1 safety trials were in process and completed by the end of that year. The remaining increase in direct program expenses for fiscal 2015 for cavosonstat of approximately $2.0 million was attributed to the production of cavosonstat for clinical trials and initiation of long-term toxicology studies. Partially offsetting these increases were decreased clinical trial expenses for N6022 of $1.6 million during the comparable periods as the Phase 1b trial of N6022 in people with CF was completed in April 2014. The combined increase in personnel and other expenses during fiscal 2015 compared to the prior year was primarily attributable to increased travel to support the clinical trials and overall increases in insurance.

General and Administrative Expenses. General and administrative expenses for the years ended December 31, 2016, 2015 and 2014 were as follows:

	Year Ended December 31,		
	2016	2015	2014
	(in thousands)		
General and administrative expenses	$ 8,586	$ 6,844	$ 2,287
Increase from prior period	$ 1,742	$ 4,557	—
% change from prior period	25.5 %	199.3 %	—

Fiscal 2016 as compared to Fiscal 2015 – The increase in general and administrative expenses for the year ended December 31, 2016 compared to the prior year was partially due to increased expenses related to patent and marketing expenses as well as operating on a full-year basis as a publicly-traded company, including increased investor relations expenses. These expense categories on a combined basis increased by $564,000 during the year ended December 31, 2016, compared with the prior year. Additionally, stock-based compensation expense increased by $1.0 million during the year ended December 31, 2016, compared with the prior year, primarily due to stock options granted in September 2015 and September 2016.

Fiscal 2015 as compared to Fiscal 2014 – The increase in general and administrative expenses for the year ended December 31, 2015 compared to the prior year was primarily due to increased expenses related to becoming and operating as a publicly-traded company, including increased salary expense, employee benefits and stock-based compensation expense tied to a revised employee incentive plan and the hiring of a new CEO and CFO during the early part of 2015. Additionally, audit fees, legal support costs, patent expenses, travel costs and various marketing and investor relations expenses increased by approximately $2.5 million during fiscal 2015, compared to the prior year.

Interest and Other Income, Net.

Fiscal 2016 as compared to Fiscal 2015 – The increase in interest income during 2016 over the prior year period 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.

Fiscal 2015 as compared to Fiscal 2014 – The decrease in interest and other income, net for the year ended December 31, 2015 compared to the prior year was primarily due to approximately $266,000 recorded as a gain during fiscal 2014 due to the change in the fair value of preferred stock warrant liabilities that were adjusted to fair market value. These preferred stock warrant liabilities were reclassified as a component of equity during September 2014. Therefore, no similar mark-to-market adjustment was recorded during 2015. During fiscal 2015, approximately $80,000 was earned as interest on marketable securities.

Interest Expense.

There was no interest expense for the year ended December 31, 2016 or 2015 due to full repayment of the Horizon Loan in July 2014 and conversion of the convertible debt in September 2014 compared to the prior year in which interest was paid on the outstanding Horizon Loan and interest accrued on the convertible debt outstanding.

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 December 31, 2016, we had cash, cash equivalents and marketable securities of $61.0 million and no debt.

The following table sets forth the primary sources and uses of cash for years ended December 31, 2016, 2015 and 2014:

	Year Ended December 31,		
	2016	2015	2014
	(in thousands)		
Net cash used in operating activities	$ (26,259)	$ (19,207)	$ (14,448)
Net cash provided by (used in) investing activities	25,305	(62,448)	(4)
Net cash provided by financing activities	166	78,834	41,166
Net increase (decrease) in cash and cash equivalents	$ (788)	$ (2,821)	$ 26,714

Operating Activities

Fiscal 2016 as compared to Fiscal 2015 – During the year ended December 31, 2016, our net loss of $31.5 million included noncash charges of $3.4 million, primarily associated with stock-based compensation. During this same period, our net operating liabilities, excluding cash, cash equivalents and marketable securities, increased by $1.8 million from the prior year period, and thus decreased our net cash used in operating activities to $26.3 million. The increase in net operating liabilities is primarily related to higher accrued direct program expenses, accounts payable, and accrued employee benefits of $2.2 million, slightly offset by decreases in accrued other liabilities of $142,000 and increases in prepaid expenses of $282,000. Increases in accrued direct program expenses and accounts payable were directly related to research and development costs for our two Phase 2 clinical trials and a Phase 1 multiple ascending dose trial that were completed or near completion at the end of 2016. Prepaid expenses increased due to the timing of various direct program expense prepayments.

Fiscal 2015 as compared to Fiscal 2014 – During the year ended December 31, 2015, our net loss of $22.8 million included noncash charges of $1.4 million, primarily associated with stock based compensation. During this same period, our net operating liabilities, excluding cash, cash equivalents and marketable securities, increased by approximately $2.2 million and thus decreased our net cash used in operating activities to $19.2 million. Net operating liabilities increased primarily because of higher accrued employee benefits of $1.5 million, increases in accounts payable and accrued direct program expenses of $376,000, increases in other liabilities of $163,000 and decreases in prepaid expenses of $198,000. Accrued employee benefit costs increased due to implementation of 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 that completed in September 2015 along with the initiation of the Phase 2 clinical trial during the fourth quarter of 2015.

During fiscal 2014, our net loss of $15.0 million included noncash charges of $570,000. During the same period, our net operating liabilities, excluding cash, cash equivalents and marketable securities, increased by $18,000, largely the result of increased accounts payable and accrued direct program expenses that were offset by decreased employee benefits and increased prepaid expenses.

Investing Activities

Fiscal 2016 as compared to Fiscal 2015 – The net cash provided by investing activities of $25.3 million for the year ended December 31, 2016 was primarily related to proceeds from maturities and sales of marketable securities outweighing our purchases of replacement securities during the period.

Fiscal 2015 as compared to Fiscal 2014 – The net cash used in investing activities of $62.4 million for the year ended December 31, 2015 was primarily related to the net purchase of marketable securities.

Financing Activities

Fiscal 2016 as compared to Fiscal 2015 – The cash provided by financing activities for the year ended December 31, 2016 was primarily related to the exercise of stock options and shares issued under the employee stock purchase plan.

Fiscal 2015 as compared to Fiscal 2014 – The cash provided by financing activities for the year ended December 31, 2015 resulted from $78.8 million of net proceeds for the sale of common stock in our IPO that closed during June 2015. The cash provided by financing activities for the year ended December 31, 2014 was primarily driven by the receipt of $29.9 million in net proceeds from the sale of convertible preferred stock, receipt of $11.9 million in net proceeds from the issuance of convertible debt and $2.5 million from the release of restricted cash associated with the full repayment of the Horizon Loan. These sources of cash were partially offset by the full repayment of $3.1 million outstanding on the Horizon Loan.

Funding Requirements

Based on our current operating plan, and expectations regarding significantly lower operating expenses following the discontinuation of a substantial portion of our research and development activities and the subsequent restructurings in the first quarter of 2017, we expect our $61.0 million in cash and cash equivalents as of December 31, 2016 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 a strategic transaction for the company;
- the timing, complexity and costs required for completion of any transaction that may result from our ongoing 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 Item 1A. – “Risk Factors” set forth elsewhere in the Annual Report on Form 10-K.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. 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 described in more detail below. 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.

We believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Direct Program Expenses

Substantial portions of our preclinical studies and clinical trials are performed by third parties, such as CROs, laboratories, medical centers and other vendors. As part of the process of preparing our financial statements, we are required to estimate our accrued direct program expenses. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our direct program expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us. Examples of direct program expenses include:

- fees owed to contract research organizations in connection with preclinical and toxicology studies and clinical trials;
- fees owed to investigative sites in connection with clinical trials;
- fees owed to contract manufacturers in connection with the production of drug supply materials; and
- other fees owed in relation to direct programs.

We have not had any material adjustments to estimated amounts recorded in previous periods. At December 31, 2016 and 2015, we had accrued direct program expenses of $2.6 million and $1.6 million, respectively.

Income Taxes

We are subject to corporate taxes in the United States. Significant judgment is required in determining the use of net operating loss carryforwards for corporate tax purposes. There are many transactions and calculations for which the ultimate tax determination is uncertain. Where the final tax outcome of these matters is different from the amounts that were initially recorded, such differences will impact the current and deferred corporate tax assets and liabilities in the period in which such determination is made.

We have not recognized any taxes or income since the conversion of our company to a Delaware corporation in 2012. As of December 31, 2016, the total amount of federal and state tax losses carried forward was approximately $75.7 million and $83.0 million, respectively. The utilization of these tax loss carryforwards may be subject to limitations as described further in the section titled “Tax Loss Carryforwards” below in this Management’s Discussion and Analysis of Financial Condition and Results of Operations.

We have a history of tax losses, and therefore recognize deferred tax assets arising from unused tax losses or tax credits only to the extent that we have sufficient taxable temporary differences or there is convincing other evidence that sufficient taxable profit will be available against which the unused tax losses or unused tax credits can be utilized. We believe that other sufficient evidence is not currently available and therefore we have recorded a full valuation allowance against our net deferred tax assets.

Stock-Based Compensation

Determining the amount of stock-based compensation to be recorded in connection with the issuance of stock options requires us to develop estimates of the fair value of the stock options as of their grant date. Compensation expense is recognized over the vesting period of the award. Calculating the fair value of stock-based awards requires that we make highly subjective assumptions. We use the Black-Scholes option pricing model to value our stock option awards.

The fair value of stock options for the years ended December 31, 2016 and 2015 was estimated at the grant date using the following weighted average assumptions for the respective periods:

	2016	2015
Estimated dividend yield	–	–
Weighted-average expected stock price volatility	79.1 %	75.7 %
Weighted-average risk-free interest rate	1.5 %	1.8 %
Weighted-average expected life of option (in years)	6.20	6.22
Weighted-average fair value per option	$ 5.09	$ 5.09

There were no stock options granted during the year ended December 31, 2014

Expected dividend yield. The expected dividend yield for all of our stock option grants is 0%, as we have not declared a cash dividend since inception, and do not expect to do so in the foreseeable future.

Expected stock price volatility. The expected volatility was estimated using peer data of companies in the biopharmaceutical industry with similar equity plans.

Risk free interest rate. We use the average yield on current U.S. Treasury instruments with terms that approximate the expected term of the stock options being valued.

Expected life of option in years. The expected term of a stock option is the period of time for which the option is expected to be outstanding. We used a simplified method of determining expected term by selecting the midpoint between the average vesting date and the contractual terms, which is in accordance with the simplified method.

Forfeitures. The stock-based compensation expense recognized has been reduced for estimated forfeitures. The estimated forfeiture rate is based on historical experience of our option plan, which we expect to continue at the current level, and any adjustments in the forfeiture rate in the future will result in a cumulative adjustment in the period that this estimate is changed. Ultimately, the total compensation expense recognized for any given stock based award over its vesting period will only be for those shares that actually vest.

We recognized stock-based compensation expense of approximately $3.3 million, $1.3 million and $70,000 for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had $10.0 million in total unrecognized stock-based compensation expense, net of related forfeiture estimates. During the first quarter of 2017, we expect to record approximately $2.3 million of stock-based compensation expense due to the accelerated vesting of options and RSUs offered to employees affected by the restructuring plan and workforce reduction announced on January 12, 2017.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2016:

	Payments due by period (in thousands)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Purchase obligations	$ 1,678	$ 1,678	$ 0	$ —	$ —
Operating leases	375	295	80	—	—
Total obligations	$ 2,053	$ 1,973	$ 80	$ —	$ —

We have entered into contracts with third parties to provide future services, which include research and development, clinical development support and testing services. 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.

On February 9, 2017, we notified the landlord under our facility lease that we are electing to exercise our right to terminate the lease, effective April 30, 2017, and we paid the required $25,000 termination fee to the landlord. As a result, approximately $241,000 of future operating lease obligations listed in the above table will not be paid.

Related Party Transactions

At various points during fiscal year 2014, we issued an aggregate of $12.0 million of convertible debt to certain existing investors. Interest accrued on these loans until the loans and all accrued interest were converted in full on September 23, 2014 to Series 1 convertible preferred stock.

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.

Tax Loss Carryforwards

As of December 31, 2016, we had federal and state income loss carryforwards, research and development credits and orphan drug credits of $75.7 million, $83.0 million, $2.0 million and $7.3 million, respectively that begin to expire in 2032 for both federal and state purposes. The utilization of the federal net operating loss carryforwards and credits may be subject to limitations under the rules regarding a change in stock ownership as determined by the Internal Revenue Code and state laws. Section 382 of the Internal Revenue Code of 1986, as amended, imposes annual limitations on the utilization of net operating loss, or NOL, carryforwards, other tax carryforwards, tax credits, and certain built-in losses upon an ownership change as defined by that section. In general terms, an ownership change may result from transactions that increase the aggregate ownership of certain stockholders in Nivalis stock by more than 50 percentage points over a three year testing period, or a Section 382 Ownership Change. If Nivalis has undergone a Section 382 Ownership Change, an annual limitation would be imposed on certain tax attributes of Nivalis, including NOL and capital loss carryforwards, and certain other losses and credits. Such a Section 382 Ownership Change may occur as a result of the completion of a transaction that may result from our review of strategic alternatives. As of December 31, 2016, we have not performed a formal study to determine whether there are Section 382 limitations that apply and such limitations could be significant.

JOBS Act

We qualify as an “emerging growth company” pursuant to the provisions of the JOBS Act. For as long as we are an “emerging growth company,” we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies,” including, but not limited to,

not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, reduced disclosure obligations relating to the presentation of financial statements in Management's Discussion and Analysis of Financial Condition and Results of Operations, exemptions from the requirements of holding advisory "say-on-pay" votes on executive compensation and stockholder advisory votes on golden parachute compensation. We have availed ourselves of the reduced reporting obligations and executive compensation disclosure in this Annual Report on Form 10-K, and expect to continue to avail ourselves of the reduced reporting obligations available to emerging growth companies in future filings.

In addition, an emerging growth company can delay its adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we have chosen 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. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

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 audited financial statements included elsewhere in this Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of December 31, 2016, we had cash, cash equivalents and marketable securities of $61.0 million, consisting of deposits with commercial banks in checking, interest-bearing and demand money market accounts, 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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this Item are included in Item 15 of this report and presented beginning on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. 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 Annual Report on Form 10-K, 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 December 31, 2016.

Management's Assessment of Internal Control over Financial Reporting

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we have included a report on management's assessment of the design and effectiveness of our internal control over financial reporting as part of this Annual Report on Form 10-K for the year ended December 31, 2016. Management's report is included under the caption entitled "Management's Report on Internal Control Over Financial Reporting" in the section called "Item 15. Exhibits and Financial Statement Schedules" of this Annual Report on Form 10-K and are incorporated herein by reference.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B.OTHER INFORMATION

We lease approximately 15,000 square feet of office and laboratory space in Boulder, Colorado pursuant to a Lease dated March 11, 2010, as subsequently amended, with Aweida Properties, Inc., which expires in March 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. On February 9, 2017, we notified the landlord under the Lease that we are electing to exercise our right to terminate the Lease. The decision to terminate the Lease was a result of our strategic shift to focus on identifying and evaluating various strategic alternatives and preserving our cash resources. The termination will be effective April 30, 2017, and we have paid the required $25,000 termination fee to Aweida Properties, Inc.

PART III

As permitted by General Instruction G(3) of Form 10-K, certain information required by Part III is omitted from this Annual Report on Form 10-K and is incorporated herein by reference from our definitive proxy statement relating to our 2017 annual meeting of stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, also referred to in this Form 10-K as our 2016 Proxy Statement, which we expect to file with the SEC no later than April 30, 2017.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item regarding our directors, executive officers and corporate governance matters, including the audit committee and audit committee financial experts and compliance with Section 16(a) of the Exchange Act will be included in our 2016 Proxy Statement and is incorporated herein by reference.

We have adopted a Code of Business Ethics for all of our directors, officers and employees as required by NASDAQ governance rules and as defined by applicable SEC rules. Stockholders may locate a copy of our Code of Business Ethics on our website at www.nivalis.com, or request a copy without charge from:

Nivalis Therapeutics, Inc.
Attention: Investor Relations
3122 Sterling Circle, Suite 200
Boulder, CO 80301

We will post to our website any amendments to the Code of Business Ethics and any waivers that are required to be disclosed by the rules of either the SEC or NASDAQ.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item regarding executive compensation will be included in our 2016 Proxy Statement and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item regarding security ownership of certain beneficial owners and management will be included in the 2016 Proxy Statement and is incorporated herein by reference.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2016, about the shares of common stock that may be issued upon the exercise of options under our existing equity compensation plans, which include the N30 Pharmaceuticals, Inc. 2012 Stock Incentive Plan (the "2012 Plan"), the Nivalis Therapeutics, Inc. 2015 Equity Incentive Plan (the "2015 Plan") and shares that may be issued under the Nivalis Therapeutics, Inc. Employee Stock Purchase Plan (the "ESPP"). The table also provides information about the issuance of 216,667 restricted stock units ("RSUs") and stock options to purchase 108,333 shares of the Company's common stock ("Inducement Options") to Dr. David Rodman, our former Chief Medical Officer, as inducement grants made in accordance with NASDAQ Listing Rule 5635(c)(4) in April 2016 that were not approved by our stockholders.

	Number of securities to be issued upon exercise of outstanding options and rights	Weighted-average exercise price of outstanding options and rights	Number of securities remaining available for issuance under equity compensation plans excluding securities reflected in column (a)
Equity Compensation Plans Approved by Shareholders:	(a)	(b)	(c)
2012 Plan and 2015 Plan (1)	2,734,630	$ 7.50	391,927
ESPP	—	—	180,845
Equity Compensation Plans Not Approved by Shareholders:			
Inducement Option Grants	108,333	$ 4.68	—
Inducement RSU Grants	180,556	—	—
Total	3,023,519		572,772

(1) The 2015 Plan provides that an additional number of shares will automatically be added to the shares authorized for issuance under the 2015 Plan on January 1 of each calendar year, from January 1, 2016 through January 1, 2025. The shares available for issuance under the 2015 Plan are increased automatically each year by an amount equal to (a) 5% of the total number of shares of Common Stock issued and outstanding on December 31 of the preceding calendar year; or (b) such lesser number of shares of Common Stock approved by the Board of Directors on or prior to such immediately preceding December 31. On January 1, 2016 and 2017, a total of 773,102 and 778,299 additional shares, respectively, were automatically added to the shares authorized for issuance under the 2015 Plan. In no event shall the number of additional authorized shares determined pursuant to this formula exceed, when added to the number of shares of common stock outstanding and reserved for issuance under the 2012 Plan, the 2015 Plan other than pursuant to this formula, under the ESPP and upon conversion or exercise of outstanding warrants or unvested RSUs or Inducement Options, the total number of shares of common stock authorized for issuance under Nivalis' Amended and Restated Certificate of Incorporation.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item regarding certain relationships and related transactions and director independence will be included in the 2016 Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item regarding principal accounting fees and services will be included in the 2016 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are being filed as part of this report:

(1) Financial Statements.
Reference is made to the Index to Financial Statements of Nivalis Therapeutics, Inc. appearing on page F-1 of this report.

(2) Financial Statement Schedules.
All financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the Financial Statements or the Notes thereto.

(3) Exhibits.
Reference is made to the Index to Exhibits filed as a part of this Annual Report on Form 10-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

NIVALIS THERAPEUTICS, INC.

By: /S/ R. MICHAEL CARRUTHERS
R. Michael Carruthers
Interim President and Chief Financial Officer

Date: February 13, 2017

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Name	Title	Date
/S/ R. MICHAEL CARRUTHERS R. Michael Carruthers	Interim President and Chief Financial Officer (Principal Executive, Financial and Accounting Officer)	February 13, 2017
/S/ HOWARD FURST Howard Furst	Chairman of the Board of Directors	February 13, 2017
/S/ ROBERT CONWAY Robert Conway	Director	February 13, 2017
/S/ EVAN LOH Evan Loh	Director	February 13, 2017
/S/ JOHN MOORE John Moore	Director	February 13, 2017
/S/ PAUL SEKHRI Paul Sekhri	Director	February 13, 2017
/S/ CYNTHIA SMITH Cynthia Smith	Director	February 13, 2017

INDEX TO FINANCIAL STATEMENTS

Nivalis Therapeutics, Inc.
Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control over financial reporting is a process designed 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.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Interim President and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2016 based on the framework set forth in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on that evaluation, our management concluded that, as of December 31, 2016, our internal control over financial reporting was effective.

Date: February 13, 2017

/s/ R. MICHAEL CARRUTHERS
R. Michael Carruthers
Interim President and Chief Financial Officer

Report of Independent Registered Public Accounting Firm

The Stockholders and Board of Directors
Nivalis Therapeutics, Inc.

We have audited the accompanying balance sheets of Nivalis Therapeutics, Inc. (the "Company") as of December 31, 2016 and 2015, and the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Nivalis Therapeutics, Inc., at December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Denver, Colorado
February 13, 2017

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

	December 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 24,203	$ 24,991
Marketable securities	36,832	62,263
Prepaid expenses and other current assets	628	432
Total current assets	61,663	87,686
Property and equipment and other assets, net	272	223
Total assets	$ 61,935	$ 87,909
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,921	$ 994
Accrued direct program expenses	2,646	1,555
Accrued employee benefits	1,879	1,675
Accrued other liabilities	53	195
Total current liabilities	6,499	4,419
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized for both periods presented; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized for both periods presented; 15,565,973 and 15,462,030 shares issued and outstanding, respectively	16	15
Additional paid-in capital	235,737	232,309
Accumulated other comprehensive income (loss)	(17)	3
Accumulated deficit	(180,300)	(148,837)
Total stockholders' equity	55,436	83,490
Total liabilities and stockholders' equity	$ 61,935	$ 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 share and per share amounts)

	Years Ended December 31,		
	2016	2015	2014
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	23,316	16,054	12,200
General and administrative	8,586	6,844	2,287
Loss from operations	(31,902)	(22,898)	(14,487)
Interest and other income, net	439	80	296
Interest expense	—	—	(845)
Net loss	(31,463)	(22,818)	(15,036)
Gain on extinguishment of convertible debt as a capital transaction	—	—	378
Net loss attributable to common stockholders	$ (31,463)	$ (22,818)	$ (14,658)
Unrealized gains (losses) on marketable securities, net	(20)	3	—
Comprehensive loss	$ (31,483)	$ (22,815)	$ (14,658)
Weighted average shares outstanding - basic and diluted	15,492	9,371	723
Net loss per share attributable to common stockholders - basic and diluted	$ (2.03)	$ (2.43)	$ (20.27)

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

Nivalis Therapeutics, Inc.
Statements of Convertible Preferred Stock and Stockholders' Equit y (Deficit)
(In thousands)

	Series 1 Convertible Preferred Stock		Series 2 Convertible Preferred Stock		Series A-2 Convertible Preferred Stock		Series C-1 Convertible Preferred Stock		Series C-2 Convertible Preferred Stock		Series D Convertible Preferred Stock		Series E Convertible Preferred Stock	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance as of December 31, 2013	—	$ —	—	$ —	1,393	$ 9,000	2,811	$ 18,155	2,379	$ 19,980	7,203	$ 15,675	4,266	$ 14,983
Conversion of 2013 notes payable, net of issuance costs	—	—	—	—	—	—	—	—	—	—	—	—	3,528	12,326
Recapitalization	—	—	—	—	(1,393)	(9,000)	(2,811)	(18,155)	(2,379)	(19,980)	(7,203)	(15,675)	(7,794)	(27,309)
Conversion of 2014 notes payable, net of issuance costs	8,813	12,329	—	—	—	—	—	—	—	—	—	—	—	—
Gain on extinguishment of convertible debt	—	(384)	—	—	—	—	—	—	—	—	—	—	—	—
Sale of convertible preferred stock, net of issuance costs	—	—	11,166	29,935	—	—	—	—	—	—	—	—	—	—
Restricted stock units forfeited	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Exercise of incentive stock options	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Reclass of preferred stock warrant liabilities to equity	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Employee stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Balance as of December 31, 2014	8,813	$ 11,945	11,166	$ 29,935	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —
Conversion of convertible preferred stock to common stock	(8,813)	(11,945)	(11,166)	(29,935)	—	—	—	—	—	—	—	—	—	—
Issuance of common stock, net of $9.8 million of offering costs	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Issuance of common stock under employee share plans and awards	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Employee stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Unrealized gains on marketable securities	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Balance as of December 31, 2015	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —
Issuance of common stock, net of issuance costs	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Issuance of common stock under employee share plans and awards	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Employee stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Unrealized losses on marketable securities	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Balance as of December 31, 2016	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —

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

Nivalis Therapeutics, Inc.
Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit) (Continued)
(In thousands)

	Series A-1 Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2013	1,992	$ 2	171	$ —	$ 19,693	$ —	$ (110,983)	$ (91,288)
Conversion of 2013 notes payable, net of issuance costs	—	—	—	—	—	—	—	—
Recapitalization	(1,992)	(2)	2,040	2	90,120	—	—	90,120
Conversion of 2014 notes payable, net of issuance costs	—	—	—	—	—	—	—	—
Gain on extinguishment of convertible debt	—	—	—	—	378	—	—	378
Sale of convertible preferred stock, net of issuance costs	—	—	—	—	—	—	—	—
Restricted stock units forfeited	—	—	(1)	—	—	—	—	—
Exercise of incentive stock options	—	—	1	—	2	—	—	2
Reclass of preferred stock warrant liabilities to equity	—	—	—	—	2	—	—	2
Employee stock-based compensation expense	—	—	—	—	70	—	—	70
Net loss	—	—	—	—	—	—	(15,036)	(15,036)
Balance as of December 31, 2014	—	$ —	2,211	$ 2	$110,265	$ —	$ (126,019)	$ (15,752)
Conversion of convertible preferred stock to common stock	—	—	6,916	7	41,873	—	—	41,880
Issuance of common stock, net of $9.8 million of offering costs	—	—	6,325	6	78,765	—	—	78,771
Issuance of common stock under employee share plans and awards	—	—	10	—	63	—	—	63
Employee stock-based compensation expense	—	—	—	—	1,343	—	—	1,343
Unrealized gains on marketable securities	—	—	—	—	—	3	—	3
Net loss	—	—	—	—	—	—	(22,818)	(22,818)
Balance as of December 31, 2015	—	$ —	15,462	$ 15	$232,309	$ 3	$ (148,837)	$ 83,490
Issuance of common stock,								

net of issuance costs	—	—	20	—	20	—	—	20
Issuance of common stock under employee share plans and awards	—	—	84	1	145	—	—	146
Employee stock-based compensation expense	—	—	—	—	3,263	—	—	3,263
Unrealized losses on marketable securities	—	—	—	—	—	(20)	—	(20)
Net loss	—	—	—	—	—	—	(31,463)	(31,463)
Balance as of December 31, 2016	—	$ —	15,566	$ 16	$235,737	$ (17)	$ (180,300)	$ 55,436

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

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

	Years Ended December 31,		
	2016	**2015**	**2014**
Operating activities			
Net loss	$ (31,463)	$ (22,818)	$ (15,036)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and loss on disposal of assets	143	66	88
Stock-based compensation expense	3,263	1,343	70
Change in value of preferred stock warrant liabilities and derivative	—	—	(296)
Amortization of deferred financing costs and noncash interest	—	—	708
Changes in operating assets and liabilities:			
Prepaid expenses and other	(282)	198	(380)
Accounts payable	927	65	258
Accrued direct program expenses	1,091	311	355
Accrued employee benefits	204	1,465	(183)
Accrued other liabilities	(142)	163	(32)
Net cash used in operating activities	(26,259)	(19,207)	(14,448)
Investing activities			
Purchases of property and equipment	(106)	(188)	(4)
Purchases of marketable securities	(75,324)	(76,260)	—
Proceeds from maturities and sales of marketable securities	100,735	14,000	—
Net cash provided by (used in) investing activities	25,305	(62,448)	(4)
Financing activities			
Proceeds from issuance of common stock, net of offering costs	20	78,771	—
Proceeds from issuance of common stock under employee share plans	146	63	2
Proceeds from issuance of convertible preferred stock, net	—	—	29,935
Decrease in restricted cash	—	—	2,500
Proceeds from notes payable, net	—	—	11,868
Principal payment on debt	—	—	(3,139)
Net cash provided by financing activities	166	78,834	41,166
Net increase (decrease) in cash and cash equivalents	(788)	(2,821)	26,714
Cash and cash equivalents, beginning of period	24,991	27,812	1,098
Cash and cash equivalents, end of period	$ 24,203	$ 24,991	$ 27,812
Supplemental disclosures of cash flow information			
Cash paid for interest	$ —	$ —	$ 165
Conversion of convertible preferred stock to common stock	$ —	$ 41,880	$ —
Conversion of convertible debt and accrued interest to convertible preferred stock, net	$ —	$ —	$ 24,655

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

NIVALIS THERAPEUTICS, INC.

NOTES TO 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.

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 December 31, 2016, the Company had an accumulated deficit of $180.3 million. For the year ended December 31, 2016, net loss was $31.5 million and net cash used in operating activities was $26.3 million.

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 engaged financial advisors and established a Special Committee of the Board to explore strategic alternatives.

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 5 remaining positions in order to conserve cash while the Company continues to evaluate business 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 to reduce expenditures. After considering the actions taken by management, the Company has sufficient cash and marketable securities to fund operations for at least the next twelve 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.

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.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company has established guidelines to limit its exposure to credit risk by placing investments with high credit quality financial institutions, diversifying its investment portfolio and making investments with maturities that maintain safety and liquidity. At December 31, 2016 and 2015, the Company's cash equivalents were with money market funds that invest in securities issued by the U.S. Treasury. At December 31, 2016 and 2015, the Company's marketable securities were in U.S. Treasury securities, obligations of U.S. government agencies, reverse repurchase agreements and high-grade corporate debt securities.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Lab equipment, computer equipment and software are depreciated using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are depreciated over the shorter of the estimated useful lives of the assets or the lease term. Maintenance and repairs are expensed as incurred.

Impairment of Long-Lived Assets

The Company assesses the potential impairments of its long-lived assets whenever events or changes in circumstances indicate that an asset's carrying value may not be recoverable. If the carrying value exceeds the undiscounted future cash flows estimated to result from the use and eventual disposition of the asset, the Company writes down the asset to its estimated fair value. Management believes that no long-lived assets were materially impaired as of December 31, 2016 and 2015.

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. No vendor comprised more than 10% of all external costs in 2016, 2015, and 2014.

Research and Development

The Company expenses costs associated with research and development as incurred. These costs include direct program expenses, which are payments made to third parties that specifically relate to the Company's research and development, such as payments to clinical research organizations, clinical investigators, manufacturing of clinical material, pre-clinical testing and consultants. In addition, employee costs (salaries, payroll taxes, benefits and travel) for employees contributing to research and development activities are classified as research and development costs.

Stock-Based Compensation

The Company measures employee and director stock-based compensation expense for all stock and purchase awards at the grant date based on the fair value measurement of the award. The expense is recorded over the related service period, generally the vesting period, net of estimated forfeitures. Any changes to the estimated forfeiture rates are accounted for prospectively. The Company calculates the fair value measurement of stock options using the Black-Scholes valuation model and the single-option method and recognizes expense using the straight-line attribution approach.

Income Taxes

The Company accounts for income taxes under an asset and liability approach. Deferred income taxes reflect the impact of temporary differences between assets and liabilities recognized for tax and financial reporting purposes measured by applying enacted tax rates and laws that will be in effect when the differences are expected to reverse, net operating loss and tax credit carryforwards. Tax benefits are recorded when the benefit is more likely than not to be sustained upon audit. The Company accrues interest and penalties related to uncertain tax positions in income tax expense. Valuation allowances are provided when necessary to reduce net deferred tax assets to an amount that is more likely than not to be realized.

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is on discovering and developing potential drugs. No revenue has been generated since inception, and all tangible assets are held in the United States.

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 year ended December 31, 2016 and 2015.

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.

Recently Adopted Accounting Pronouncements

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements – Going Concern Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern, which requires management to evaluate whether there are conditions or events that raise substantial doubt about an entity's ability to continue as a going concern and to provide disclosures when certain criteria are met. The guidance is effective for annual periods beginning after December 15, 2016 and interim reporting periods starting in the first quarter of 2017. The Company adopted this standard as of December 31, 2016.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The new guidance requires organizations that lease assets to recognize assets and liabilities on the balance sheet related to the rights and obligations created by those leases, regardless of whether they are classified as finance or operating leases. Consistent with current guidance, the recognition, measurement, and presentation of expenses and cash flows arising from a lease primarily will depend on its classification as a finance or operating lease. The guidance also requires new disclosures to help financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. The new standard is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, with early application permitted. The new standard is to be applied using a modified retrospective approach. The Company does not expect the standard will have a material impact on its disclosures.

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.

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.

The Company accounted for warrants to purchase its redeemable preferred stock pursuant to ASC Topic 480, *Distinguishing Liabilities from Equity*, and classified them as liabilities. The fair value of the outstanding preferred stock warrant liabilities at December 31, 2013 was $267,750. Subsequent to the completion of the Stock Conversion on September 23, 2014, whereby all outstanding shares of preferred stock were converted into shares of common stock, and the warrants became exercisable for shares of common stock pursuant to the adjustment provisions of the warrants, the fair value of the preferred stock warrant liabilities was remeasured and reclassified into equity. During the year ended December 31, 2014 a remeasurement gain of $265,750 was recognized in interest and other income, net in the statement of operations and comprehensive loss. Upon the Stock Conversion, the remaining balance of $2,000 was reclassified from liabilities to equity.

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 years ended December 31, 2016 and 2015.

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

Description	December 31, 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	$ 14,186	$ 14,186	$ —	$ 12,131	$ 12,131	$ —
U.S. Treasury securities, obligations of U.S. government agencies, corporate debt securities and reverse repurchase agreements	41,832	—	41,832	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 December 31, 2016 and 2015 (in thousands):

	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Fair market value
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
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. Property and Equipment

Property and equipment consisted of the following as of December 31, 2016 and 2015 (in thousands):

	Estimated Useful Life (in years)	December 31, 2016	December 31, 2015
Lab equipment	5	$ 1,145	$ 1,146
Computer equipment and software	3	456	421
Leasehold improvements	1	143	102
Total		1,744	1,669
Less accumulated depreciation		(1,569)	(1,456)
Property and equipment, net		$ 175	$ 213

Depreciation expenses were approximately $143,000, $66,000 and $86,000 for the years ended December 31, 2016, 2015 and 2014, respectively.

6. Notes Payable

As of December 31, 2016, the Company had no debt outstanding.

Convertible Debt

During February 2014 through September 2014, the Company issued subordinated secured convertible promissory notes (the "2014 Notes"), to two related party investors totaling $12.0 million at an interest rate of 8.0% per annum. The outstanding principal and accrued and unpaid interest was convertible at the option of the investor into preferred shares in the Company.

The 2014 Notes included a change in control redemption which was deemed an embedded derivative. This redemption right and the right to convert at 75% of the price at which a new series of preferred stock was issued required the Company to bifurcate and separately account for the embedded derivatives, however the amount recorded and the impact on net loss was not material.

As part of the Stock Conversion on September 23, 2014, the holders of the 2014 Notes agreed to the issuance of shares of a newly created Series 1 convertible preferred stock in settlement of the 2014 Notes. The Company issued 8,813,203 Series 1 convertible preferred shares at a price of $1.40 per share through the settlement of $12,373,741 of convertible debt and related interest held by two separate investors. This transaction resulted in a gain on extinguishment of $378,251, which was recognized through equity during the year ended December 31, 2014, as this was a transaction with stockholders.

7. Commitments and Contingencies

Operating Lease

The Company has a lease obligation for office and laboratory space, which will expire on March 31, 2018. The Company has the option to renew the lease for an additional three-year term and has the option to terminate the lease at any time after March 31, 2017, for a termination fee of $25,000.

The approximate future minimum payments under these lease arrangements as of December 31, 2016, are as follows (in thousands):

2017	$ 295
2018	80
Total	$ 375

During 2016, 2015 and 2014, the Company incurred approximately $279,000, $267,000 and $225,000 for rent expense, respectively.

Purchase Commitments

The Company has entered into contracts with external parties to provide the Company future services, which include research and development, clinical development support and testing services. As of December 31, 2016, the Company's obligation for future services under these contracts approximated $1.7 million.

8. Stockholders' Equity

Convertible Preferred Stock

Immediately prior to the Stock Conversion, the Company had six series of outstanding convertible preferred stock: Series A-1 convertible preferred stock, Series A-2 convertible preferred stock, Series C-1 convertible preferred stock, Series C-2 convertible preferred stock, Series D convertible preferred stock and Series E convertible preferred stock. The convertible preferred stock was initially recorded at the issuance price on the date of issuance, net of issuance costs. As a result of the Stock Conversion on September 23, 2014, all outstanding preferred stock was converted into shares of common stock on an 11.556-for-1 basis. Concurrent with the Stock Conversion, a newly created Series 1 convertible preferred stock was issued in the settlement of the 2014 Notes. In November and December 2014, the Company raised $31.0 million gross proceeds in a private placement of Series 2 convertible preferred stock.

On June 22, 2015, prior to the closing of the Company's IPO, all outstanding shares of convertible preferred stock, amounting to 19,978,986 shares, were automatically converted into 6,915,525 shares of common stock in accordance with the terms of the Company's amended and restated certificate of incorporation then in existence.

As of December 31, 2016 and 2015, the Company had no preferred stock or convertible preferred stock outstanding.

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, at a price to the public of $14.00 per share for aggregate gross proceeds of $88.6 million. The Company received proceeds of $78.8 million from its IPO, net of $3.6 million in expenses and $6.2 million in 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).

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 December 31, 2016, 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 December 31, 2016, shares of common stock have been reserved for issuance as follows:

Options to purchase common stock - issued	2,756,921
Options to purchase common stock - unissued	391,927
Inducement grants - issued	288,889
Employee stock purchase plan - unissued	180,845
Warrants to purchase common stock	18,534
Total	3,637,116

Stock-Based Compensation

Stock Options and Restricted Stock Units

In August 2012, the Company adopted the 2012 Stock Incentive Plan (the "2012 Plan"). A total of 147,109 shares of common stock were originally reserved for issuance under the 2012 Plan. On November 17, 2014, and December 12, 2014, the Company's Board of Directors approved an increase of 623,052 and 519,210 shares, respectively, to the total number of shares that may be issued under the 2012 Plan, which after these increases totaled 1,289,371 shares. As of December 31, 2015, 1,288,174 accumulated shares had been granted under the 2012 Plan to employees and directors, while 685 shares had been exercised and 512 shares were terminated upon the termination of the 2012 Plan effective with the closing of the Company's IPO.

In May 2015, the Company's Board of Directors and its stockholders approved the 2015 Equity Incentive Plan (the "2015 Plan"). Effective with the Company's IPO closing, a total of 1,081,700 shares of common stock were originally reserved for issuance under the 2015 Plan. The 2015 Plan provides that an additional number of shares will automatically be added to the shares authorized for issuance under the 2015 Plan on January 1 of each calendar year, from January 1, 2016 through January 1, 2025. The number of shares added each year will be equal to: (a) 5% of the total number of shares of Common Stock issued and outstanding on December 31 of the preceding calendar year; or (b) such lesser number of shares of Common Stock approved by the Board of Directors on or prior to such immediately preceding December 31. On January 1, 2016 a total of 773,102 additional shares were automatically added to the shares authorized for issuance under the 2015 Plan.

The 2015 Plan provides for the granting of incentive and nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance-based awards and other stock-based awards to its employees, directors and consultants. Stock options granted vest over either a one-year period or three-year period for Board of Director grants or over a four-year period for employee grants and expire 10 years from the date of grant.

The fair value of each option grant for the year ended December 31, 2016 and 2015 was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	2016	2015
Estimated dividend yield	–	–
Weighted-average expected stock price volatility	79.1 %	75.7 %
Weighted-average risk-free interest rate	1.5 %	1.8 %
Weighted-average expected life of option (in years)	6.20	6.22
Weighted-average fair value per option	$ 5.09	$ 5.09

There were no stock options granted during the year ended December 31, 2014

Due to limited historical data, the Company estimates stock price volatility based on the actual volatility of comparable publicly traded companies over the expected life of the option. The expected term represents the average time that options that vest are expected to be outstanding. The Company does not have sufficient history of exercise of stock options to estimate the expected term for employee stock options and, thus, continues to calculate expected life based on the midpoint between the average vesting date and the contractual term, which is in accordance with the simplified method. The risk-free rate is based on the United States Treasury yield curve for the expected life of the option. The fair value of the common stock utilized in the fair value estimation of option and restricted stock arrangements prior to the Company's IPO of June 2015 has been determined utilizing contemporaneous valuations primarily based on an option pricing methodology.

The tables below summarize the stock option activity for the year ended December 31, 2016:

	Options Outstanding	Weighted Average Exercise Price	Weighted - Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value
Balance as of December 31, 2015	1,787,864	$ 7.54		
Granted	1,101,958	7.37		
Exercised	(5,722)	4.52		
Forfeited	(33,488)	12.81		
Canceled or Expired	(7,649)	16.20		
Balance as of December 31, 2016	2,842,963	7.39	8.76	$ –
Exercisable at December 31, 2016	821,934	6.80	8.10	–
Options expected to vest, net of estimated forfeitures	2,723,085	$ 7.36	8.74	$ –

A summary of the status of our non-vested RSUs as of December 31, 2016 and changes during the year ended December 31, 2016, is presented below:

	Number of RSUs	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2015	–	$ -
Granted	216,667	4.68
Vested	(36,111)	4.68
Unvested as of December 31, 2016	180,556	$ 4.68

During 2016, 2015 and 2014, the Company recorded approximately $3.3 million, $1.3 million and $70,000, respectively, in stock-based compensation expense for the vesting of stock options and RSUs. No stock options or RSUs have been granted to consultants. As of December 31, 2016, there was approximately $10.0 million of total unrecognized stock-based compensation expense related to nonvested stock options and nonvested RSUs, net of related forfeiture

estimates. During the first quarter of 2017, we expect to record approximately $2.3 million of stock-based compensation expense due to the accelerated vesting of options and RSUs offered to employees affected by the restructuring plan and workforce reduction announced on January 12, 2017.

The Company did not recognize a tax benefit related to stock-based compensation expense during the years ended December 31, 2016, 2015 and 2014 as the Company maintains net operating loss carryforwards and has established a valuation allowance against the entire net deferred tax asset as of December 31, 2016.

Employee Stock Purchase Plan

In May 2015, the Company's Board of Directors and its stockholders approved the Nivalis Therapeutics, Inc. Employee Stock Purchase Plan (the "Purchase Plan"). Effective on the closing of the Company's IPO, a total of 231,800 shares of common stock were made available for sale under the Purchase Plan. The Purchase Plan may be amended, suspended or terminated at any time by the Board of Directors, however stockholder approval is required to increase the number of common stock available under the Purchase Plan or to change the employees eligible to participate in the Purchase Plan.

The Purchase Plan provides for a series of successive six-month offering periods, from January to June and July to December of each calendar year during which participating employees may elect to have up to 15% of their compensation withheld and applied to the purchase of common stock at the end of each offering period. The purchase price of the common stock is 85% of the lower of the fair value of a share of common stock on the first trading date of each offering period or the fair value of a share of common stock on the last trading day of the offering period. The Company sold 42,031 and 8,924 shares to employees during 2016 and 2015, respectively. There were 180,845 shares available for sale under the Purchase Plan as of December 31, 2016. The weighted-average estimated grant date fair value of purchase awards under the Purchase Plan during the year ended December 31, 2016 and 2015 was $1.98 and $5.18, respectively. The total stock-based compensation expense recorded as a result of the Purchase Plan was approximately $73,000 and $22,000 during the year ended December 31, 2016 and 2015, respectively.

The fair value of purchase awards granted to our employees during the year ended December 31, 2016 and 2015 was estimated using the Black-Scholes option pricing model using the weighted-average assumptions provided in the following table:

	2016	2015
Estimated dividend yield	–	–
Expected stock price volatility	66.4 %	62.5 %
Risk-free interest rate	0.4 %	0.1 %
Expected life of option (in years)	0.5	0.5

The Company estimates stock price volatility based on the actual volatility of its publicly traded stock over the expected life of the purchase right. The risk-free rate is based on the U.S. Treasury yield in effect at the time of grant with terms similar to the contractual term of the purchase right. The expected term represents the six-month offering period for the Purchase Plan.

9. Income Taxes

No provision for federal or state income tax expense has been recorded for the years ended December 31, 2016, 2015 and 2014, since the Company generated net operating losses in all years.

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities at December 31, 2016 and 2015 are as follows (in thousands):

	2016	2015
Deferred tax assets:		
Net operating loss carryforwards	$ 28,271	$ 20,280
Income tax credit carryforwards	9,268	1,813
Accrued benefits and other	613	643
Stock-based compensation	1,221	–
Property and equipment	20	–
Intangible assets	107	125
Valuation allowance	(39,500)	(22,858)
Net deferred tax assets	–	3
Deferred tax liabilities:		
Property and equipment	–	(3)
	$ –	$ –

The Company records a full valuation allowance against its net deferred tax assets since the Company cannot conclude that it was more likely than not that its deferred tax assets would be realized.

At December 31, 2016, the Company had federal and state income loss carryforwards of $75.7 million and $83.0 million, respectively, that begin to expire in 2032 for both federal and state purposes. Additionally, the Company has research and development credits and orphan drug credits of approximately $2.0 million and $7.3 million, respectively, available for federal purposes, which begin to expire in 2032 and 2036, respectively. The utilization of the federal net operating loss and credit carryforwards to reduce future income taxes will depend on the Company's ability to generate sufficient taxable income prior to the expiration of the carryforwards. In addition, the utilization of the federal net operating loss and credit carryforwards may be subject to limitations under the rules regarding a change in stock ownership as determined by the Internal Revenue Code and state laws. Section 382 of the Internal Revenue Code of 1986, as amended, imposes annual limitations on the utilization of net operating loss ("NOL") carryforwards, other tax carryforwards and certain built-in losses upon an ownership change as defined by that section. In general terms, an ownership change may result from transactions that increase the aggregate ownership of certain stockholders in the Company stock by more than 50 percentage points over a three year testing period ("Section 382 Ownership Change"). If the Company has undergone a Section 382 Ownership change, an annual limitation would be imposed on certain tax attributes of the Company, including NOL and capital loss carryforwards and certain other losses and credits. As of December 31, 2016, the Company has not performed a formal study to determine whether there are Section 382 limitations that apply and such limitations could be significant.

The difference between actual income tax rate for the years ended December 31, 2016, 2015 and 2014, and the statutory federal income tax rate are as follows:

	2016 % of Pretax Earnings	2015 % of Pretax Earnings	2014 % of Pretax Earnings
Income tax benefit at statutory rate	34.0 %	34.0 %	34.0 %
State income taxes, net of federal tax benefit	3.1 %	3.1 %	3.1 %
Income tax credits	23.7 %	2.6 %	3.5 %
Nondeductible expenses and other	(7.9)%	(1.9)%	(1.0)%
Change in valuation allowance	(52.9)%	(37.8)%	(39.6)%
Income tax expense (benefit)	0.0 %	0.0 %	0.0 %

As of December 31, 2016 and 2015, the Company had no unrecognized tax benefits. The Company has analyzed its filing positions in all significant federal and state jurisdictions where it is required to file income tax returns,

as well as open tax years in these jurisdictions. With few exceptions, the Company is no longer subject to U.S. federal, state and local tax examinations by taxing authorities for years before 2013. No income tax returns are currently under examination by taxing authorities.

10. Employment Benefit Plan

The Company outsources its payroll, benefits and human resource administration functions to a Professional Employer Organization (PEO). The Company's employees are eligible to participate in the PEO's Multiple Employer Retirement Savings Plan (401(k) plan). The 401(k) plan allows immediate participation by U.S. employees that are 20 years of age or older. Participants may defer up to 75% of their gross pay, up to a maximum limit determined by U.S. federal law. The Company provides all active employees with a safe harbor contribution equal to 3% of compensation (regardless of participation in the 401(k) plan) up to maximum U.S. federal law limits. These safe harbor contributions vest immediately. During 2016, 2015 and 2014, the Company paid approximately $150,000, $115,000 and $129,000, respectively, for employer contributions and plan expenses.

11. Net Loss per Share

The Company excluded the following common stock equivalents, outstanding as of the years ended December 31, 2016, 2015 and 2014, from the computation of diluted net loss per share for these same periods because they had an anti-dilutive impact on the computation:

	December 31,		
	2016	2015	2014
Options to purchase common stock - issued	2,756,921	1,810,155	88,346
Inducement grants - issued	288,889	—	—
Unvested restricted common stock	—	318	3,342
Convertible preferred stock	—	—	6,915,525
Warrants to purchase convertible preferred and common stock	18,534	18,534	18,534
Total	3,064,344	1,829,007	7,025,747

12. Quarterly Financial Data (Unaudited)

The results of operations on a quarterly basis for the years ended December 31, 2016 and 2015 were as follows (in thousands, except per share data):

	March 31, 2016	June 30, 2016	September 30, 2016	December 31, 2016	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
Revenue	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Operating expenses:								
Research and development	5,567	6,424	5,669	5,656	3,017	4,465	4,279	4,293
General and administrative	2,367	2,172	1,879	2,168	1,298	1,387	1,822	2,337
Loss from operations	(7,934)	(8,596)	(7,548)	(7,824)	(4,315)	(5,852)	(6,101)	(6,630)
Interest and other income, net	96	117	115	111	1	—	12	67
Interest expense	—	—	—	—	—	—	—	—
Net loss	$ (7,838)	$ (8,479)	$ (7,433)	$ (7,713)	$ (4,314)	$ (5,852)	$ (6,089)	$ (6,563)
Weighted average shares outstanding - basic and diluted	15,462	15,462	15,504	15,540	2,209	4,159	15,451	15,452
Net loss per share - basic and diluted	$ (0.51)	$ (0.55)	$ (0.48)	$ (0.50)	$ (1.95)	$ (1.41)	$ (0.39)	$ (0.42)

13. Subsequent Events

In January 2017, following the failure of a Phase 2 trial of cavosonstat in patients with CF to meet its primary endpoint, the Company initiated a process to explore and review a range of strategic alternatives focused on maximizing stockholder value from its clinical assets and cash resources. As a result, the Company ceased its research activities and further development of cavosonstat and its other GSNOR inhibitors and began implementation of a workforce reduction of 25 positions to better align its workforce to its revised operating plan. The workforce reduction will be substantially completed during the first quarter of 2017, at which time the Company expects to have approximately five remaining employees. Cash payments in connection with the workforce reduction, comprised principally of severance and benefits continuation costs, are estimated to be approximately $3.0 million and expected to be paid during the first half of 2017.

In addition to severance payments, all unvested stock options held by employees affected by the workforce reduction were 100% vested and a portion of unvested RSUs held by one employee vested. As a result, the Company expects to record in the first quarter of 2017 approximately $2.3 million of stock-based compensation expense related to this accelerated vesting.

The Company has not incurred, nor does it expect to incur, significant cancellation charges with its vendors as a result of winding down research and development activities.

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 of 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 II, LLC (2)
4.4	Second Amended and Restated Investor Rights Agreement dated November 18, 2014 (2)
10.1	Nivalis Therapeutics, Inc. 2015 Equity Incentive Plan (2)*
10.2	Form of Notice of Stock Option Grant and Stock Option Agreement for Employees under the Nivalis Therapeutics, Inc. 2015 Equity Incentive Plan (1)*
10.3	Form of Notice of Stock Option Grant and Stock Option Agreement for Non-Employee Directors under the Nivalis Therapeutics, Inc. 2015 Equity Incentive Plan (1)*
10.4	N30 Pharmaceuticals, Inc. 2012 Stock Incentive Plan (2)*
10.5	Form of Stock Option Agreement pursuant to N30 Pharmaceuticals, Inc. 2012 Stock Incentive Plan (2)*
10.6	Nivalis Therapeutics, Inc. Employee Stock Purchase Plan (2)*
10.7	Employment Agreement, dated as of January 1, 2015, by and between the Registrant and Jon Congleton (2)*
10.8	Amendment to Employment Agreement, dated as of March 6, 2015, by and between the Registrant and Jon Congleton (2)*
10.9	Amendment to Employment Agreement, dated as of January 12, 2017, by and between the Registrant and Jon Congleton*
10.10	Confidential Separation Agreement and General Release, dated as of January 15, 2017, by and between the Registrant and Jon Congleton*
10.11	Employment Agreement, dated as of November 1, 2012, by and between the Registrant and Janice Troha (2)*
10.12	Amendment to Employment Agreement, dated as of December 15, 2014, by and between the Registrant and Janice Troha (2)*
10.13	Amendment to Employment Agreement, dated as of March 6, 2015, by and between the Registrant and Janice Troha (2)*
10.14	Amendment to Employment Agreement, dated as of January 12, 2017, by and between the Registrant and Janice Troha*
10.15	Retention Bonus letter agreement, dated as of January 9, 2017, by and between the Registrant and Janice Troha*
10.16	Employment Agreement, dated as of January 21, 2015, by and between the Registrant and R. Michael Carruthers (2)*
10.17	Amendment to Employment Agreement, dated as of January 12, 2017, by and between the Registrant and R. Michael Carruthers*
10.18	Retention Bonus letter agreement, dated as of January 9, 2017, by and between the Registrant and R. Michael Carruthers*
10.19	Employment Agreement, dated as of April 18, 2016, by and between the Registrant and David M. Rodman, M.D. (3)*
10.20	Amendment to Employment Agreement, dated as of January 12, 2017, by and between the Registrant and David M. Rodman, M.D.*
10.21	Confidential Separation Agreement and General Release, dated as of January 15, 2017, by and between the Registrant and David Rodman, M.D.*

10.22	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)*
10.23	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)*
10.24	Form of Indemnification Agreement entered into by and between the Registrant and its directors and officers (2)
10.25	Lease, dated March 11, 2010, by and between the Registrant and Aweida Properties, Inc. (2)
10.26	1st Amendment to Lease, dated December 5, 2014, by and between the Registrant and Aweida Properties, Inc. (2)
10.27	2nd Amendment to Lease, dated February 11, 2015, by and between the Registrant and Aweida Properties, Inc. (2)
10.28	Outside Director Compensation Guidelines (4)
23.1	Consent of Independent Registered Public Accounting Firm
31.1	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 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.
(4) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (File No.001-37449), filed August 4, 2015.
* Indicates a management contract or a compensatory plan, contract or arrangement.

CONFIDENTIAL SEPARATION AGREEMENT AND GENERAL RELEASE

This Confidential Separation Agreement and General Release (this " **Agreement**") is entered into by and between Nivalis Therapeutics, Inc. ("**EMPLOYER**") and **Jon Congleton** ("**EMPLOYEE**"). For purposes of this Agreement, EMPLOYER includes TriNet Group, Inc. ("**TriNet**") as well as any company related to EMPLOYER, in the past or present; the past and present officers, directors, employees, shareholders, attorneys, agents, insurers and representatives of EMPLOYER; any present or past employee benefit plan sponsored by EMPLOYER and/or the officers, directors, trustees, administrators, employees, attorneys, agents, insurers and representatives of such plan; and any person who acted on behalf of EMPLOYER or on instruction from EMPLOYER.

In exchange for the releases and other agreements specified in this Agreement, the parties agree as follows:

A. **EMPLOYEE'S Separation.** EMPLOYEE's last day of employment is January 15, 2017 (the "**Separation Date**").

B. **Separation Pay.**

1. EMPLOYEE acknowledges and agrees that EMPLOYEE has received all compensation and benefits to which EMPLOYEE is entitled through and including the Separation Date, including but not limited to wages and accrued but unused vacation/PTO time. Subject to EMPLOYEE's compliance with the terms and conditions of this Agreement, EMPLOYER will provide EMPLOYEE with the additional benefits described below in exchange for EMPLOYEE'S release of any and all claims EMPLOYEE may have against EMPLOYER. This Agreement is entered into as contemplated by the Employment Agreement between EMPLOYER and EMPLOYEE dated January 1, 2015 (the "**Employment Agreement**").

2. As consideration for EMPLOYEE'S release of all claims against EMPLOYER, and in accordance with the terms of the Employment Agreement, and provided EMPLOYEE complies with his/her obligations under this Agreement and the NDA (as defined below): (i) EMPLOYER will pay EMPLOYEE the gross sum of **Six Hundred Seventy-Five Thousand dollars ($675,000.00)**, less applicable Federal, state and local tax withholdings and other amounts required by law to be withheld (the "**Separation Pay**"), (ii) provided that EMPLOYEE is eligible and timely elects continuation of his/her health insurance pursuant to COBRA, an amount necessary to reimburse EMPLOYEE for the cost of COBRA premiums to be paid in order for EMPLOYEE to maintain medical insurance coverage through January 15, 2018 that is substantially equivalent to that which EMPLOYEE received immediately prior to the Separation Date less the amount paid by EMPLOYEE immediately prior to the Separation Date for EMPLOYEE'S contribution to premiums for EMPLOYER'S health insurance, *provided, however*, that EMPLOYER'S obligation to pay EMPLOYEE COBRA premiums will cease immediately in the event EMPLOYEE becomes eligible for group health insurance prior to January 15, 2018, and EMPLOYEE agrees to promptly notify EMPLOYER if EMPLOYEE becomes eligible to be covered by group health insurance in such event ("**COBRA Reimbursement**"); and (iii) all outstanding stock options held by EMPLOYEE shall vest and become exercisable in full as of the Effective Date (as defined in Section D.6 below) ("**Option Acceleration**").

3. The Separation Pay, COBRA Reimbursement and Option Acceleration is in addition to any and all other payments and benefits that may be owed to EMPLOYEE by EMPLOYER. The Separation Pay will be payable in eighteen substantially equal monthly installments payable on the last business day of each month following execution of this Agreement. The COBRA Reimbursement will be payable monthly following submission of evidence to EMPLOYER of payment of the COBRA premium by EMPLOYEE so long as EMPLOYEE is eligible to receive such reimbursement hereunder. Notwithstanding the foregoing, no payments will begin sooner than the first business day following expiration of the seven (7) day period following the Effective Date. EMPLOYEE authorizes EMPLOYER to pay the Separation Pay by direct deposit processed through the TriNet Employer Payroll System.

4. In the event of a closing of a Change in Control (as defined in the Employment Agreement) prior to expiration of EMPLOYER's obligations to pay the Separation Pay or the COBRA Reimbursement hereunder, EMPLOYER will pay EMPLOYEE (i) the remaining amount of the aggregate Separation Pay and (ii) the amount of the remaining COBRA Reimbursements plus an amount equal to EMPLOYEE's estimated income tax obligation payable, using a flat rate of 32%, as a result of the payment in advance of the amount of such remaining COBRA Reimbursement, if any, in each case a single lump sum payment to EMPLOYEE on or immediately after consummation of such Change in Control.

C. **EMPLOYEE'S General Release of EMPLOYER.** In exchange for the consideration set forth in this Agreement, EMPLOYEE, on behalf of EMPLOYEE and his/her heirs, executors, representatives, successors and assigns, fully and completely releases and forever discharges EMPLOYER from any and all claims, demands, damages, losses, obligations, rights and causes of action of every kind and nature whatsoever, whether known or unknown, which EMPLOYEE has had, now has, or may have against EMPLOYER at any time through the date EMPLOYEE signs this Agreement, with the exception of any claims that arise after execution of this Agreement, claims that cannot legally be waived, and claims for breach of this Agreement. Subject to the limitations in the immediately preceding sentence, this general release of claims includes all claims arising under any Federal, state or local statute or ordinance, constitutional provision, public policy or common law, including claims under Title VII of the Civil Rights Act of 1964 and 1991, the Age Discrimination in Employment Act of 1967, the Civil Rights Act of 1866, the Civil Rights Act of 1871, the Employee Retirement Income Security Act (solely with respect to unvested benefits), the Consolidated Omnibus Budget Reconciliation Act, the Americans with Disabilities Act, the Rehabilitation Act of 1973, the Family Medical Leave Act, the Lilly Ledbetter Fair Pay Act of 2009, the Genetic Information Non-discrimination Act, the Worker Adjustment and Retraining Notification Act, the Fair Credit Reporting Act, Colorado Anti-Discrimination Act (Colo. Rev. Stat. § 24-34-401 *et seq.*), the Colorado Family Care Act (Colo. Rev. Stat. § 8-13.3-201 *et. seq.*), and workers' compensation non-interference or non-retaliation statutes, all as amended; all claims arising under laws relating to violation of public policy, retaliation, or interference with legal rights; all claims arising under other employment or discrimination laws; all claims that a past unlawful decision has or has had a continuing effect on my compensation; all claims for compensation of any type whatsoever (including but not limited to claims for wages, bonuses, commissions, incentive compensation, vacation and/or severance); all claims arising under tort, contract and/or quasi-contract law; and all claims for monetary or equitable relief, including but not limited to attorneys' fees, back pay, front pay, reinstatement, experts' fees, medical fees or expenses, costs and disbursements.

D. **EMPLOYEE'S Specific ADEA Release of EMPLOYER.** EMPLOYEE acknowledges and agrees that by entering into this Agreement, he/she is waiving any and all rights that he/she may have under the Age Discrimination in Employment Act of 1967, as amended (the "**ADEA**"). EMPLOYEE further expressly acknowledges and agrees that:

1. EMPLOYEE is entering into this Agreement voluntarily.

2. EMPLOYEE understands and agrees that, by signing this Agreement, he/she is giving up any right to file legal proceedings against the EMPLOYER for any claims arising on or before the date EMPLOYEE signs this Agreement. EMPLOYEE is not waiving (or giving up) rights or claims that may arise after the date EMPLOYEE signs this Agreement.

3. In return for this Agreement, EMPLOYEE will receive compensation that is in addition to any benefits to which he/she is already entitled to receive.

4. EMPLOYEE is hereby advised in writing by this Agreement to consult with an attorney before signing this Agreement.

5. EMPLOYEE understands that he/she has had at least forty-five (45) calendar days from the day he/she received this Agreement, not counting the day upon which he/she received it, to consider whether he/she wishes to sign this Agreement. If EMPLOYEE decides to sign this Agreement before the end of the forty-five (45) day period, which is solely EMPLOYEE's choice, EMPLOYEE represents that his/her decision is knowing and voluntary and that he/she has not been pressured to make a decision sooner.

6. EMPLOYEE further understands that he/she may revoke (that is, cancel) this Agreement for any reason within seven (7) calendar days after signing it. EMPLOYEE agrees that the revocation must be in writing and hand-delivered or mailed to EMPLOYER. If mailed, the revocation must be postmarked within the seven (7) day period, properly addressed to Tom Sokolowski, VP Finance, Nivalis Therapeutics, Inc., 3122 Sterling Circle, Suite 200, Boulder, CO 80301; and sent by certified mail, return receipt requested. This Agreement will not be effective or enforceable until the eighth day after EMPLOYEE has signed this Agreement without having revoked it (the "**Effective Date**"). EMPLOYEE understands that he/she will not receive any Separation Pay, the COBRA Reimbursement or the Option Acceleration if he/she revokes this Agreement.

7. EMPLOYEE acknowledges that pursuant to the Older Workers Benefit Protection Act, he/she has been provided a copy of the disclosure form attached as Addendum A.

E. **Agreement to Release Claims.** Except for an action brought to enforce this Agreement, actions which are not waivable as a matter of law or actions challenging the validity of EMPLOYEE's release of claims under the ADEA, EMPLOYEE agrees to refrain from initiating or participating in any proceeding of any kind against EMPLOYER relating to matters released in this Agreement. If any such proceeding has been initiated by EMPLOYEE or on his/her behalf, EMPLOYEE shall use his/her best efforts to cause it immediately to be withdrawn and dismissed with prejudice. Notwithstanding the foregoing, nothing in this Agreement prohibits EMPLOYEE

from filing a charge with or participating in an investigation or proceeding by the United States Equal Employment Opportunity Commission or any other governmental agency, from providing information to a governmental agency, or from participating in an investigation conducted by a governmental agency. However, EMPLOYEE understands and agrees that with the exception of money provided to EMPLOYEE by a governmental agency as an award for providing information, EMPLOYEE is not entitled to receive money or other relief (including any money damages, reinstatement or other legal or equitable relief) in connection with or on account of any of the claims released in this Agreement regardless of who initiated or filed the charge or other proceeding.

F. **No Admission of Liability.** By entering into this Agreement, EMPLOYER does not admit that it is legally obligated to make any payment of Separation Pay or COBRA Reimbursement to EMPLOYEE or to effect the Option Acceleration and denies that it is responsible or legally obligated for any claims or that it has engaged in any improper conduct or wrongdoing.

G. **Confidentiality of Agreement.** EMPLOYEE agrees that EMPLOYEE will not disclose any of the terms of or amounts paid under this Agreement to any individual or entity; provided, however, that EMPLOYEE will not be prohibited from making disclosures to EMPLOYEE's attorneys, tax advisors and/or immediate family members, or as may be required or authorized by law or court order, or as may be necessary in providing truthful information to a government agency.

H. **Return of EMPLOYER Property.** By no later than the Separation Date, EMPLOYEE shall (1) deliver to EMPLOYER all property belonging to EMPLOYER in EMPLOYEE's possession or control, including but not limited to all keys, access cards, credit cards, cell phones, computers, hard drives, flash drives, documents, and any other materials belonging to EMPLOYER (including but not limited to those that constitute or contain any trade secrets or confidential information), together with all copies of the foregoing; and (2) delete all electronically stored information containing any trade secrets or confidential information stored on any networks, computers or information storage devices not owned by EMPLOYER that are within EMPLOYEE's possession or control.

I. **Non-disparagement.** EMPLOYEE agrees not to make, publish or communicate to any person or entity or in any public forum (including social media) at any time any defamatory remarks, comments or statements concerning EMPLOYER. Notwithstanding the foregoing, this paragraph does not, in any way, restrict or impede EMPLOYEE from exercising protected rights to the extent that such rights cannot be waived by agreement or from complying with any applicable law or court order.

J. **Interpretation of Agreement**. This Agreement should be interpreted as broadly as possible to achieve EMPLOYEE'S intention to resolve all of EMPLOYEE'S claims against EMPLOYER. If this Agreement is held by a court to be inadequate to release a particular claim, this Agreement will remain in full force and effect with respect to all of the rest of my released claims.

K. **Severability.** If any provision of this Agreement is declared by any court of competent jurisdiction to be invalid for any reason, such invalidity shall not affect the remaining provisions of this Agreement, which shall be fully severable, and given full force and effect.

L. **Governing Law.** This Agreement shall be construed in accordance with the laws of the State of Colorado without reference to conflicts of law provisions thereunder.

M. **Continuing Confidentiality Noncompete Obligations.** Regardless of whether EMPLOYEE signs this Agreement, EMPLOYEE has continuing obligations under his/her Proprietary Information and Inventions Agreement and Noncompete Agreement (the "**NDA**") and EMPLOYEE acknowledges and affirms such continuing obligations under the provisions of the NDA, which shall survive termination of EMPLOYEE'S employment.

N. **Entire Agreement.** This Agreement is the complete understanding between the parties regarding the subject matter of this Agreement and supersedes all prior agreements relating to the same subject matter.

O. **Modification; Waiver.** No provision of this Agreement may be amended, changed, altered, waived, or modified except in writing signed by each of the parties, which writing shall specifically reference this Agreement and the provision that the parties intend to modify.

P. **Counterparts.** This Agreement may be executed in two or more counterparts, each of which will be deemed an original, and all of which together will constitute one document.

[Signature Page Follows]

The parties hereto have executed this Agreement on the date(s) shown below to be effective as of the Effective Date.

NIVALIS THERAPEUTICS, INC.

By: /s/ R. Michael Carruthers

Name: R. Michael Carruthers

Title: Chief Financial Officer

Date: 1/15/17

AGREED TO AND ACCEPTED:

EMPLOYEE

/s/ Jon Congleton

Name: Jon Congleton

Date: 1/12/17

Exhibit 10.14

AMENDMENT to the
EMPLOYMENT AGREEMENT
between
Nivalis Therapeutics, Inc.
and
Janice M. Troha ("Employee")

WHEREAS, Nivalis Therapeutics, Inc. (the "Company") and the Employee entered into an employment agreement (the "Agreement") effective as of November 1, 2012, as amended;

WHEREAS, the Company and the Employee desire to amend the Agreement to change the provision relating to accelerated vesting of stock options in connection with Termination/Severance;

NOW, THEREFORE, in consideration of the promises and mutual covenants contained herein and for other good and valuable consideration, the parties agree as follows:

1. A new Section 5(e) shall be inserted in the Agreement as follows and the sections currently designated as Section 5(e), 5(f), 5(g) and 5(h), and all cross references in the Agreement thereto, shall be amended to be designated as Section 5(f), 5(g), 5(h) and 5(i), respectively:

> (e) The Employee may terminate this Agreement upon at least thirty (30) days' notice for Good Reason. "Good Reason" means (A) a ten percent (10%) or more reduction in Employee's salary to which Employee has not consented; (B) a material diminution in Employee's authority, duties or responsibilities without Employee's consent (which shall not include a change in reporting obligations resulting from a Corporate Transaction); (C) a requirement by the Company, without Employee's consent, that Employee's primary work site be relocated to a site that is more than twenty five (25) miles away from Employee's work site prior to the Corporate Transaction; or (D) any other action or inaction that constitutes a material breach by the Company of Employee's employment agreement, if any. Notwithstanding the foregoing, a termination of Employee for Good Reason shall not have occurred unless (i) Employee gives written notice to the Company, of termination within thirty (30) days after Employee first becomes aware of the occurrence of the circumstances constituting Good Reason, specifying in reasonable detail the circumstances constituting Good Reason, (ii) the Company has failed within thirty (30) days after receipt of such notice to cure the circumstances constituting Good Reason, and (iii) Employee terminates employment within five (5) days after the Company's cure period ends.

2. Section 5(f) (as newly designated pursuant to Section 1 of this Amendment) is amended and restated in its entirety to read as follows:

> (f) If this Agreement is terminated by the Company prior to the end of the term pursuant to any provision other than 5(a) or 5(c), or by the Employee pursuant to Section 5(e), then (i) the Company shall pay to Employee twelve (12) month's salary, or the amount due Employee through the remainder of the term, whichever is greater, in equal monthly installments, subject to all applicable deductions and withholdings; (ii) the Company shall provide Employee with paid COBRA benefits during the twelve-month period following the Termination Date; and (iii) the Company shall cause any issued but unvested options scheduled to vest in the year of termination to immediately vest in full.

3. Section 5(g) (as newly designated pursuant to Section 1 of this Amendment) is amended and restated in its entirety to read as follows:

(f) If a Change in Control occurs, then all outstanding options granted to Employee shall immediately vest (to the extent they are not already vested).

4. Except as amended herein, the provisions of the Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the Company has caused this Amendment to be executed and Employee has hereunto set his hand as of January 12, 2017.

NIVALIS THERAPEUTICS, INC.

By: /s/ R. Michael Carruthers
Name: R. Michael Carruthers
Title: Chief Financial Officer
Date: 1/12/17

EMPLOYEE

By: /s/ Janice M. Troha
Janice M. Troha

Nivalis Therapeutics, Inc.
3122 Sterling Circle, Suite 200, Boulder, CO 80301

January 9, 2017

Janice Troha
Nivalis Therapeutics, Inc.
3122 Sterling Circle
Suite 200
Boulder, Colorado 80301

Re: Retention Bonus

Dear Janice:

In recognition of your continued service with Nivalis Therapeutics, Inc. (the "Company"), and subject to the other terms and conditions of this letter agreement (this "Agreement"), we are pleased to offer you a retention bonus in the amount of **$100,000.00,** less applicable withholdings and deductions required by law (the "Retention Bonus") and an option grant to purchase **200,000** shares of Common Stock of the Company which option shall vest in full upon the termination of your employment by the Company other than for Cause or a Corporate Transaction (as defined in the stock option agreement to be entered into by you and the Company) and be subject to the terms and conditions of such stock option agreement and the Company's 2015 Equity Incentive Plan (the "Stock Option").

The Retention Bonus will be processed and paid through the Company's payroll on the closing date of a Change in Control (the "Payment Date"), provided you have remained actively and continuously employed in good standing by the Company through the Payment Date. For purposes of this Agreement, "Change in Control" shall mean the sale of all or substantially all of the outstanding shares of capital stock, assets or business of the Company, by merger, consolidation, sale of assets or otherwise (other than a transaction in which all or substantially all of the persons who were beneficial owners of the capital stock of the Company immediately prior to such transaction beneficially own, directly or indirectly, more than 50% of the outstanding voting securities (on an as-converted to Common Stock basis) of the resulting, surviving or acquiring entity in such transaction).

In order to be considered in "good standing," you must have been employed continuously from the date hereof to the Payment Date and you must not be the subject of any disciplinary warning, whether written or oral. In order to receive the Retention Bonus, you must (a) be in good standing, (b) execute a release of claims to be provided to you by the Company, and (c) otherwise comply with the terms and conditions of this letter and the Company's policies and procedures.

Neither the Retention Bonus, the Stock Option grant nor this letter have any bearing on your right to employment with the Company. **Your employment remains at-will, meaning that you and the Company may terminate the employment relationship at any time, with or without cause or**

reason, and with or without notice. For clarity, should your employment terminate for any reason other than by the Company without cause (as defined in the employment agreement between you and the Company) prior to the Payment Date, you will not receive the Retention Bonus and the vesting of the Stock Option shall cease. Compensation paid pursuant to this Agreement is intended to be exempt from, Section 409A of the Internal Revenue Code of 1986, as amended, as a short term deferral.

This letter supersedes in their entirety any prior or contemporaneous agreements between you and the Company regarding retention bonuses or payments, whether written, oral, express or implied.

This Agreement may not be amended or modified unless in writing signed by both you and an authorized officer of the Company. This Agreement, for all purposes, shall be construed in accordance with the laws of the State of Colorado without regard to conflicts-of-law principles.

Sincerely,

NIVALIS THERAPEUTICS, INC.

By: /s/ R. Michael Carruthers
R. Michael Carruthers
Chief Financial Officer

ACCEPTED AND AGREED:
/s/ Janice Troha
Janice Troha

1/9/17
Date

Exhibit 10.17

AMENDMENT to the
EMPLOYMENT AGREEMENT
between
Nivalis Therapeutics, Inc.
and
R. Michael Carruthers ("Employee")

WHEREAS, Nivalis Therapeutics, Inc. (the "Company") and the Employee entered into an employment agreement (the "Agreement") effective as of January 21, 2015;

WHEREAS, the Company and the Employee desire to amend the Agreement to change the provision relating to accelerated vesting of stock options in connection with Termination/Severance;

NOW, THEREFORE, in consideration of the promises and mutual covenants contained herein and for other good and valuable consideration, the parties agree as follows:

1. A new Section 5(e) shall be inserted in the Agreement as follows and the sections currently designated as Section 5(e), 5(f), 5(g) and 5(h), and all cross references in the Agreement thereto, shall be amended to be designated as Section 5(f), 5(g), 5(h) and 5(i), respectively:

> (e) The Employee may terminate this Agreement upon at least thirty (30) days' notice for Good Reason. "Good Reason" means (A) a ten percent (10%) or more reduction in Employee's salary to which Employee has not consented; (B) a material diminution in Employee's authority, duties or responsibilities without Employee's consent (which shall not include a change in reporting obligations resulting from a Corporate Transaction); (C) a requirement by the Company, without Employee's consent, that Employee's primary work site be relocated to a site that is more than twenty five (25) miles away from Employee's work site prior to the Corporate Transaction; or (D) any other action or inaction that constitutes a material breach by the Company of Employee's employment agreement, if any. Notwithstanding the foregoing, a termination of Employee for Good Reason shall not have occurred unless (i) Employee gives written notice to the Company, of termination within thirty (30) days after Employee first becomes aware of the occurrence of the circumstances constituting Good Reason, specifying in reasonable detail the circumstances constituting Good Reason, (ii) the Company has failed within thirty (30) days after receipt of such notice to cure the circumstances constituting Good Reason, and (iii) Employee terminates employment within five (5) days after the Company's cure period ends.

2. The first sentence of Section 5(f) (as newly designated pursuant to Section 1 of this Amendment) is amended and restated in its entirety to read as follows:

> (f) If this Agreement is terminated by the Company prior to the end of the term pursuant to any provision other than Sections 4, 5(a) or 5(c) or by the Employee pursuant to Section 5(e) (the "Termination Date"), then, provided Employee executes the release described in Section 5(g) below and complies with his obligations under the Confidential Information Agreement and Noncompete Agreement incorporated by reference in Sections 6 and 7 of this Agreement:

3. Section 5(f)(iii) (as newly designated pursuant to Section 1 of this Amendment) is amended and restated in its entirety to read as follows:

(iii) the Company shall cause any issued but unvested options to immediately vest in full.

4. Section 5(h) (as newly designated pursuant to Section 1 of this Amendment) is amended and restated in its entirety to read as follows:

> In the event of a Change of Control, all outstanding options granted to Employee as of such event shall immediately vest (to the extent they are not already vested). For purposes of this Agreement, "Change in Control" shall mean the sale of all or substantially all of the outstanding shares of capital stock, assets or business of the Company, by merger, consolidation, sale of assets or otherwise (other than a transaction in which all or substantially all of the persons who were beneficial owners of the capital stock of the Company immediately prior to such transaction beneficially own, directly or indirectly, more than 50% of the outstanding voting securities (on an as-converted to Common Stock basis) of the (i) resulting, surviving or acquiring entity in such transaction in the case of a merger, consolidation or sale of outstanding shares, or (ii) acquiring entity in the case of a sale of assets). Notwithstanding the foregoing, sale of Company stock pursuant to an initial public offering or follow-on public offering shall not constitute a Change in Control.

5. Except as amended herein, the provisions of the Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the Company has caused this Amendment to be executed and Employee has hereunto set his hand as of January 12, 2017.

NIVALIS THERAPEUTICS, INC.

By: /s/ Janice Troha
Name: Janice Troha
Title: Chief Operating Officer
Date: 1/12/17

EMPLOYEE

By: /s/ R. Michael Carruthers
R. Michael Carruthers

Nivalis Therapeutics, Inc.
3122 Sterling Circle, Suite 200, Boulder, CO 80301

January 9, 2017

R. Michael Carruthers
Nivalis Therapeutics, Inc.
3122 Sterling Circle
Suite 200
Boulder, Colorado 80301

Re: Retention Bonus

Dear Mike:

In recognition of your continued service with Nivalis Therapeutics, Inc. (the "Company"), and subject to the other terms and conditions of this letter agreement (this "Agreement"), we are pleased to offer you a retention bonus in the amount of **$100,000.00,** less applicable withholdings and deductions required by law (the "Retention Bonus") and an option grant to purchase **200,000** shares of Common Stock of the Company which option shall vest in full upon the termination of your employment by the Company other than for Cause or a Corporate Transaction (as defined in the stock option agreement to be entered into by you and the Company) and be subject to the terms and conditions of such stock option agreement and the Company's 2015 Equity Incentive Plan (the "Stock Option").

The Retention Bonus will be processed and paid through the Company's payroll on the closing date of a Change in Control (the "Payment Date"), provided you have remained actively and continuously employed in good standing by the Company through the Payment Date. For purposes of this Agreement, "Change in Control" shall mean the sale of all or substantially all of the outstanding shares of capital stock, assets or business of the Company, by merger, consolidation, sale of assets or otherwise (other than a transaction in which all or substantially all of the persons who were beneficial owners of the capital stock of the Company immediately prior to such transaction beneficially own, directly or indirectly, more than 50% of the outstanding voting securities (on an as-converted to Common Stock basis) of the resulting, surviving or acquiring entity in such transaction).

In order to be considered in "good standing," you must have been employed continuously from the date hereof to the Payment Date and you must not be the subject of any disciplinary warning, whether written or oral. In order to receive the Retention Bonus, you must (a) be in good standing, (b) execute a release of claims to be provided to you by the Company, and (c) otherwise comply with the terms and conditions of this letter and the Company's policies and procedures.

Neither the Retention Bonus, the Stock Option grant nor this letter have any bearing on your right to employment with the Company. **Your employment remains at-will, meaning that you and the Company may terminate the employment relationship at any time, with or without cause or**

reason, and with or without notice. For clarity, should your employment terminate for any reason other than by the Company without cause (as defined in the employment agreement between you and the Company) prior to the Payment Date, you will not receive the Retention Bonus and the vesting of the Stock Option shall cease. Compensation paid pursuant to this Agreement is intended to be exempt from, Section 409A of the Internal Revenue Code of 1986, as amended, as a short term deferral.

This letter supersedes in their entirety any prior or contemporaneous agreements between you and the Company regarding retention bonuses or payments, whether written, oral, express or implied.

This Agreement may not be amended or modified unless in writing signed by both you and an authorized officer of the Company. This Agreement, for all purposes, shall be construed in accordance with the laws of the State of Colorado without regard to conflicts-of-law principles.

Sincerely,

NIVALIS THERAPEUTICS, INC.

By: /s/ Janice Troha
Janice Troha
Chief Operating Officer

ACCEPTED AND AGREED:
/s/ R. Michael Carruthers
R. Michael Carruthers

1/9/17
Date

Exhibit 10.20

AMENDMENT to the
EMPLOYMENT AGREEMENT
between
Nivalis Therapeutics, Inc.
and
David M. Rodman, M.D. ("Employee")

WHEREAS, Nivalis Therapeutics, Inc. (the "Company") and the Employee entered into an employment agreement (the "Agreement") effective as of April 18, 2016;

WHEREAS, the Company and the Employee desire to amend the Agreement to change the provision relating to accelerated vesting of stock options in connection with Termination/Severance;

NOW, THEREFORE, in consideration of the promises and mutual covenants contained herein and for other good and valuable consideration, the parties agree as follows:

1. Section 5(e)(iii) is amended and restated in its entirety to read as follows:

> (iii) the Company shall cause any issued but unvested options to vest in full and to cause any issued but unvested restricted stock units scheduled to vest in the twelve (12) months following Employee's Termination Date to immediately vest; provided, however, that this sentence shall not diminish the 100% vesting contemplated by 5(g) below in connection with a Change of Control.

2. Except as amended herein, the provisions of the Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the Company has caused this Amendment to be executed and Employee has hereunto set his hand as of January 12, 2017.

NIVALIS THERAPEUTICS, INC.

By: /s/ R. Michael Carruthers
Name: R. Michael Carruthers
Title: Chief Financial Officer
Date: 1/12/17

EMPLOYEE

By: /s/ David M. Rodman, M.D.
David M. Rodman, M.D.

CONFIDENTIAL SEPARATION AGREEMENT AND GENERAL RELEASE

This Confidential Separation Agreement and General Release (this " **Agreement**") is entered into by and between Nivalis Therapeutics, Inc. ("**EMPLOYER**") and **David M. Rodman, M.D.** ("**EMPLOYEE**"). For purposes of this Agreement, EMPLOYER includes TriNet Group, Inc. ("**TriNet**") as well as any company related to EMPLOYER, in the past or present; the past and present officers, directors, employees, shareholders, attorneys, agents, insurers and representatives of EMPLOYER; any present or past employee benefit plan sponsored by EMPLOYER and/or the officers, directors, trustees, administrators, employees, attorneys, agents, insurers and representatives of such plan; and any person who acted on behalf of EMPLOYER or on instruction from EMPLOYER.

In exchange for the releases and other agreements specified in this Agreement, the parties agree as follows:

A. **EMPLOYEE'S Separation.** EMPLOYEE's last day of employment is January 15, 2017 (the "**Separation Date**").

B. **Separation Pay.**

1. EMPLOYEE acknowledges and agrees that EMPLOYEE has received all compensation and benefits to which EMPLOYEE is entitled through and including the Separation Date, including but not limited to wages and accrued but unused vacation/PTO time. Subject to EMPLOYEE's compliance with the terms and conditions of this Agreement, EMPLOYER will provide EMPLOYEE with the additional benefits described below in exchange for EMPLOYEE'S release of any and all claims EMPLOYEE may have against EMPLOYER. This Agreement is entered into as contemplated by the Employment Agreement between EMPLOYER and EMPLOYEE dated April 18, 2016 (the "**Employment Agreement**").

2. As consideration for EMPLOYEE'S release of all claims against EMPLOYER, and in accordance with the terms of the Employment Agreement, and provided EMPLOYEE complies with his/her obligations under this Agreement and the NDA (as defined below): (i) EMPLOYER will pay EMPLOYEE the gross sum of **Four Hundred Fifty Thousand dollars ($450,000.00)**, less applicable Federal, state and local tax withholdings and other amounts required by law to be withheld (the "**Separation Pay**"), (ii) provided that EMPLOYEE is eligible and timely elects continuation of his/her health insurance pursuant to COBRA, an amount necessary to reimburse EMPLOYEE for the cost of COBRA premiums to be paid in order for EMPLOYEE to maintain medical insurance coverage through January 15, 2018 that is substantially equivalent to that which EMPLOYEE received immediately prior to the Separation Date less the amount paid by EMPLOYEE immediately prior to the Separation Date for EMPLOYEE'S contribution to premiums for EMPLOYER'S health insurance, *provided, however*, that EMPLOYER'S obligation to pay EMPLOYEE COBRA premiums will cease immediately in the event EMPLOYEE becomes eligible for group health insurance prior to January 15, 2018, and EMPLOYEE agrees to promptly notify EMPLOYER if EMPLOYEE becomes eligible to be covered by group health insurance in such event ("**COBRA Reimbursement**"); (iii) all outstanding stock options held by EMPLOYEE shall vest and become exercisable in full as of the Effective Date (as defined in Section D.6 below) ("**Option Acceleration**"); and (iv) restricted stock units

representing 72,223 shares of Common Stock shall vest and such shares shall be issued to you as of the Effective Date (the "**RSU Accleration**").

3. The Separation Pay, COBRA Reimbursement, Option Acceleration and the RSU Acceleration is in addition to any and all other payments and benefits that may be owed to EMPLOYEE by EMPLOYER. The Separation Pay will be payable in twelve substantially equal monthly installments payable on the last business day of each month following execution of this Agreement. The COBRA Reimbursement will be payable monthly following submission of evidence to EMPLOYER of payment of the COBRA premium by EMPLOYEE so long as EMPLOYEE is eligible to receive such reimbursement hereunder. Notwithstanding the foregoing, no payments will begin sooner than the first business day following expiration of the seven (7) day period following the Effective Date. EMPLOYEE authorizes EMPLOYER to pay the Separation Pay by direct deposit processed through the TriNet Employer Payroll System.

4. In the event of a closing of a Change in Control (as defined in the Employment Agreement) prior to expiration of EMPLOYER's obligations to pay the Separation Pay or the COBRA Reimbursement hereunder, EMPLOYER will pay EMPLOYEE (i) the remaining amount of the aggregate Separation Pay and (ii) the amount of the remaining COBRA Reimbursements plus an amount equal to EMPLOYEE's estimated income tax obligation payable, using a flat rate of 32%, as a result of the payment in advance of the amount of such remaining COBRA Reimbursement, if any, in each case a single lump sum payment to EMPLOYEE on or immediately after consummation of such Change in Control.

C. **EMPLOYEE'S General Release of EMPLOYER.** In exchange for the consideration set forth in this Agreement, EMPLOYEE, on behalf of EMPLOYEE and his/her heirs, executors, representatives, successors and assigns, fully and completely releases and forever discharges EMPLOYER from any and all claims, demands, damages, losses, obligations, rights and causes of action of every kind and nature whatsoever, whether known or unknown, which EMPLOYEE has had, now has, or may have against EMPLOYER at any time through the date EMPLOYEE signs this Agreement, with the exception of any claims that arise after execution of this Agreement, claims that cannot legally be waived, and claims for breach of this Agreement. Subject to the limitations in the immediately preceding sentence, this general release of claims includes all claims arising under any Federal, state or local statute or ordinance, constitutional provision, public policy or common law, including claims under Title VII of the Civil Rights Act of 1964 and 1991, the Age Discrimination in Employment Act of 1967, the Civil Rights Act of 1866, the Civil Rights Act of 1871, the Employee Retirement Income Security Act (solely with respect to unvested benefits), the Consolidated Omnibus Budget Reconciliation Act, the Americans with Disabilities Act, the Rehabilitation Act of 1973, the Family Medical Leave Act, the Lilly Ledbetter Fair Pay Act of 2009, the Genetic Information Non-discrimination Act, the Worker Adjustment and Retraining Notification Act, the Fair Credit Reporting Act, Colorado Anti-Discrimination Act (Colo. Rev. Stat. § 24-34-401 *et seq.*), the Colorado Family Care Act (Colo. Rev. Stat. § 8-13.3-201 *et. seq.*), and workers' compensation non-interference or non-retaliation statutes, all as amended; all claims arising under laws relating to violation of public policy, retaliation, or interference with legal rights; all claims arising under other employment or discrimination laws; all claims that a past unlawful decision has or has had a continuing effect on my compensation; all claims for compensation of any type whatsoever (including but not limited to claims for wages, bonuses, commissions, incentive compensation, vacation and/or severance); all claims arising under tort, contract and/or quasi-

contract law; and all claims for monetary or equitable relief, including but not limited to attorneys' fees, back pay, front pay, reinstatement, experts' fees, medical fees or expenses, costs and disbursements.

D. **EMPLOYEE'S Specific ADEA Release of EMPLOYER .** EMPLOYEE acknowledges and agrees that by entering into this Agreement, he/she is waiving any and all rights that he/she may have under the Age Discrimination in Employment Act of 1967, as amended (the "**ADEA**"). EMPLOYEE further expressly acknowledges and agrees that:

1. EMPLOYEE is entering into this Agreement voluntarily.

2. EMPLOYEE understands and agrees that, by signing this Agreement, he/she is giving up any right to file legal proceedings against the EMPLOYER for any claims arising on or before the date EMPLOYEE signs this Agreement. EMPLOYEE is not waiving (or giving up) rights or claims that may arise after the date EMPLOYEE signs this Agreement.

3. In return for this Agreement, EMPLOYEE will receive compensation that is in addition to any benefits to which he/she is already entitled to receive.

4. EMPLOYEE is hereby advised in writing by this Agreement to consult with an attorney before signing this Agreement.

5. EMPLOYEE understands that he/she has had at least forty-five (45) calendar days from the day he/she received this Agreement, not counting the day upon which he/she received it, to consider whether he/she wishes to sign this Agreement. If EMPLOYEE decides to sign this Agreement before the end of the forty-five (45) day period, which is solely EMPLOYEE's choice, EMPLOYEE represents that his/her decision is knowing and voluntary and that he/she has not been pressured to make a decision sooner.

6. EMPLOYEE further understands that he/she may revoke (that is, cancel) this Agreement for any reason within seven (7) calendar days after signing it. EMPLOYEE agrees that the revocation must be in writing and hand-delivered or mailed to EMPLOYER. If mailed, the revocation must be postmarked within the seven (7) day period, properly addressed to Tom Sokolowski, VP Finance, Nivalis Therapeutics, Inc., 3122 Sterling Circle, Suite 200, Boulder, CO 80301; and sent by certified mail, return receipt requested. This Agreement will not be effective or enforceable until the eighth day after EMPLOYEE has signed this Agreement without having revoked it (the "**Effective Date**"). EMPLOYEE understands that he/she will not receive any Separation Pay, the COBRA Reimbursement, the Option Acceleration or the RSU Acceleration if he/she revokes this Agreement.

7. EMPLOYEE acknowledges that pursuant to the Older Workers Benefit Protection Act, he/she has been provided a copy of the disclosure form attached as Addendum A.

E. **Agreement to Release Claims .** Except for an action brought to enforce this Agreement, actions which are not waivable as a matter of law or actions challenging the validity of EMPLOYEE's release of claims under the ADEA, EMPLOYEE agrees to refrain from initiating or participating in any proceeding of any kind against EMPLOYER relating to matters released in this

Agreement. If any such proceeding has been initiated by EMPLOYEE or on his/her behalf, EMPLOYEE shall use his/her best efforts to cause it immediately to be withdrawn and dismissed with prejudice. Notwithstanding the foregoing, nothing in this Agreement prohibits EMPLOYEE from filing a charge with or participating in an investigation or proceeding by the United States Equal Employment Opportunity Commission or any other governmental agency, from providing information to a governmental agency, or from participating in an investigation conducted by a governmental agency. However, EMPLOYEE understands and agrees that with the exception of money provided to EMPLOYEE by a governmental agency as an award for providing information, EMPLOYEE is not entitled to receive money or other relief (including any money damages, reinstatement or other legal or equitable relief) in connection with or on account of any of the claims released in this Agreement regardless of who initiated or filed the charge or other proceeding.

F. **No Admission of Liability.** By entering into this Agreement, EMPLOYER does not admit that it is legally obligated to make any payment of Separation Pay or COBRA Reimbursement to EMPLOYEE or to effect the Option Acceleration or the RSU Acceleration and denies that it is responsible or legally obligated for any claims or that it has engaged in any improper conduct or wrongdoing.

G. **Confidentiality of Agreement.** EMPLOYEE agrees that EMPLOYEE will not disclose any of the terms of or amounts paid under this Agreement to any individual or entity; provided, however, that EMPLOYEE will not be prohibited from making disclosures to EMPLOYEE's attorneys, tax advisors and/or immediate family members, or as may be required or authorized by law or court order, or as may be necessary in providing truthful information to a government agency.

H. **Return of EMPLOYER Property.** By no later than the Separation Date, EMPLOYEE shall (1) deliver to EMPLOYER all property belonging to EMPLOYER in EMPLOYEE's possession or control, including but not limited to all keys, access cards, credit cards, cell phones, computers, hard drives, flash drives, documents, and any other materials belonging to EMPLOYER (including but not limited to those that constitute or contain any trade secrets or confidential information), together with all copies of the foregoing; and (2) delete all electronically stored information containing any trade secrets or confidential information stored on any networks, computers or information storage devices not owned by EMPLOYER that are within EMPLOYEE's possession or control.

I. **Non-disparagement.** EMPLOYEE agrees not to make, publish or communicate to any person or entity or in any public forum (including social media) at any time any defamatory remarks, comments or statements concerning EMPLOYER. Notwithstanding the foregoing, this paragraph does not, in any way, restrict or impede EMPLOYEE from exercising protected rights to the extent that such rights cannot be waived by agreement or from complying with any applicable law or court order.

J. **Interpretation of Agreement**. This Agreement should be interpreted as broadly as possible to achieve EMPLOYEE'S intention to resolve all of EMPLOYEE'S claims against EMPLOYER. If this Agreement is held by a court to be inadequate to release a particular claim, this Agreement will remain in full force and effect with respect to all of the rest of my released claims.

K. **Severability.** If any provision of this Agreement is declared by any court of competent jurisdiction to be invalid for any reason, such invalidity shall not affect the remaining provisions of this Agreement, which shall be fully severable, and given full force and effect.

L. **Governing Law.** This Agreement shall be construed in accordance with the laws of the State of Colorado without reference to conflicts of law provisions thereunder.

M. **Continuing Confidentiality Noncompete Obligations.** Regardless of whether EMPLOYEE signs this Agreement, EMPLOYEE has continuing obligations under his/her Proprietary Information and Inventions Agreement and Noncompete Agreement (the "**NDA**") and EMPLOYEE acknowledges and affirms such continuing obligations under the provisions of the NDA, which shall survive termination of EMPLOYEE'S employment.

N. **Entire Agreement.** This Agreement is the complete understanding between the parties regarding the subject matter of this Agreement and supersedes all prior agreements relating to the same subject matter.

O. **Modification; Waiver.** No provision of this Agreement may be amended, changed, altered, waived, or modified except in writing signed by each of the parties, which writing shall specifically reference this Agreement and the provision that the parties intend to modify.

P. **Counterparts.** This Agreement may be executed in two or more counterparts, each of which will be deemed an original, and all of which together will constitute one document.

[Signature Page Follows]

The parties hereto have executed this Agreement on the date(s) shown below to be effective as of the Effective Date.

NIVALIS THERAPEUTICS, INC.

By: /s/ R. Michael Carruthers

Name: R. Michael Carruthers

Title: Chief Financial Officer

Date: 1/15/17

AGREED TO AND ACCEPTED:

EMPLOYEE

/s/ David M. Rodman, M.D.

Name: David M. Rodman, M.D.

Date: 1/15/17

Exhibit 10.9

AMENDMENT to the
EMPLOYMENT AGREEMENT
between
Nivalis Therapeutics, Inc.
and
Jon Congleton ("Employee")

WHEREAS, Nivalis Therapeutics, Inc. (the "Company") and the Employee entered into an employment agreement (the "Agreement") effective as of January 1, 2015, as amended;

WHEREAS, the Company and the Employee desire to amend the Agreement to change the provisions relating to the severance payable to Employee and relating to the accelerated vesting of stock options in connection with Termination/Severance;

NOW, THEREFORE, in consideration of the promises and mutual covenants contained herein and for other good and valuable consideration, the parties agree as follows:

1. Section 5(e)(i) is amended and restated in its entirety to read as follows:

> (i) the Company shall pay to Employee as severance an amount equal to eighteen (18) month's Base Salary, in equal installments, subject to all applicable deductions and withholdings;

2. Section 5(e)(iii) is amended and restated in its entirety to read as follows:

> (iii) the Company shall cause any issued but unvested options to immediately vest in full.

3. Except as amended herein, the provisions of the Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the Company has caused this Amendment to be executed and Employee has hereunto set his hand as of January 12, 2017.

NIVALIS THERAPEUTICS, INC.

By: /s/ R. Michael Carruthers
Name: R. Michael Carruthers
Title: Chief Financial Officer
Date: 1/12/17

EMPLOYEE

By: /s/ Jon Congleton
Jon Congleton

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statement (Form S-8 No. 333-205220) pertaining to the 2012 Stock Incentive Plan, 2015 Equity Incentive Plan, and Employee Stock Purchase Plan of Nivalis Therapeutics, Inc.,

2. Registration Statement (Form S-8 No. 333-211197) pertaining to the Employment Inducement Awards, granted by Nivalis Therapeutics, Inc., and

3. Registration Statement (Form S-3 No. 333-212404) of Nivalis Therapeutics, Inc.

of our report dated February 13, 2017, with respect to the financial statements of Nivalis Therapeutics, Inc., included in this Annual Report (Form 10-K) of Nivalis Therapeutics, Inc. for the year ended December 31, 2016.

/s/ Ernst & Young, LLP

Denver, Colorado
February 13, 2017

Exhibit 31.1

CERTIFICATION OF CHIEF FINANCIAL OFFICER
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 annual report on Form 10-K of Nivalis Therapeutics, Inc. for the year ended December 31, 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. 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: February 13, 2017

/s/ R. MICHAEL CARRUTHERS
R. Michael Carruthers
Interim President and Chief Financial Officer

Exhibit 32.1

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

In connection with the Annual Report of Nivalis Therapeutics, Inc., a Delaware corporation (the "Company"), on Form 10-K for the year ended December 31, 2016, 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: February 13, 2017

/s/ R. MICHAEL CARRUTHERS
R. Michael Carruthers
Interim President and Chief Financial Officer