Adamas Pharmaceuticals Inc
Form 10-K
March 03, 2015

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

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2014

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
Commission File Number: 001-36399

ADAMAS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**2834**	**42-1560076**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

1900 Powell Street, Suite 750
Emeryville, CA 94608
(510) 450-3500
(Address, including zip code, and telephone number, including area code, of Principal Executive Offices)

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 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 o No ý

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 o No ý

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 ý No o

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No o

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. ý

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 definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer o	Non-accelerated filer ý (Do not check if a smaller reporting company)	Smaller reporting company o

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates was $175,750,227 computed by reference to the last sales price of $18.28 as reported by the NASDAQ Global Market, as of the last business day of the registrant's most recently completed second fiscal quarter, June 30, 2014. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of February 23, 2015, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 17,642,207.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference to the definitive proxy statement for the registrant's Annual Meeting of Stockholders to be held on or about May 14, 2015, to be filed within 120 days of the registrant's fiscal year ended December 31, 2014.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report, including the sections titled "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases you can identify these statements by forward-looking words, such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "potential," "seek," "expect," "goal" or the negative or plural of these words or similar expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- our expectation as to the therapeutic profile of our products and product candidates, including the safety and efficacy thereof;
- our anticipated ability to obtain and maintain regulatory approval of our product candidates;
- our anticipated ability to successfully commercialize any of our products that are approved;
- the rate and degree of market acceptance of our products in the future;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;
- the anticipated scope, rate of progress and cost of our pre-clinical studies and clinical trials and other research and development activities;
- the potential cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the anticipated cost and timing of regulatory submissions and approvals;
- our expectation as to the legal proceedings and related stays and terms of settlements;
- our expectation that our existing capital resources will be sufficient to enable us to complete our ongoing clinical studies;
- our anticipated ability to obtain and maintain intellectual property protection for our products and product candidates;
- the anticipated ability to negotiate manufacturing arrangements and scale up manufacturing of our product candidates to commercial scale;
- the anticipated performance by our collaboration partners over which we do not have control;
- the anticipated receipt and timing of any royalties from our collaborators;

our anticipated ability to successfully establish and successfully maintain appropriate collaborations and derive significant revenue from those collaborations;

the anticipated performance of third parties to conduct our clinical studies;

the anticipated ability of third-party contract manufacturers to manufacture and supply our product candidates for us;

our anticipated ability to identify, develop, acquire and in-license new products and product candidates;

our anticipated ability to initiate sites and enroll patients in our clinical studies at the pace that we project;

our anticipated ability to retain and recruit key personnel;

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our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act;

our anticipated financial performance; and

our anticipated developments and projections relating to our competitors or our industry.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

You should read this report and the documents that we reference in this report and have filed with the Securities and Exchange Commission as exhibits to this report with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

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PART I

ITEM 1. BUSINESS

Overview

We are a specialty pharmaceutical company driven to improve the lives of those affected by chronic disorders of the central nervous system, or CNS. We achieve this by enhancing the pharmacokinetic profiles of approved drugs to create novel therapeutics for use alone and in fixed-dose combination products. Our business strategy is twofold. We intend to develop and commercialize our wholly owned products directly. In addition, we may form partnerships with companies that have an already established CNS market presence. We are developing our lead wholly owned product candidate, ADS-5102, for a complication associated with the treatment of Parkinson's disease known as levodopa induced dyskinesia, or LID, and potentially as a treatment for one or more additional CNS indications. We have successfully completed a Phase 2/3 clinical trial, in which patients receiving ADS-5102 had a statistically significant 43% reduction in LID compared to their baseline LID experienced prior to taking ADS-5102. In 2014, we initiated the remaining Phase 3 registration trials of ADS-5102 for LID. We plan to commercialize ADS-5102 and potentially other wholly owned product candidates, if approved, by developing a specialty CNS commercial organization, including a sales force to reach high volume prescribing neurologists and movement disorder specialists in the United States. Our late stage therapeutics portfolio includes memantine-based products focused on Alzheimer's disease, which have been exclusively licensed to Forest Laboratories, Inc., or Forest, a subsidiary of Actavis plc, in the United States. The first product, Namenda XR®, which Forest developed and is marketing in the United States under a license from us, is a controlled-release product, and the second product, Namzaric (formerly known as MDX-8704), which we co-developed with Forest, is a fixed-dose combination product, recently approved by the U.S. Food and Drug Administration, or FDA, that Forest is expected to market and launch in the first half of 2015.

We estimate that approximately 36 million people in the United States suffer from chronic CNS disorders, including hypokinetic movement disorders associated with Parkinson's disease, multiple sclerosis, and post stroke deficits, hyperkinetic movement disorders similar to LID, such as Huntington's chorea and tardive dyskinesia, and other disorders, such as Alzheimer's disease, depression, epilepsy, and traumatic brain injury, or TBI. We believe that many of these disorders could be better treated if existing CNS drugs were pharmacokinetically enhanced and were used alone or in fixed-dose combinations with other existing CNS drugs. Our initial development efforts have yielded a series of patent-protected, controlled-release therapies based on either amantadine or memantine, approved CNS drugs that are part of a class of molecules called aminoadamantanes. We initially focused on aminoadamantanes because they modulate multiple neurotransmitter systems, and we believed that by applying our innovative product development strategy we could develop aminoadamantane-based products with broad therapeutic utility. We are implementing this strategy to develop additional product candidates based on ADS-5102, a controlled-release version of amantadine. We also intend to develop product candidates based on approved CNS therapeutics outside the aminoadamantane class.

Our most advanced wholly owned product candidate is ADS-5102, an once-daily, high dose, controlled-release version of amantadine that we are developing for the treatment of LID. LID is a movement disorder that frequently occurs in patients with Parkinson's disease after long-term treatment with levodopa, the most widely-used drug for Parkinson's disease. Patients with LID suffer from involuntary non-purposeful movements and reduced control over voluntary movements. We estimate that approximately half of Parkinson's disease patients in the United States develop motor complications within five years after initiating levodopa therapy and approximately 70% of these patients suffer from LID. There are no drugs approved by the FDA or the European Medicines

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Agency, or EMA, for the treatment of LID. Clinicians typically manage LID by decreasing the dose of levodopa, which can lessen control of the underlying symptoms of Parkinson's disease.

We selected LID as the initial indication for ADS-5102 based on results seen in investigator-initiated clinical studies of amantadine and in established preclinical models. In our Phase 2/3 clinical study ADS-5102 met its primary endpoint, reduction of LID, and several key secondary endpoints. If our Phase 3 registration trials of ADS-5102 are successful, we expect to submit a New Drug Application, or NDA, to the FDA for ADS-5102 in 2016. Amantadine has shown promising results in multiple other CNS indications, and we expect to initiate a Phase 2 study of ADS-5102 in one or more additional CNS indications by the end of 2015.

Our memantine-based therapeutics are being developed and commercialized in the United States through our partnership with Forest. Forest currently sells one product that is subject to our license agreement, Namenda XR, a treatment of moderate to severe dementia associated with Alzheimer's disease. Namenda XR, a controlled-release version of the approved CNS drug memantine, was launched in the United States in June of 2013 and is part of Forest's Namenda franchise. In addition, Forest and we co-developed Namzaric, a once-daily fixed-dose combination of Namenda XR and the approved CNS drug donepezil, for the treatment of moderate to severe dementia related to Alzheimer's disease, which was approved by the FDA in late 2014. Forest has stated that it projects commercial launch of Namzaric in the first half of 2015. Under our license agreement with Forest, we received a $65 million upfront payment in November 2012 and since then a total of $95 million of development and regulatory milestones, including a final $30 million milestone payment in the fourth quarter of 2014. Commencing five years after the launch of each of Namenda XR and Namzaric, we will be entitled to receive royalties from the sales of these products.

We have developed our current portfolio of late-stage therapeutics in a capital efficient manner. As of December 31, 2014, we had raised a total of $129.9 million from equity financings and had received $160.0 million in upfront and milestone payments and $2.4 million in development funding from our partnership with Forest. At December 31, 2014, we had $158.7 million in cash, cash equivalents, investments and no debt obligations.

Our strategy

Our goal is to build an independent, CNS-focused, specialty pharmaceutical company that improves the lives of patients affected by chronic CNS disorders by enhancing the pharmacokinetic profiles of proven drugs to create novel therapeutics that address significant unmet clinical needs. We intend to achieve this goal by leveraging our existing product development process and focusing on key development objectives.

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Product development strategy

Our strategy is supported by a product development process that allows us to discover, patent, develop, and commercialize novel therapeutics in a capital efficient manner. Our integrated process combines a number of capabilities that together allow us to identify, enhance, patent, and then develop proprietary controlled-release and fixed-dose combination products. These capabilities include in-depth knowledge of CNS markets and unmet medical needs, pharmacokinetic and pharmacodynamic competencies, and regulatory expertise. Our goal is to develop products that are clinically differentiated from approved drugs that in turn create significant benefits for patients, caregivers, physicians, and payors.

The key elements of this strategy are:

Market attractiveness. We identify approved products that are sub-optimally utilized due to tolerability issues driven by factors other than the peak concentration of the drug in the blood stream. We believe that these products, with pharmacokinetic enhancements, can significantly improve the treatment of chronic CNS conditions. For products to be successful, this improvement must be recognized by patients, caregivers, physicians, and payors. A key element of this strategy is targeting conditions treated by a concentrated prescriber base.

Intellectual property. We seek to discover novel pharmacokinetic and pharmacodynamic relationships and to obtain patent protection for a range of dose strengths, pharmacokinetic profiles, timing of administration, and drug combinations as opposed to protecting just specific formulations. Pharmacokinetics refers to the manner in which a drug is absorbed, distributed, metabolized, and excreted by the body. Pharmacodynamics refers to the biochemical and physiological effects of a drug on the body.

Regulatory pathways. We intend to use the regulatory pathway provided by Section 505(b)(2) of the U.S. Food, Drug and Cosmetic Act, or FDCA, to obtain approval for innovative therapeutics based on existing drugs in a manner that we believe will be more time and capital efficient than the standard Section 505(b)(1) pathway used for new chemical entities. While the

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Section 505(b)(2) pathway is commonly used to obtain approval for fairly simple reformulations of existing drugs, it can also be used to obtain approval for new versions of a drug that enhance the efficacy or tolerability of the drug or that allow the drug to be used in a new indication, as well as for a novel fixed-dose combination. By using the Section 505(b)(2) pathway in this way, we are able to pursue approval for novel therapeutics that we believe have improved clinical utility as compared to the existing drug with less time and expense than are typically associated with the Section 505(b)(1) pathway.

Research and development. We have developed a core competency in identifying, formulating and manufacturing controlled-release drug products based on coated pellet capsule technology. We believe this expertise will enable us to first develop the controlled-release drug and then leverage this experience to further develop this drug in fixed-dose combinations with other CNS therapeutics.

Strategic focus

We are implementing our strategy by focusing on the following key objectives:

Obtain FDA approval of ADS-5102 for LID. We are currently conducting Phase 3 registration trials of ADS-5102 in LID in order to support the submission of an NDA. We expect to complete enrollment in 2015 and, if the trials are successful, submit an NDA for ADS-5102 for the treatment of LID in 2016.

Develop ADS-5102 for the treatment of additional CNS indications. In 2015, we intend to increase the number of potential indications for ADS-5102 by initiating additional Phase 2 trials in one or more other CNS indications.

Commercialize ADS-5102 by developing a specialty commercial organization. Assuming ADS-5102 is approved for the treatment of LID, we would expect to commercialize it in the United States by developing a commercial organization, including an approximately 60 person sales force that would target the approximately 4,000 neurologists and movement disorder specialists who treat over 60% of late stage Parkinson's disease patients. If ADS-5102 is approved in additional indications, this sales force could be expanded to target the specialist physicians who focus on patients with those conditions. Furthermore, we also believe a targeted sales force will allow us to more effectively compete for future acquisitions and in-licensing opportunities.

Develop additional novel therapeutics based on existing CNS drugs. We have identified several areas of significant unmet clinical need that we believe could be addressed by fixed-dose combination products incorporating ADS-5102 and another existing CNS drug, and intend to initiate development efforts in these areas in 2015. We also intend to apply our product development approach to other CNS drugs with pharmacokinetic profiles that limit their dosing and efficacy. These could present potential opportunities for improved drugs to be developed with partners or wholly owned products that we may choose to develop and commercialize on our own.

Our market opportunity

We estimate that approximately 36 million people in the United States suffer from chronic CNS disorders, including hypokinetic movement disorders associated with Parkinson's disease, multiple sclerosis, and post stroke deficits, hyperkinetic movement disorders similar to LID, such as Huntington's chorea and tardive dyskinesia, and other disorders, such as Alzheimer's disease, depression, epilepsy, and TBI. We believe that many of these disorders could be better treated if the pharmacokinetic profiles of existing CNS drugs were altered to enhance tolerability and efficacy and if these enhanced drugs were combined with other existing CNS drugs to improve and streamline the management of these complicated conditions.

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CNS diseases are frequently treated with multiple medications having different mechanisms of action with the goal of maximizing symptomatic benefits for patients. Existing CNS drugs often require frequent dosing and may have tolerability issues that limit the amount of the drug that can be taken each day. Onerous side effects due to sub-optimal pharmacokinetic/pharmacodynamic profiles of CNS drugs are also common. Several novel controlled-release CNS drugs that address these effects have been introduced, such as Adderall XR (Shire Specialty Pharmaceuticals), Concerta (Janssen Pharmaceuticals), and Wellbutrin XL (GlaxoSmithKline), and we believe many additional opportunities exist. Further, over the past decade combination therapies have been introduced in a number of non-CNS therapeutic areas, easing the burden associated with complex medical regimens. The *New England Journal of Medicine* reported in 2011 that sophisticated public health models of adherence to complex medical regimens have validated the clinical relevance of combination therapies in multiple therapeutic areas. We believe there are significant opportunities to develop new fixed-dose combinations of approved CNS medications that enhance pharmacokinetic/pharmacodynamics profiles, improve efficacy and tolerability, and support greater adherence to the complex medical regimens faced by many CNS patients.

Therapeutic approach and portfolio

We have developed a portfolio of CNS therapeutics addressing significant unmet clinical needs.

Our initial therapeutic approach

Our initial product and product candidates are based upon pharmacokinetic enhancements of two approved CNS drugs, amantadine and memantine, which belong to a class of drugs known as aminoadamantanes. We selected aminoadamantanes as our initial area of focus because they have the ability to modulate multiple neurotransmitter systems and we believe they potentially have broader therapeutic utility than previously realized. Our pharmacokinetic enhancement strategy demands a deep understanding of the relationship between blood level changes and both efficacy and side effects of these drugs. These insights supported the development of a series of novel controlled-release aminoadamantane product candidates that contain significantly higher dose strengths than immediate-release formulations of the same active pharmaceutical ingredients and can be given once daily, as opposed to multiple times daily.

Our Therapeutics Portfolio

Product and Product Candidates	Target Indication(s)	Development Status	Commercial Rights
Wholly Owned			
ADS-5102 Amantadine	Levodopa-Induced Dyskinesia	Phase 3	Adamas, worldwide
ADS-5102	Undisclosed	Phase 2 planning	Adamas, worldwide
ADS 8800 series	Undetermined	Planning	Adamas, worldwide
ADS-5102 based combination therapies			
ADS 9000 series	Undetermined	Planning	Adamas, worldwide
Additional programs			
ADS-8704	Moderate to severe	Planning	Adamas, ex-US only
Memantine/donepezil	Alzheimer's dementia		
Partnered			
Namenda XR	Moderate to severe	Marketed	US-only; licensed to Forest
Memantine	Alzheimer's dementia		
Namzaric	Moderate to severe	NDA approved	US-only; licensed to Forest
Memantine/donepezil	Alzheimer's dementia		

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Our wholly owned product candidates

Our diversified business model includes plans to develop and commercialize a number of wholly owned product candidates. The most advanced of these are based on the approved drug amantadine. We also anticipate developing and commercializing product candidates based upon other approved CNS therapies.

ADS-5102

ADS-5102 is a controlled-release version of the approved drug amantadine that we are developing initially for LID. We selected LID from an extensive list of potential indications supported by the peer review literature based on results seen in both investigator-initiated clinical studies and in established preclinical models. Further, there is no FDA or EMA approved drug for treating LID despite significant investment by the pharmaceutical industry.

Overview of Parkinson's disease and LID

Parkinson's disease is a chronic, progressive motor disorder that causes tremors, rigidity, slowed movements, and postural instability. The Parkinson's Disease Foundation estimates that there were approximately one million people living with Parkinson's disease in the United States in 2014. Prevalence of Parkinson's disease increases with age, with approximately 1.6% of people 65 years old or older having the disease compared with 0.3% of people in the general population. As the U.S. population ages, the number of people living with Parkinson's disease in the United States is expected to grow at approximately 3% per year.

The most commonly prescribed treatments for Parkinson's disease are levodopa-based therapies. Levodopa is converted to dopamine in the body to replace the dopamine loss caused by the disease. Levodopa is generally effective in providing at least partial relief from the symptoms of Parkinson's disease, but fails to modify the underlying disease process. Patients initially take levodopa therapy approximately three times daily and receive relief from symptoms of Parkinson's disease for much of the day. This period of relief is known as "ON" time. As the effects of levodopa wear off, the symptoms of Parkinson's disease return. This is known as "OFF" time. By properly managing the timing of levodopa administration, patients with early stage Parkinson's disease can largely avoid "OFF" time during the day.

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The table below defines the various terms that are used to describe the fluctuating symptoms of Parkinson's disease.

Term	Definition
"ON" time	"ON" time refers to periods of adequate control of Parkinson's disease symptoms.
"OFF" time	"OFF" time refers to periods of the day when medication is not working well, causing return of Parkinson's disease symptoms.
Dyskinesia	Involuntary twisting, turning movements and loss of control of voluntary movements.
LID	Levodopa induced dyskinesia, which is a side effect of administration of levodopa and occurs during "ON" time.
Troublesome LID	LID that interferes with the patient's daily function or causes meaningful discomfort.
"ON" with troublesome LID	Periods of adequate control of Parkinson's disease symptoms but with troublesome LID.
"ON" without troublesome LID	Periods of adequate control of Parkinson's disease symptoms without troublesome LID.

Over time, as Parkinson's disease progresses and dopaminergic neurons further degenerate, most patients require increasing doses of levodopa to achieve equivalent therapeutic benefit. Even with increased doses of levodopa, patients may begin to exhibit unpredictable "OFF" episodes throughout the day. In the later stages of the disease, many patients will suffer from LID. Patients with LID suffer from involuntary non-purposeful movements and reduced control over voluntary movements. The cause of LID is unknown, but it is associated with the pulsatile administration of levodopa treatment, degeneration of key brain structures, the duration of levodopa treatment, total levodopa exposure, and other factors. LID can become severely disabling, rendering patients unable to perform routine daily tasks and increasing their risk of falling and social isolation. As Parkinson's disease progresses, the symptoms of LID worsen in frequency and severity. Eventually the total time that a patient spends either "OFF" or "ON" with troublesome LID can become a majority of his or her day. In addition, many Parkinson's disease patients at this stage have difficulty swallowing solid food or pills.

The chart below illustrates the fluctuating symptoms that an early and a late stage Parkinson's disease patient may experience during a two-dose cycle of levodopa taken during a portion of the waking hours.

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LID can be managed by decreasing the amount of levodopa administered to a patient, but this change can result in an increase in "OFF" time and a decrease in "ON" time. Many patients would rather endure periodic episodes of LID than face unpredictable "OFF" episodes. As a result, these patients will choose to maintain their dose of levodopa even though they will experience times when they are "ON" but suffering from troublesome LID. We estimate that half of Parkinson's disease patients in the United States develop motor complications within five years of initiating levodopa therapy, and approximately 70% of these patients suffer from LID.

Limitations of existing Parkinson's treatments

There are currently no medications that are approved for marketing in the United States or Europe for the treatment of LID, a motor complication associated with use of the levodopa-based therapies. As a result, clinicians sometimes attempt to manage LID with existing Parkinson's disease products designed to increase the levels of dopamine activity in the brain. Examples include Azilect® (Teva), Requip XL (GSK), Mirapex ER (BI), Neupro® Patch (UCB), Comtan® (Novartis), Duopa (Abbvie), and Rytary (IMPAX). These Parkinson's therapies produce clinically relevant reductions in "OFF" time ranging from 0.7-1.9 hours, which mostly translate into increases in "ON" time without troublesome LID. However, none of these products reduce LID and some actually increase LID.

Physicians may also attempt to use the immediate-release form of amantadine to treat LID, even though only approved for the treatment of Parkinson's disease. This approach is supported by a number of investigator-initiated clinical studies and case studies, which suggest that it may be effective for the treatment of LID. However, these studies were not well-controlled clinical trials that meet evidence-based clinical or regulatory standards.

In addition to the limited data regarding its effectiveness, we believe that the use of amantadine to treat LID has also been limited by potential side effects at dose levels considered to be effective. The majority of Parkinson's disease patients tolerate twice-daily dosing of 100 mg of amantadine, but often this dosing regimen is insufficient to provide adequate symptom relief. The available literature on amantadine for the treatment of LID indicates that higher doses of amantadine produce a greater reduction in LID symptoms. However, the increased frequency of adverse events at higher doses, in particular CNS events and sleep disturbances, generally limits the use of amantadine at doses greater than 200 mg per day. Immediate-release versions of amantadine are absorbed relatively rapidly by the body with peak concentrations in the blood being reached two to four hours after administration. We believe that the side effects associated with immediate-release amantadine are associated with this rapid rise in concentration within a few hours after dosing.

The Adamas Solution ADS-5102

ADS-5102 is a controlled-release version of amantadine that addresses many of the limitations of immediate-release amantadine by allowing higher daily doses of amantadine to be administered once-daily at bedtime without a significant increase in side effects. In patients taking ADS-5102, the amantadine plasma concentration achieved in the early morning through mid-day is estimated to be approximately two-times that reached following administration of immediate-release amantadine, providing symptomatic relief to patients as they engage in their daily activities. Further, the lower concentrations occur in the evening, reducing the potential negative impact of amantadine's sleep-related side effects. In addition, ADS-5102 capsules can be opened to sprinkle the contents on food for use by Parkinson's disease patients who have difficulty swallowing due to their illness.

In our Phase 2/3 trial, ADS-5102 demonstrated statistically significant improvements when compared to placebo. In addition, at the chosen 340 mg dose, the benefits compared to baseline prior to taking ADS-5102 included a 3.8-hour increase in "ON" time without troublesome LID, a 43% reduction in troublesome LID (a reduction in the functional impact of LID), no worsening of

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Parkinson's disease symptoms, and a trend towards reduction in "OFF" time. This 3.8-hour increase in "ON" time without troublesome LID was related to a 2.7 hours decrease in "ON" time with troublesome LID and a 1.1 hour reduction in "OFF" time, though this latter result was not statistically significant. Notably, there was no difference from placebo in the incidence of sleep-related adverse events. By both increasing "ON" time without troublesome LID and reducing LID, ADS-5102 provides a combination of significant clinical benefits that we believe cannot be achieved with other drugs for Parkinson's disease. While there are a number of approved drugs and certain drug candidates that have been demonstrated to reduce "OFF" time, none have been demonstrated to reduce LID and in most cases actually increase LID.

ADS-5102 Phase 3 registration trials for LID

In December 2013, after completion of our Phase 2/3 study, we had a written interaction with the FDA to discuss the remaining clinical studies required to support the submission of an NDA for ADS-5102 for the treatment of LID. Based on the FDA interaction, we initiated the following Phase 3 registration trials:

EASE LID was initiated in June 2014. The study is planned to enroll approximately 130 subjects in a 26-week multi-center, randomized, double-blind, placebo-controlled trial and will assess the efficacy of a once daily 340 mg dose of ADS-5102 administered at bedtime for the treatment of LID in individuals with Parkinson's disease. The primary endpoint of this study is a reduction in LID as assessed at 12 weeks by changes in the Unified Dyskinesia Rating Scale (UDysRS) along with supporting data from secondary endpoints. The secondary endpoints include changes in the UDysRS as assessed at 24 weeks, "ON" time without troublesome dyskinesia and "OFF" time based on home diaries, the Unified Parkinson's Disease Rating Scale (MDS-UPDRS), and the clinician's global impressions.

EASE LID 2 is an open label safety study which was initiated in July 2014. The study is planned to enroll approximately 200 subjects in a 52-week trial.

EASE LID 3 was initiated in October 2014. The study is planned to enroll approximately 70 subjects in a 13-week multi-center, randomized, double-blind, placebo-controlled trial and will assess the efficacy of a once daily 340 mg dose of ADS-5102 administered at bedtime for the treatment of LID in individuals with Parkinson's disease. The primary endpoint of this study is a reduction in LID as assessed at 12 weeks by changes in the Unified Dyskinesia Rating Scale (UDysRS) along with supporting data from secondary endpoints, which includes changes in "ON" time without troublesome dyskinesia and "OFF" time based on home diaries.

Enrollment of all of the Phase 3 registration trials is expected to be completed in 2015. We expect to announce top line results from the EASE LID trial by the first quarter of 2016 with the results from the remaining trials later in 2016. If the results of the Phase 3 registration trials are successful, we plan to submit the NDA for ADS-5102 in support of our LID indication in 2016.

Commercialization plan for ADS-5102 in LID

We intend to commercialize ADS-5102 in the United States, subject to FDA approval, by developing our own sales force and in other markets through distribution agreements and collaborations with CNS-focused pharmaceutical companies. We plan to focus our commercial efforts on the approximately 4,000 neurologists and movement disorder specialists in the United States who are responsible for the treatment of greater than 60% of the patients with late stage Parkinson's disease. As these physician specialists are heavily concentrated in major urban markets, we believe an approximately 60 member specialty sales force will provide adequate reach and frequency of communication for successful commercialization.

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We will be responsible for negotiating coverage, reimbursement, and formulary placement decisions for ADS-5102 in the United States. We believe that if ADS-5102 is approved as the first product indicated in the United States for the treatment of LID, most payors are likely to extend coverage to it and that its placement on payor formularies and the amount of reimbursement will be influenced by the availability and pricing of branded treatments for symptoms of Parkinson's disease, branded treatments for other forms of dyskinesia, generic amantadine, and surgical treatments for symptoms of Parkinson's disease.

Prior to completing the Phase 3 registration trials, we intend to hold a pre-NDA meeting with the FDA to determine the contents of the NDA submission for ADS-5102. In addition, prior to submitting the NDA, we intend to meet with regulators in certain markets outside the United States to determine the regulatory pathways for access to those markets.

ADS-5102 Phase 1 data pharmacokinetic profile

Our development of ADS-5102 was driven by the discovery that the side effects of amantadine are not caused solely by the absolute levels of amantadine in the blood, but rather by the speed at which the maximum concentrations are reached. Immediate-release amantadine is rapidly absorbed by the body, with its maximum concentration in the blood being reached in two to four hours. This rapid increase in blood concentration levels is associated with an increased level of CNS side effects. In contrast, the same amount of ADS-5102 is absorbed more slowly with the maximum concentration being achieved many hours later. This slower increase in blood concentration levels is associated with fewer CNS side effects than a more rapid one.

Because of this improved tolerability due to the novel pharmacokinetic profile, we were able to investigate ADS-5102 in clinical studies at dose strengths from 1.3 to 2.1 times greater than the 100 mg twice-daily dose typically used with immediate-release amantadine.

Based on our clinical experience, we are developing a 340 mg dose of ADS-5102 to be taken once-daily at bedtime. With this regimen, highest amantadine plasma concentration would be achieved from the early morning through mid-day, providing relief to patients as they engage in their daily activities, and the lowest concentrations would occur in the evening, reducing the potential for sleep-related side effects. The once-daily dosing regimen may also provide enhanced convenience and compliance as compared to a twice-daily dosing regimen.

We have completed seven Phase 1 pharmacokinetic studies in healthy subjects with two controlled-release versions of amantadine having slightly different release rates. The most frequently occurring adverse events reported in the Phase 1 studies were headache, fatigue, and dizziness, occurring in 5-10% of subjects, and the majority of adverse events were categorized as mild.

ADS-5102 Phase 2/3 data

In 2013, we completed a successful Phase 2/3 clinical trial of ADS-5102 for the treatment of LID. This trial was designed to investigate the safety and efficacy of three dose levels of ADS-5102 administered once-daily at bedtime for the treatment of LID in Parkinson's disease. The study enrolled 83 Parkinson's disease patients, who were randomized in a 1:1:1:1 ratio to the four treatment groups: placebo, 260 mg ADS-5102, 340 mg ADS-5102, and 420 mg ADS-5102. The table below summarizes the change from baseline compared to placebo for the key efficacy endpoints measured in the study. In

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the two charts and discussion below relating to ADS-5102, only results with a p-value of 0.05 or less are considered to be statistically significant.

Outcome Measure	260 mg ADS-5102 N=19	340 mg ADS-5102 N=20	420 mg ADS-5102 N=19
	LS Mean Treatment Difference vs. Placebo (95% CI)		
UDysRS Total Score	5.6 (13.4, 2.2) p=0.159	11.3 (19.1, 3.5) p=0.005	10.0 (17.8, 2.2) p=0.013
ON Time w/o Troublesome LID, hours	3.3 (1.1, 5.5) p=0.004	3.0 (0.8, 5.2) p=0.008	2.7 (0.5, 5.0) p=0.018
OFF Time, hours	1.3 (2.7, 0.1) p=0.074	0.9 (2.3, 0.5) p=0.199	0.1 (1.4, 1.5) p=0.934
MDS-UPDRS (Part I, II, III)	1.2 (7.7, 10.1) p=0.786	2.2 (11.2, 6.9) p=0.636	1.7 (7.2, 10.6) p=0.705
MDS-UPDRS (Part IV, Item 4.2) Functional Impact of Dyskinesia	0.8 (1.4, 0.2) p=0.014	1.0 (1.6, 0.4) p=0.002	1.3 (2.0, 0.7) p=<0.001

The chart below shows the change in the Unified Dyskinesia Rating Scale, or UDysRS, score for each group in the EASED study after 8 weeks:

Both the 340 mg and 420 mg dose levels significantly reduced LID as measured by the change in the UDysRS total score over eight weeks versus placebo, meeting the primary endpoint for the clinical study (p=0.005 and p=0.013, respectively). The magnitude of the change for the 340 mg ADS-5102 group was a 43% reduction versus baseline and a 27% reduction versus placebo.

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In addition, ADS-5102 significantly increased "ON" time without troublesome LID at the 260 mg, 340 mg, and 420 mg dose levels from baseline to week eight relative to placebo by 3.3, 3.0 and 2.7 hours per day, respectively, as measured by patient diaries after eight weeks of treatment (least square means, p=0.004, p=0.008 and p=0.018, respectively). At the 340 mg dose level, "OFF" time was reduced by 0.9 hours per day from baseline relative to placebo after 8 weeks of treatment, though this latter result was not statistically significant (p=0.199).

Based on analysis of the pharmacokinetic, safety, and efficacy data from the Phase 2/3 study, we selected 340 mg ADS-5102 taken once-daily at bedtime as the recommended dose regimen and are using that dose in our ongoing Phase 3 trials. We believe that this dose offers the best benefit/risk ratio of the doses we have studied.

The chart below shows the average levels of "ON" time without troublesome LID, "ON" time with troublesome LID, "OFF" time, and sleep, recorded by patients in the 340 mg dose group and the placebo group at baseline and after eight weeks of treatment.

Treatment with ADS-5102 did not result in worsening of Parkinson's disease symptoms, as measured by the MDS-UPDRS combined score, a standard measurement of Parkinson's disease related disability. The adverse events reported in this study were typically mild to moderate in severity and consistent with Parkinson's disease and the known amantadine adverse event profile. Five patients had serious adverse events. The most common adverse events, occurring in more than 10% of the subjects or by more than two subjects in any ADS-5102 group, were constipation, dizziness, hallucination, dry mouth, fall, confusional state, headache, nausea, and asthenia. Notably, there was no difference from placebo in the incidence of sleep-related adverse events.

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Additional indications for ADS-5102

We intend to continue to review the results of preclinical studies, clinical trials, and case reports published in peer reviewed medical journals to evaluate additional potential CNS indications for ADS-5102, including hypokinetic movement disorders such as multiple sclerosis and post stroke deficits, and hyperkinetic movement disorders similar to LID, such as Huntington's chorea and tardive dyskinesia, and other disorders, such as depression, epilepsy, and TBI. We anticipate that by using the 505(b)(2) regulatory pathway, we will be able to initiate the clinical development of ADS-5102 in new indications typically with Phase 2 studies and will not need to conduct any Phase 1 studies prior to initiating such Phase 2 studies. As a result, we expect to retain substantial flexibility in our development plans and may be able to respond to new clinical data and changes in the commercial environment. We currently expect to initiate Phase 2 studies of ADS-5102 for one or more additional CNS indications in 2015.

ADS-8800 series (ADS-5102-based combination products)

Using the product development strategy we employed with memantine, we are investigating and will potentially develop additional combination products based upon combining ADS-5102 with second agents. We have identified certain approved CNS drugs that we believe have the potential to be combined with ADS-5102 to treat one or more chronic CNS conditions, such as Alzheimer's disease, Parkinson's disease, multiple sclerosis, epilepsy, psychosis, depression and TBI. Each combination will be designed to provide clinical benefits in specific indications where it appears that combination therapy including ADS-5102 can address a significant unmet clinical need. We believe we will be able to use the 505(b)(2) regulatory pathway to initiate clinical development of these product candidates. Additional drug-drug interaction studies to assess the potential for interaction between ADS-5102 and the second agent may be required unless the two agents have been previously studied. We anticipate progressing into Phase 2/3 studies in combination therapies with minimal additional work.

Additional programs (ADS-9000 series)

We believe our product development strategy is broadly applicable to addressing limitations of other CNS drugs beyond aminoadamantanes whose pharmacokinetic profiles limit dosing, and intend to initiate additional programs in 2015. We are currently evaluating several different approved CNS drugs to enhance pharmacokinetics for such drugs alone or in fixed-dose combinations with other approved drugs for potential use in a range of CNS indications.

Other wholly owned product candidates

ADS-8704 (outside of the United States only)

We have retained the rights to develop fixed-dose combinations of controlled-release memantine and donepezil outside of the United States. We are currently evaluating potential development and commercialization pathways for ADS-8704, a fixed-dose combination of our proprietary controlled-release version of memantine and donepezil for the treatment of moderate to severe dementia related to Alzheimer's disease in various non-U.S. markets.

ADS-8902 for severe influenza

We developed ADS-8902, a triple combination antiviral drug therapy for influenza, which is designed to inhibit viral replication at multiple points in the virus proliferation pathway. ADS-8902 is a proprietary fixed-dose combination product containing three FDA approved products, amantadine, oseltamivir, and ribavirin. The National Institutes of Health, or NIH, is currently conducting a multi-center, 520 patient Phase 2/3 trial of amantadine, oseltamivir, and ribavirin for the treatment of severe influenza. The trial was initiated in 2011 and as of February 2015 it had randomized 318 patients. As

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the rate of enrollment in the trial is heavily dependent on the incidence and severity of seasonal influenza each year, we have not projected an anticipated completion date for the trial. If the NIH trial is successful, we may seek to license rights to ADS-8902 to pharmaceutical companies for which the treatment of influenza is a commercial focus. In 2010, we suspended further activities on ADS-8902, due to the expected length of the clinical trial and a change in our strategic focus.

Our partnered products

Our memantine-based therapeutics are being developed and commercialized in the United States through our partnership with Forest for the treatment of dementia associated with moderate to severe Alzheimer's disease.

Namenda XR and Namzaric

Namenda XR is a controlled-release version of memantine approved in the United States in 2010 for the treatment of moderate to severe dementia related to Alzheimer's disease and is marketed in the United States by our partner Forest. Pursuant to our agreement, we have exclusively licensed to Forest multiple U.S. patents covering Namenda XR.

Namzaric is a once-daily fixed-dose combination of the approved drugs Namenda XR and donepezil that we co-developed with Forest for the treatment of moderate to severe dementia related to Alzheimer's disease in the United States.

Overview of Alzheimer's disease dementia

Alzheimer's disease dementia is a progressive neurodegenerative condition that affects over 5 million people in the United States. There is no known cure for Alzheimer's disease or any of the other conditions that cause dementia. Existing pharmaceutical therapies are approved for the treatment of symptoms of the disease, but have not been shown to alter disease progression. Even if disease modifying therapies are developed and approved, we believe it is likely that there will be a continuing need for symptomatic treatments. In 2014, approximately 2.7 million people in the United States were treated for Alzheimer's disease dementia, and U.S. sales of pharmaceutical treatments for Alzheimer's disease were approximately $2.9 billion. We believe that the number of people treated for Alzheimer's disease will continue to increase as the number of elderly people in the United States increases, diagnosis of dementia becomes more common, and health care reform improves access to treatments.

Existing treatments for Alzheimer's disease dementia

The only two classes of drugs approved for the treatment of Alzheimer's disease dementia are acetylcholinesterase inhibitors, or AChEIs, and NMDA receptor antagonists. Donepezil is the leading AChEI, and forms of memantine are the only NMDA receptor antagonists approved for Alzheimer's disease. Memantine is currently marketed by Forest in the United States in an immediate-release version under the brand name Namenda and in a controlled-release version under the brand name Namenda XR. Donepezil is sold by Pfizer and Eisai under the brand name Aricept and as a generic drug by a number of manufacturers. Namenda XR is approved for the treatment of moderate to severe dementia related to Alzheimer's disease, and donepezil is approved for the treatment of dementia in patients with mild to severe Alzheimer's disease.

Both memantine and donepezil are considered to be generally safe and well tolerated. The most common side effects of memantine are headache, diarrhea, and dizziness. The most common side effects of donepezil are nausea, diarrhea, not sleeping well, vomiting, muscle cramps, feeling tired, and not wanting to eat.

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Treatment of moderate to severe Alzheimer's disease dementia with combination therapy

The concurrent use of memantine and donepezil is a well-established treatment option for patients with moderate to severe dementia related to Alzheimer's disease. The current treatment recommendations from the American Association of Geriatric Psychiatry encourage the use of an AChEI for the treatment of mild Alzheimer's disease and then to add memantine when patients progress to the moderate phase of the disease. Of the approximately 1,200,000 patients treated with Namenda/Namenda XR annually in the U.S., we estimate that approximately 70% of these patients also receive an AChEI treatment.

Concurrent use of memantine and donepezil is supported by clinical data, which shows that in patients with moderate to severe Alzheimer's disease, combination therapy resulted in a statistically significant improvement in the Severe-Impairment-Battery, or SIB, a commonly used outcome measure, as compared to treatment with donepezil alone. A second study demonstrated that concurrent use of Namenda XR and an AChEI also demonstrated a statistically significant improvement in the SIB as compared to treatment with donepezil alone.

Concurrent treatment with memantine and donepezil is generally safe and well tolerated with the most common side effects seen in clinical trials being dizziness, headache, and diarrhea. Of these side effects, incidence of dizziness with concurrent treatment is 5% as compared with 1% for treatment with donepezil alone.

The Namzaric solution

In conjunction with Forest, we developed Namzaric, a once-daily fixed-dose combination of Namenda XR and donepezil, to simplify the co-administration of these drugs by a patient or caregiver with the goal of increasing compliance and adherence to the prescribed regimen. Namenda XR exhibits a much lower initial rise in plasma concentration when compared to immediate-release memantine, which we believe is central to its dosing protocol of once-daily administration and at a higher daily dose as compared to immediate-release memantine. By improving the tolerability and formulating a once-daily preparation of memantine, we have enabled a once-daily fixed-dose combination of memantine with donepezil. In addition, Namzaric capsules can be opened to sprinkle the contents on apple sauce. Forest plans to make Namzaric available in two dose strengths, initially, a combination of 28 mg memantine ER and 10 mg donepezil and a combination of 14 mg memantine ER and 10 mg donepezil. We believe that Namzaric has the potential to be adopted by patients already taking combination therapy, as well as moderate to severe patients currently taking donepezil alone.

Namzaric development pathway

We anticipate that while Namzaric has received initial FDA approval, Forest plans to submit a supplemental application to expand the indication for Namzaric to include patients who are on a stable dose of 10 mg donepezil and are ready to initiate treatment with Namzaric. This supplemental application will include manufacturing information to support two additional Namzaric doses: a fixed-dose combination of 7 mg Namenda XR/10 mg donepezil and a fixed-dose combination of 21 mg Namenda XR/10 mg donepezil. These additional dose combinations will allow patients who are receiving a stable dose of 10 mg donepezil but are naïve to Namenda XR to initiate treatment with Namzaric while utilizing the same three-step titration that is currently approved for Namenda XR.

Research and Development

We continue to maintain our commitment to research and development, and a significant portion of our operating expenses is related to research and development. See "Item 8. Financial Statements and Supplementary Data" of this Annual Report on Form 10-K for costs and expenses related to

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research and development, and other financial information for each of the fiscal years 2014, 2013 and 2012.

Intellectual property

Our success will significantly depend upon our ability to obtain and maintain patent and other intellectual property and proprietary protection for our drug candidates, including usage, pharmacokinetic, composition-of-matter, and formulation patents, as well as patent and other intellectual property and proprietary protection for our novel discoveries and other important technology inventions and know-how. In addition to patents, we rely upon unpatented trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position.

We seek to protect our proprietary information, in part, by using confidentiality agreements with our commercial partners, collaborators, employees, and consultants and invention assignment agreements with our employees and selected consultants. Despite these measures, any of our intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed, or misappropriated, or such intellectual property and proprietary rights may not be sufficient to permit us to take advantage of current market trends or otherwise to provide competitive advantages. For more information, please see "Risk factors Risks related to intellectual property."

Our current products and product candidates are based on novel discoveries related to the clinical implications of the timing of administration of drugs and pharmacokinetic and pharmacodynamic relationships. These discoveries led us to modify the pharmacokinetic profile of existing drugs in a manner that enables increased tolerability of higher doses as compared to immediate-release versions. We are able to apply these pharmacokinetic and pharmacodynamic insights to the development of novel fixed-dose combination therapeutics, potentially yielding significant clinical benefits. As such, our intellectual property covers the novel pharmacokinetic properties of our formulations and combinations and their methods of use.

As of February 15, 2015, we owned 24 issued U.S. patents, 17 U.S. patent applications and additional patents and patent applications in other jurisdictions. The patent portfolios for Namenda XR, Namzaric, ADS-8704, and ADS-5102 as of February 15, 2015 are summarized below:

Namenda XR, Namzaric and ADS-8704

Namenda XR and Namzaric are covered by a total of 13 of our issued U.S. patents containing method and compositions claims relating to their pharmacokinetic profile and method claims relating to dosing of memantine. These patents expire as late as 2029 and are exclusively licensed to Forest. We also own additional foreign patents and patent applications covering Namenda XR, Namzaric, and ADS-8704.

ADS-5102

ADS-5102 is currently covered by a total of nine issued U.S. patents and 16 additional patent applications containing method and composition claims relating to their pharmacokinetic profile and dosing of amantadine. These patents expire as late as 2030. These patents and patent applications are wholly owned by us and are not subject to any license agreements. We also own additional foreign patent applications covering ADS-5102.

Sales and marketing

We intend to commercialize ADS-5102 in the United States, subject to FDA approval, by developing our own sales force and in other markets through distribution agreements and collaborations with CNS-focused pharmaceutical companies. We plan to focus our commercial efforts

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on the approximately 4,000 neurologists and movement disorder specialists who are responsible for the treatment of approximately 60% of the patients in the United States with LID. As these physician specialists are heavily concentrated in major urban markets, we believe an approximately 60 member specialty sales force will provide adequate reach and frequency of communication for successful commercialization. We intend that the members of our specialty salesforce will have proven experience and be able to effectively communicate the clinical value and pharmacoeconomic advantage of ADS-5102. To complement the specialty sales force, we will recruit experienced sales management, marketing, and third party reimbursement professionals to support our commercialization efforts. We believe a targeted sales force will allow us to more effectively compete for future acquisitions and in-licensing opportunities.

License agreement with Forest

In November 2012, we entered in a license agreement with a wholly owned subsidiary of Forest, which was acquired by Actavis in July 2014. Subject to the terms of the license agreement, we granted Forest: an exclusive license, with the right to sublicense, under the relevant elements of our intellectual property, to commercialize human therapeutics containing memantine in the United States; a co-exclusive license along with us, with the right to sublicense, to develop and manufacture such products in the United States; and a non-exclusive license, with a right to sublicense, to develop and manufacture (but not commercialize) such products outside of the United States solely in support of the development or commercialization of such products within the United States. The license agreement established a joint development committee consisting of representatives from us and Forest to oversee the development of a fixed-dose memantine-donepezil product, such as Namzaric, in the United States with Forest having final decision making authority with certain restrictions. Forest is required to use commercially reasonable efforts to develop such a product in accordance with development and regulatory plans that we and Forest have mutually agreed upon that may be modified by the joint development committee or by Forest pursuant to the terms of the agreement. Forest is responsible for paying all costs associated with such development and reimburses us on a cost-plus basis for work performed by us at its request in support of the development. In addition, Forest is required at its expense to use commercially reasonable efforts to commercialize fixed-dose memantine-donepezil product in the United States.

Under our license agreement with Forest, we received a $65 million upfront payment in November 2012 and since 2012, a total of $95 million of development and regulatory milestones, including a final $30 million milestone payment in the fourth quarter of 2014. Commencing five years after the initial launch of a fixed-dose memantine-donepezil product in the United States, such as Namzaric, which Forest expects to launch in first half of 2015, we are entitled to receive royalties at rates ranging from the low double digits to the mid-teens on the net sales by Forest, its affiliates, and any sublicensees of such products in the United States. In addition, commencing in June of 2018, we are entitled to receive low to mid-single digit royalties on net sales in the United States by Forest, its affiliates, or any of its sublicensees of controlled-release versions of memantine, such as Namenda XR, or any other product covered by the terms of the license agreement. Forest's obligation to pay royalties with respect to fixed-dose memantine-donepezil products continues until the later of (i) 15 years after the commercial launch of the first fixed-dose memantine-donepezil product by Forest in the United States or (ii) the expiration of the Orange Book listed patents for which Forest obtained rights from us covering such product. Forest's obligations to pay royalties with respect to controlled-release versions of memantine or any other product covered by the agreement continue until the expiration of our Orange Book listed patents covering such product. Forest's obligations to pay royalties are subject to reduction in certain circumstances. In addition, Forest shall have no obligation to pay any royalty with respect to any product covered by the license agreement in any quarter in which there is significant competition from generic products, as defined in the agreement, in the United States. Under the terms of the license agreement, Forest substantially controls the commercialization of the products and the intellectual

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property rights subject to the license agreement, including the prosecution, maintenance, and enforcement of such rights. If we or our affiliates develop or commercialize the licensed products outside of the United States (other than in Japan) or otherwise enable a third party to do so, and such development or commercialization requires the use of or reference to certain data generated pursuant to the development plan, we will be obligated to make certain payments to Forest.

The license agreement terminates on a product by product basis upon the expiration of all royalty obligations with respect to each product and terminates in its entirety upon the expiration of all royalty obligations with respect to all products covered by the license agreement. Upon expiration of the license agreement with respect to a product, all licenses, and other rights granted to Forest by us with respect to that product become fully paid up and irrevocable. In addition, Forest may terminate the license agreement with respect to fixed-dose memantine-donepezil products by delivering to us notice of its intent to cease development and commercialization of such products.

As Forest has fully paid all the milestone payments to us under the license agreement, our rights to participate in and influence the prosecution, maintenance, and enforcement of the intellectual property rights subject to the license has decreased. In addition, our remedy for any breach of the license agreement by Forest is to seek damages or equitable relief, not termination of the license agreement. Furthermore, we have no right to terminate the license agreement with respect to controlled-release version of memantine or other products that are not fixed-dose memantine-donepezil products.

Competition

Our industry is highly competitive and subject to rapid and significant technological change. While we believe that our development experience and scientific knowledge provide us with competitive advantages, we may face competition from large pharmaceutical and biotechnology companies, smaller pharmaceutical and biotechnology companies, specialty pharmaceutical companies, generic drug companies, academic institutions, government agencies and research institutions, and others.

Many of our competitors may have significantly greater financial, technical, and human resources than we have. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel technologies that are more effective, safer, or less costly than any that will be commercialized by us, or obtain regulatory approval for their products more rapidly than we may obtain approval for ours. Our success will be based in part on our ability to identify, develop, and manage a portfolio of drugs that are safer, more efficacious, and/or more cost-effective than alternative therapies.

ADS-5102

Currently, there are no FDA or EMA drug therapies approved for the treatment of LID. While a number of pharmaceutical companies, including Merck, Novartis, Osmotica Pharmaceuticals, Avanir Pharmaceuticals, Newron Pharmaceuticals, Neurolixis Inc, Amarantus BioScience, Addex Pharma, and Neurim Pharmaceuticals Ltd have had programs aimed at developing treatments for LID, we believe ADS-5102 is one of the most advanced. Other products in late stage development for Parkinson's disease include product candidates from Kyowa Hakko, Acorda, Neuroderm, Acadia, Bial-Portela CSA, Biotie Therapies Corp, Genervon Biopharmaceuticals, Pharma Two B, and Depomed. Products approved to treat late stage Parkinson's disease include Azilect (Teva), Requip XL (GlaxoSmithKline), Mirapex ER (Boehringer Ingelheim), Neupro Patch (UCB), Comtan (Novartis), Sinemet® (Merck & Co., Inc.), Parcopa® (Jazz Pharmaceuticals, Inc.), Apokyn® (Bertek), Bromocriptine (Mylan Laboratories, Inc.), Zelapar (Valeant Pharmaceuticals International), Eldepryl® (Somerset

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Pharmaceuticals Inc.), Tasmar® (Valeant Pharmaceuticals International), Cogentin® (Oaks Pharma Akorn), Exelon® (Novartis Pharmaceuticals Corp.), Stalevo® (Novartis), Rytary (Impax), Duopa (Abbvie), and generic versions of amantadine and other drugs. Physicians may use these drugs to attempt to manage LID. In selective cases for late stage patients, physicians and patients/caregivers will consider neurosurgical intervention, such as deep brain stimulation.

Namenda XR/Namzaric

In the market for Alzheimer's disease treatments, Namenda XR and Namzaric compete or will compete with generic products such as galatamine, rivastigmine, and donepezil, as well as branded products such as the Exelon patch (Novartis) and Aricept 23 mg (Eisai). In addition, Forest currently markets Namenda, the immediate-release version of memantine, which physicians and patients may favor instead of Namenda XR, the controlled-release version. In addition, generic versions of Namenda may be available in 2015. Several generic manufacturers are currently seeking regulatory approval to market generic versions of Namenda XR and, with the recent FDA approval of Namzaric, they may seek to market generic versions of Namzaric. We are also aware that Lundbeck, Otsuka and other biopharmaceutical companies are developing treatments for Alzheimer's disease that may compete with Namenda XR and Namzaric.

Third-party reimbursement

Sales of pharmaceutical products depend in significant part on the availability of coverage and adequate reimbursement by third-party payors, such as state and federal governmental authorities, including those that administer the Medicare and Medicaid programs, managed care organizations and private insurers. Decisions regarding the extent of coverage and amount of reimbursement to be provided for Namenda XR, Namzaric and ADS-5102 are or will be made on a plan by plan basis. Each plan determines whether or not it will provide coverage for a drug, what amount it will pay the manufacturer for the drug, and on what tier of its formulary the drug will be placed. The position of a drug on the formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Also, third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. As a result, coverage, reimbursement, and placement determinations are complex, take time, and are often the subject of extensive negotiations between the payor and the maker of the drug.

Forest is responsible for obtaining coverage and negotiating reimbursement amounts and formulary placement for Namenda XR and Namzaric. Under our agreement with Forest, we will be entitled to receive payments from Forest based on future net sales of these products. The amount of revenue we will receive under the agreement is therefore significantly dependent on the extent to which Forest is able to obtain favorable coverage, reimbursement, and formulary placement decisions from payors.

We will be responsible for negotiating coverage, reimbursement, and formulary placement decisions for ADS-5102, if approved. Coverage, reimbursements, and placement decisions for a new product are based on many factors including the coverage, reimbursement, and placement of already marketed branded drugs for the same or similar indications, the safety and efficacy of the new product, availability of generics for similar indications, and the clinical need for the new product. Currently, there are no drugs approved for the treatment of LID, and generic amantadine is not approved for this indication.

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We have had preliminary discussions regarding the potential coverage, reimbursement, and placement of ADS-5102 with consultants and representatives of payors, but have not begun formal negotiations with any payors. Based on these discussions, we believe that if ADS-5102 is approved as the first product indicated for the treatment of LID, most payors are likely to extend coverage to it and that its placement on payor formularies and the amount of reimbursement will be influenced by the aforementioned products, generic amantadine, and generic and branded treatments for symptoms of Parkinson's disease. Within the Medicare program, as self-administered drugs, Namzaric and ADS-5102 would be, and Namenda XR is, reimbursed under the expanded prescription drug benefit, known as Medicare Part D. This program is a voluntary Medicare benefit administered by private plans that operate under contracts with the federal government. These Part D plans negotiate discounts with drug manufacturers, which are passed on to each of the plan's enrollees. Historically, Part D beneficiaries have been exposed to significant out-of-pocket costs after they surpass an annual coverage limit and until they reach a catastrophic coverage threshold. However, changes made by recent legislation will reduce this patient coverage gap, known as the "donut hole", by transitioning patient responsibility in that coverage range from 100% in 2010 to only 25% in 2020. To help achieve this reduction, since 2011, pharmaceutical manufacturers are required to pay quarterly discounts of 50% off the negotiated price of branded drugs issued to Medicare Part D patients in the donut hole.

If a drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as applicable, as well as with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, or the OBRA, and the Veterans Health Care Act of 1992, or the VHCA, each as amended. Among other things, the OBRA requires drug manufacturers to pay rebates on prescription drugs to state Medicaid programs and empowers states to negotiate rebates on pharmaceutical prices, which may result in prices for our future products that will likely be lower than the prices we might otherwise obtain. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply.

An ongoing trend has been for third-party payors, including the U.S. government, to apply downward pressure on the reimbursement of pharmaceutical products. Also, the trend towards managed health care in the United States and the concurrent growth of organizations such as health maintenance organizations may result in lower reimbursement for pharmaceutical products. We expect that these trends will continue as these payors implement various proposals or regulatory policies, including various provisions of the recent health reform legislation that affects reimbursement of these products. There are currently, and we expect that there will continue to be, a number of federal and state proposals to implement controls on reimbursement and pricing, directly and indirectly.

Manufacturing

We currently have no manufacturing facilities and limited personnel with manufacturing experience. We rely on third-party manufacturers to produce bulk drug substance and drug products required for our clinical trials of ADS- 5102. We plan to continue to rely upon contract manufacturers and to manufacture commercial quantities of our ADS-5102 and other product candidates if and when we receive approval for marketing by the applicable regulatory authorities.

Our current products and product candidates are based upon controlled-release coated pellet products that are quite difficult to manufacture. As shown below, these products consist of an inert core, a drug layer, an optional seal coating, and controlled-release coatings. Our products are made in a fluidized bed coating machine in sequential steps. At each step, the intermediate product is assayed and released if it meets the particular specification for that step. Once the extended or controlled-release coating is applied, the assay includes a step to insure that the desired dissolution rate is achieved. These coatings are relatively thin, and susceptible to changes in raw materials, temperature,

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humidity, and other manufacturing process parameters. We have invested significant time and money to understand and manipulate drug release, and will continue to do so.

Forest is responsible for all manufacturing related to Namenda XR and Namzaric. We have clinical supplies of ADS-5102 manufactured for us by a contract manufacturing organization under a development agreement and do not have any long-term contracts in place. We are currently seeking to qualify and to enter into long-term contracts with at least one manufacturer to include in our anticipated NDA for ADS-5102. Contract manufacturers often encounter difficulties involving production yields, quality control, and quality assurance, as well as shortages of qualified personnel, resources, and equipment. Qualifying and negotiating long-term contracts with manufacturers and providers of packaging services is a lengthy process. If at any time one or more of our qualified contract organizations were not able to manufacture our drug substance or provide the requisite services, our business and financial condition would be materially adversely affected.

Our third-party manufacturers, their facilities, and all lots of drug substance and drug products used in our clinical trials are required to be in compliance with current Good Manufacturing Practices, or cGMP. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP requirements and FDA satisfaction before any product is approved and we can manufacture commercial products. Our third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties. These actions could have a material impact on the availability of our products.

Government regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state, and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, recordkeeping, tracking, approval, import, export, advertising, and promotion of our products.

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The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- nonclinical laboratory and animal tests, including some that must be conducted in accordance with Good Laboratory Practices;
- submission of an IND, which must become effective before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug candidate for its intended use;
- pre-approval inspection of manufacturing facilities and selected clinical investigators for their compliance with Good Manufacturing Practices, or cGMP, and Good Clinical Practices; and
- FDA approval of an NDA to permit commercial marketing for particular indications for use.

The testing and approval process requires substantial time, effort, and financial resources. Prior to commencing the first clinical trial with a product candidate, we must submit an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the conduct of the clinical trial by imposing a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development. Further, an independent institutional review board for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial commences at that center. Regulatory authorities or an institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Some studies also include a data safety monitoring board, which receives special access to unblinded data during the clinical trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

In general, for purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1 Studies are initially conducted to test the product candidate for safety, dosage tolerance, absorption, metabolism, distribution, and excretion in healthy volunteers or patients.
- Phase 2 Studies are conducted with groups of patients with a specified disease or condition to provide enough data to evaluate the preliminary efficacy, optimal dosages and dosing schedule, and expanded evidence of safety. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 These clinical trials are undertaken in larger patient populations to further evaluate dosage, to provide statistically significant evidence of clinical efficacy, and to further test for safety in an expanded patient population at multiple clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. These trials may be done globally to support global registrations.

Our product development strategy often relies on using Phase 2/3 studies as a central element of our clinical development plans. Typically these studies involve the testing of two or more doses of a product candidate, as is characteristic of a Phase 2 study, and also include a sufficient number of patients so that statistically significant evidence of efficacy can be obtained, as is characteristic of a Phase 3 study. In addition, we conduct the studies in a manner that we believe is consistent with the requirements for a Phase 3 study. We believe this approach has the potential to significantly shorten

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the time frame required for clinical development. The FDA generally requires that sponsors successfully complete two Phase 3 studies to obtain approval for a new drug, though in certain circumstances a single Phase 3 study is sufficient. We design and conduct our Phase 2/3 studies in a manner that is intended to allow the study to qualify as a Phase 3 study for the purposes of approval. The FDA has broad discretion in determining whether or not a completed Phase 2/3 study will be considered the equivalent of a Phase 3 study for the purposes of approval, and there can be no assurance that the FDA will agree with our assessment that the design, conduct, and results of a Phase 2/3 study are such that the study should be treated as a Phase 3 study.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 studies may be made a condition to be satisfied after approval. The results of Phase 4 studies can confirm the effectiveness of a product candidate and can provide important safety information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate, as well as 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 product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

ANDA approval process

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, established abbreviated FDA approval procedures for drugs that are shown to be equivalent to proprietary drugs previously approved by the FDA through its NDA process. Approval to market and distribute these drugs is obtained by filing an abbreviated NDA, or ANDA, with the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications, and stability of the generic drug, as well as analytical methods, manufacturing process validation data, and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug. In certain situations, an applicant may obtain ANDA approval of a generic product with a strength or dosage form that differs from a referenced innovator drug pursuant to the filing and approval of an ANDA suitability petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not equivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved suitability petition. However, such a product might be approved under an NDA, with supportive data from clinical trials.

505(b)(2) approval process

Section 505(b)(2) of the FDCA provides an alternate regulatory pathway to FDA approval for new or improved formulations or new uses of previously approved drug products. Specifically, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon the FDA's findings of safety and effectiveness for an approved product that acts as the Reference Listed Drug, or RLD. The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support the change

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from the RLD. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Our current and anticipated product candidates based upon ADS-5102 are or will be based on already approved active pharmaceutical ingredients, or APIs, rather than new chemical entities, and a formulation that has been through Phase 1 studies. Accordingly, we expect to be able to rely on information from previously conducted studies involving our ADS-5102 formulation in our clinical development plans and our NDA submissions. For product candidates that involve novel fixed-dose combinations of existing drugs or for studies of an existing product or product candidate in a new indication, we expect that we will generally be able to initiate Phase 2/3 studies without conducting any new non-clinical or Phase 1 studies. In those instances where our product candidate is a pharmacokinetically enhanced version of an approved API, we will need to conduct certain non-clinical and Phase 1 studies to confirm the pharmacokinetic profile of the product candidate prior to conducting Phase 2/3 studies.

Orange Book listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use, or sale of the drug product for which the application is submitted. This last certification is known as a Paragraph IV certification. If the competitor has provided a Paragraph IV certification to the FDA, the competitor must also send notice of the Paragraph IV certification to the holder of the NDA for the RLD and the patent owner once the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification prevents the FDA from approving the application until the earlier of 30 months from the date of the lawsuit, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the applicant. The applicant may also elect to submit a "Section VIII" statement certifying that its proposed label does not contain, or carves out, any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. We and Forest have received notices of ANDAs submitted to the FDA requesting permission to manufacture and market generic versions of Namenda XR, and we, Forest, Forest Laboratories Holdings Ltd., Merz Pharma GmbH & Co. KGaA and Merz Pharmaceuticals GmbH are currently in litigation with the notifying parties. For further information, see " Legal proceedings."

NDA submission and review by the FDA

The results of product development, nonclinical studies, and clinical trials are submitted to the FDA as part of an NDA. The submission of an NDA requires payment of a substantial user fee to the FDA. The FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality, and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an

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application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Once the NDA submission has been accepted for filing, which occurs, if at all, within 60 days after submission of the NDA, the FDA's goal for a non-priority review of a 505(b)(2) NDA is ten months to complete the review process for the application and respond to the applicant, which can take the form of either a Complete Response Letter or Approval. The review process is often significantly extended by FDA requests for additional information, studies, or clarification. The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information, and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product. FDA approval of any NDA submitted by us will be at a time the FDA chooses. Also, if regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require Phase 4 post-marketing studies to monitor the effect of approved products, and may limit further marketing of the product based on the results of these post-marketing studies.

Post-approval requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences. Drug and biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP regulations and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a product from distribution, or withdraw approval of the NDA.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy, purity, and potency that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use.

Moreover, the recently enacted Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products related to product and tracking and tracing. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding the drug products to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufactures will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

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Other healthcare regulations

Our business activities, including but not limited to, research, sales, promotion, distribution, medical education, and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services and its various divisions, including the Centers for Medicare and Medicaid Services, and state and local governments. Our business activities must comply with numerous healthcare laws, including but not limited to, the federal Anti-Kickback Statute, the False Claims Act, the Veterans Health Care Act, and similar state laws.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing, or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government.

We and our business activities are subject to the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Additionally, the federal Physician Payments Sunshine Act within the Patient Protection and Affordable Care Act, or PPACA, and its implementing regulations, require certain manufacturers of drugs, devices, biological, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable business associates and possibly other persons, and gave state

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attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The Veterans Health Care Act of 1992 requires manufacturers of "covered drugs" to offer those drugs for sale to certain federal agencies, including but not limited to, the Department of Veterans Affairs, on the Federal Supply Schedule, which requires compliance with applicable federal procurement laws.

Depending on the circumstances, failure to comply with these laws can result in penalties, including criminal, civil, and/or administrative criminal penalties, damages, fines, disgorgement, exclusion of products from reimbursement under government programs, "qui tam" actions brought by individual whistleblowers in the name of the government, refusal to allow us to enter into supply contracts, including government contracts, reputational harm, diminished profits, and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our business.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals designed to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, in March 2010, the PPACA was passed, which has the potential to substantially change health care financing by both governmental and private insurers, and to significantly impact the U.S. pharmaceutical industry. The PPACA, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Federal laws providing for patent term extensions and data exclusivity

Provisions of various federal laws may allow a company to extend market exclusivity for a product beyond the expiration dates of the patents covering the product by either extending the term of the patents or limiting the right of a competitor to reference the company's data in a regulatory

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submission. These laws include the Hatch-Waxman Act and the Best Pharmaceuticals for Children Act of 2002. We do not anticipate materially benefiting from these provisions.

Foreign regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop or sell any products outside of the United States. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary greatly from country to country.

Employees

As of December 31, 2014, we had 43 full-time employees. Of these employees, 20 were engaged in research and development. Our employees are not represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Corporate and other Information

We were incorporated in Delaware in November 2000 under the name NeuroMolecular, Inc. In December 2004, we changed our name to NeuroMolecular Pharmaceuticals, Inc., and in July 2007 we changed our name to Adamas Pharmaceuticals, Inc.

Our principal executive offices are located at 1900 Powell Street, Suite 750, Emeryville, California 94608, and our telephone number is (510) 450-3500. Our website address is *www.adamaspharma.com*. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document.

We make available, free of charge on our corporate website, copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements, and all amendments to these reports, as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission pursuant to Section 13(a) or 15(d) of the Securities Exchange Act. We also show detail about stock trading by corporate insiders by providing access to SEC Forms 3, 4 and 5. This information may also be obtained from the SEC's on-line database, which is located at *www.sec.gov*. Our common stock is traded on the NASDAQ Stock Market under the symbol "ADMS".

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. As such, we are eligible for exemptions from various reporting requirements 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 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation. We will remain an emerging growth company until the earlier of (1) December 31, 2019, (2) the last day of the fiscal year (a) in which we have total annual gross revenue of at least $1.0 billion or (b) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

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Item 1A. Risk Factors

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations and future growth prospects. Our business could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Annual Report on Form 10-K, including our condensed consolidated financial statements and related notes.

Risks related to our financial condition and need for additional capital

Although we reported net income for the fiscal years ended December 31, 2014, 2013, and 2012, we incurred significant losses in prior years and expect to incur substantial losses in the future.

We are a clinical-stage specialty pharmaceutical company and do not currently directly market any products. We currently exclusively license U.S. patent rights for two approved products, Namenda XR and Namzaric (formerly known as MDX-8704), to Forest Laboratories, or Forest, a wholly owned subsidiary of Actavis plc, and Forest markets Namenda XR and intends to market Namzaric in the United States, but we do not currently receive royalties on the sales of those products. We continue to incur significant research and development and general and administrative expenses related to our product candidates and our operations. Although we reported net income for the fiscal years ended December 31, 2014, 2013, and 2012, this was almost entirely due to milestone payments we received pursuant to our license agreement with Forest. We incurred significant operating losses in 2011 and prior years and as we received our final milestone payment in 2014 pursuant to our license agreement with Forest, we expect to incur substantial and increasing losses for the foreseeable future. As of December 31, 2014, we had an accumulated deficit of $10.3 million.

We have financed our operations primarily through our collaboration with Forest, public and private equity offerings, and, to a lesser extent, government grants, venture debt, and benefits from tax credits made available under a federal stimulus program supporting drug development. We have devoted substantially all of our efforts to research and development, including clinical studies, but have not completed development of any product candidates. We anticipate that our expenses will increase substantially as we:

- conduct Phase 3 registration trials of our lead wholly owned product candidate, ADS-5102 in levodopa induced dyskinesia, or LID;
- initiate and conduct clinical trials of ADS-5102 for treatment of other indications in addition to LID;
- seek regulatory approvals for our product candidates that successfully complete clinical studies;
- establish a specialty CNS sales force and distribution and marketing capabilities to commercialize products for which we may obtain regulatory approval;
- enhance operational, financial, and information management systems and hire more personnel, including personnel to support development of our product candidates and, if a product candidate is approved, our commercial operations;
- continue the research, development, and manufacture of our current product candidates; and
- seek to discover or in-license additional product candidates.

To be profitable in the future, we or our current and future potential collaboration partners must succeed in developing and commercializing products with significant market potential. This will require us or our partners to be successful in a range of activities, including advancing product candidates into clinical trials, completing clinical studies, and obtaining regulatory approvals related to those product

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candidates, and manufacturing, marketing, and selling those products for which regulatory approvals are obtained. We or our partners may not succeed in these activities, and, as a result, we may never generate revenue that is sufficient to be profitable in the future. We will not be entitled to receive any royalty payments with respect to sales of Namenda XR until June 2018, and with respect to sales of our second partnered product, Namzaric, until the first half of 2020, five years after its expected launch in the United States.

Even if we attain profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve or sustain profitability would cause cash generated from operations to be inadequate to fund future operations and could depress the value of our stock and impair our ability to raise capital, expand our business, diversify our product candidates, market our product candidates, if approved, or continue our operations.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. We received our final milestone payment under our license agreement with Forest in 2014. Any future revenue will depend on the establishment of potential future collaboration and license agreements, if any, and the achievement of any upfront or milestone payments provided thereunder and sales of our product candidates, if approved. Accordingly, upfront and milestone payments may vary significantly from period to period, and any such variance could cause a significant fluctuation in our operating results from one period to the next. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including:

- the level of demand for our products, should any of our product candidates receive regulatory approval, which may vary significantly as they are launched and compete for position in the marketplace;
- pricing and reimbursement policies with respect to our products candidates, if approved, and the competitive response from existing and potential future therapeutic approaches that compete with our product candidates;
- the cost of manufacturing our product candidates, which may vary due to a number of factors, including the terms of our agreements with contract manufacturing organizations, or CMOs;
- the timing, cost, level of investment, and success or failure of research and development activities relating to our pre-clinical and clinical-stage product candidates, which may change from time to time;
- expenditures that we may incur to acquire and develop additional product candidates and technologies;
- the timing and success or failure of clinical studies for competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- future accounting pronouncements or changes in our accounting policies; and
- changing or volatile U.S., European, and global economic environments.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our

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failing to meet the expectations of industry or financial analysts or investors for any period. If our operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated operating results and/or earnings guidance that we may provide.

We may need additional funds and, if we cannot raise additional capital when needed, we may have to curtail or cease operations.

We are seeking to advance multiple product candidates through the research and clinical development process. The completion of the development and the potential commercialization of our product candidates, should they receive approval, will require substantial funds. As of December 31, 2014, we had approximately $158.7 million in cash, cash equivalents and investments. We believe that our available cash and cash equivalents will be sufficient to fund our anticipated level of operations for at least the next 12 months, but there can be no assurance that this will be the case. Our future financing requirements will depend on many factors, some of which are beyond our control, including:

the rate of progress and cost of our clinical studies;

the initiation of additional clinical studies or new programs;

the timing of, and costs involved in, seeking and obtaining approvals from the U.S. Food and Drug Administration, or FDA, and potentially other regulatory authorities;

the costs of commercialization activities related to our product candidates should any be approved, including initiating and expanding our sales, marketing, and distribution activities;

the degree and rate of market acceptance of any approved products launched by us, Forest, or any future partners;

the coverage of our products, if approved, by third-party payors and the formulary tier in which health plans and other payors place our products and the rate at which the products are reimbursed;

our ability to enter into additional collaboration, licensing, commercialization, or other arrangements and the terms and timing of such arrangements; and

the emergence of competing therapeutic approaches or other adverse market developments.

We do not have any committed external source of funds or other support for our development efforts other than our license agreement with Forest, which may be terminated by Forest upon delivery of notice. Until we can generate sufficient revenue from our own products and from royalties paid to us by Forest pursuant to our license agreement to finance our operations, which we may never do, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, asset sales, and other marketing and distribution arrangements. Additional financing may not be available to us when we need it or it may not be available on favorable terms. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams, or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable

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to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend one or more of our clinical studies or research and development programs or our commercialization efforts.

Risks related to the development and commercialization of our current and future products

Our success depends heavily on the approval and successful commercialization of ADS-5102, the successful U.S. commercialization by Forest of Namzaric and the successful U.S. commercialization by Forest of Namenda XR. If we are unable to successfully commercialize ADS-5102 or Forest is unable to successfully commercialize Namzaric or Namenda XR in the U.S., or if either we or Forest experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources into the development of ADS-5102, an oral once-daily controlled-release version of the FDA-approved drug amantadine, and Namzaric, a fixed-dose combination of the FDA-approved drugs memantine and donepezil. Namzaric has been exclusively licensed to Forest in the United States. In addition, we have granted Forest a royalty-bearing license under certain of our patents to commercialize Namenda XR, a controlled-release version of memantine, in the United States. Our ability to generate product and royalty revenue will depend heavily on the successful development, regulatory approval and eventual commercialization of ADS-5102 and successful commercialization of Namzaric and Namenda XR. Under the terms of our license agreement with Forest, we will not be entitled to receive royalty payments on the sale of Namenda XR until June 2018 and royalty payments on the sale of Namzaric until the first half of 2020, five years after its expected launch. The success of these drugs will depend on numerous factors, including:

- successfully completing clinical studies for ADS-5102;
- receiving marketing approval for ADS-5102 from the FDA and, to a lesser extent, similar regulatory authorities outside the United States for our product candidates;
- establishing commercial manufacturing arrangements with third parties;
- launching commercial sales of any of the product candidates that may be approved;
- the medical community and patients accepting any approved product;
- the placement of any approved products on payors' formulary tiers and the reimbursement rates established for the approved products;
- effectively competing with other therapies;
- any approved products continuing to have an acceptable safety profile following approval; and
- obtaining, maintaining, enforcing, and defending intellectual property rights and claims.

If we or Forest do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

Forest's ability to successfully commercialize Namzaric and Namenda XR will depend in part on its ability to transition patients currently being prescribed the immediate-release version of memantine, known as Namenda IR, to Namenda XR and subsequently or directly to Namzaric. The Attorney General of the State of New York has filed a lawsuit against Forest and Actavis challenging Forest's announced plan to discontinue sales of Namenda IR in the fall of 2014 and seeking to require Forest and Actavis to, among other things, continue selling Namenda IR until generic memantine is commercially available, expected to occur in the second half of 2015. If this litigation or other factors negatively impact Forest's ability to successfully commercialize Namenda XR or Namzaric, our future royalty income could be materially adversely

affected.

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ADS-5102 is our only product candidate in clinical trials, and we cannot give any assurance that the Phase 3 clinical trials or development program will be successful or completed in a timely or effective manner. If clinical studies of ADS-5102 or our other product candidates fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. Our failure to successfully complete our Phase 3 registration trials for ADS-5102, or otherwise adequately demonstrate the safety and effectiveness of this product candidate will prevent us from receiving regulatory approval and would have a material and adverse impact on our business.

ADS-5102 is our only product candidate in clinical trials. Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety and efficacy of our product candidates in humans. Clinical studies are expensive, are difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more of our clinical studies could occur at any stage of testing. The outcome of preclinical testing and early clinical studies may not be predictive of the success of later clinical studies, and interim results of a clinical study do not necessarily predict final results. For example, the successful results of our Phase 2/3 study of ADS-5102 for the treatment of LID, including the lack of difference from placebo in the incidence of sleep-related adverse events or other safety measures, may not be repeated in our Phase 3 registration trials. Furthermore, as the design of our Phase 3 registration trials differ in a number of respects from our Phase 2/3 study, including longer study periods, and the results, such as the reduction in LID compared to baseline prior to the administration of ADS-5102, may vary. This observed benefit from our Phase 2/3 study may prove to be inconclusive or negative in our Phase 3 results if the duration of response, or other efficacy measure, decreases over time or patients are found to require increasing doses of ADS-5102 to achieve equivalent therapeutic benefits, as may be the case with levodopa in some patients. As the prevalence of Parkinson's disease increases with age, there may also be worsening of Parkinson's disease symptoms of the patients, or other safety issues that arise whether related or unrelated to ADS-5102, that may negatively affect the Phase 3 registration trial results. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing promising results in earlier clinical trials. A 2009 study completed by the Tufts Center for the Study of Drug Development estimated that less than 47% of certain CNS drugs in Phase 3 clinical trials proceeded to regulatory review.

We expect to announce top line results from the first of our Phase 3 registration trials, EASE LID, by the first quarter of 2016, with the results from the remaining trials later in 2016. If the data from any of our Phase 3 registration trials fail to adequately demonstrate the safety and effectiveness of ADS-5102, we may not be able to pursue or obtain regulatory approval, which would have a material and adverse impact on our business.

We may experience numerous unforeseen events during, or as a result of, clinical studies that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including that:

clinical studies of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;

the number of patients required for clinical studies of our product candidates may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate, or patients may drop out of these clinical studies at a higher rate than we anticipate;

the cost of clinical studies of our product candidates may be greater than we anticipate;

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- the conduct of the Phase 3 registration trials for ADS-5102 for LID may require more resources than we anticipate, as these trials require the initiation and training of a large number of sites in the United States and Europe, compliance with a variety of foreign and domestic governmental regulations and new initiatives and processes for which we do not have prior experience implementing;

- our clinical sites and clinical investigators may fail to comply with, or inconsistently apply, the trial protocols, regulatory requirements including Good Clinical Practices, contractual obligations and the rating assessments;

- our patients or their caregivers may fail to comply with their treatment instructions or home diaries;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- we might have to suspend or terminate clinical studies of our product candidates for various reasons, including a finding that our product candidates have unanticipated serious side effects or other unexpected characteristics or that the patients are being exposed to unacceptable health risks;

- regulators may not approve our proposed clinical development plans or may require costly modifications to such plans;

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical study or conduct a clinical study at a prospective study site;

- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and

- the supply or quality of our product candidates or other materials necessary to conduct clinical studies of our product candidates may be insufficient or inadequate.

If we are required to conduct additional clinical studies or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical studies or other testing of our product candidates, if the results of these studies or tests are not positive or are only modestly positive, or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;

- not obtain marketing approval at all;

- obtain approval for indications that are not as broad as intended;

- have the product removed from the market after obtaining marketing approval;

- be subject to additional post-marketing testing requirements; or

be subject to restrictions on how the product is distributed, marketed, or used.

Our product development costs will increase if we experience delays in testing or approvals. Significant clinical study delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to commercialize our product candidates and harm our business and results of operations.

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Even if clinical studies demonstrate statistically significant efficacy and acceptable safety for a product, the FDA or similar regulatory authorities outside the United States may not approve it for marketing.

In 2014, we initiated our remaining Phase 3 registration trials including a separate open-label safety study of ADS-5102 for LID. If these trials are successful, we intend to submit an NDA for ADS-5102 in that indication. It is possible that the FDA may not consider the results of these studies to be sufficient for approval of the product candidates in their proposed indications. If the FDA were to require us to conduct additional studies of ADS-5102 to support the NDA for approval for the product candidate in its currently contemplated indication, our business and financial results would be materially adversely affected.

Our product candidates have never been manufactured on a commercial scale, and there are risks associated with developing manufacturing and packaging processes and scaling them up to commercial scale.

Our product candidates have never been manufactured on a commercial scale, and there are risks associated with developing manufacturing and packaging processes and scaling them up to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency, and timely availability of raw materials or equipment. Furthermore, we have no long-term contracts with any CMOs for ADS-5102, and there is no assurance we will be able to negotiate contracts with one or more of these CMOs on acceptable terms or on a timely basis. These risks could delay an NDA for ADS-5102 and adversely affect regulatory approval of a product candidate. In addition, even if we could otherwise obtain regulatory approval for any product candidate, there is no assurance that CMOs with which we contract will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities or to produce it in sufficient quantities to meet the requirements for the potential launch of the product to meet potential future demand. If our CMOs are unable to produce sufficient quantities of the approved product, our regulatory approval or commercialization efforts would be significantly impaired, which would have an adverse effect on our business, financial condition, results of operations, and growth prospects.

Our product candidates, including ADS-5102, Namzaric, and Namenda XR are complex to manufacture, and manufacturing disruptions may occur.

Our product candidates, including ADS-5102, Namzaric, and Namenda XR all include controlled-released versions of existing drugs, and some are combinations of existing drugs. The manufacture and packaging of controlled-release versions of existing drugs or combinations of existing drugs are substantially more complex than the manufacture and packaging of the immediate-release versions of drugs alone. Even after the manufacturing process for a controlled-release or combination product has been scaled to commercial levels and numerous commercial lots have been produced, manufacturing disruptions may occur. Such problems may prevent the production of lots that meet the specifications required for sale of the product and may be difficult and expensive to resolve. For example, in November 2013, Forest recalled three packaged lots of Namenda XR because Forest's dissolution testing revealed a failure to meet specification throughout shelf life. Namenda XR is one of the components of Namzaric, Forest's fixed-dose combination product for treatment of moderate to severe Alzheimer's disease. If any such issues were to arise with respect to our product candidates or future products, if any, or if Forest's sales of Namzaric or Namenda XR were to be negatively impacted by such issues, our business, financial results or stock price could be adversely affected.

If generic manufacturers use litigation and regulatory means to obtain approval for generic versions of products on which our future revenue depends, our business will suffer.

Under the U.S. Food, Drug and Cosmetic Act, or FDCA, the FDA can approve an Abbreviated New Drug Application, or ANDA, for a generic version of a branded drug without the ANDA

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applicant undertaking the clinical testing necessary to obtain approval to market a new drug. In place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient(s) and is bioequivalent to the branded product, in addition to any data necessary to establish that any difference in strength, dosage form, inactive ingredients, or delivery mechanism does not result in different safety or efficacy profiles, as compared to the reference drug.

The FDCA requires that an applicant for approval of a generic form of a branded drug certify either that its generic product does not infringe any of the patents listed by the owner of the branded drug in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the Orange Book, or that those patents are not enforceable. This process is known as a paragraph IV challenge. Upon receipt of the paragraph IV notice, the owner has 45 days to bring a patent infringement suit in federal district court against the company seeking ANDA approval of a product covered by one of the owner's patents. The discovery, trial, and appeals process in such suits can take several years. If this type of suit is commenced, the FDCA provides a 30-month stay on the FDA's approval of the competitor's application. This type of litigation is often time-consuming and costly and may result in generic competition if the patents at issue are not upheld or if the generic competitor is found not to infringe the owner's patents. If the litigation is resolved in favor of the ANDA applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the standards for approval of ANDAs.

For example, as of August 6, 2014, we had received notice that several companies had submitted ANDAs to the FDA requesting permission to manufacture and market generic versions of Namenda XR, on which we are entitled to receive royalties from Forest beginning in June 2018. In the notices, these companies allege that the patents associated with Namenda XR, one of which is owned by Forest, one of which is exclusively licensed to Forest by Merz Pharma GmbH & Co. KGaA, and others of which are owned by us and licensed by us exclusively to Forest in the United States, are invalid, unenforceable, or will not be infringed by the companies' manufacture, use or sale of generic versions of Namenda XR. In January, February, April, May, and July 2014, we, style="font-family:Arial;font-size:10pt;">—

4,805

4,804

—

—

4,804

Foreign currency exchange forward contracts

—

—

—

—

—

29

—

29

Total assets
$
37,810

$
260,148

$
—

$
297,958

$
56,553

$
240,324

$
—

$
296,877

Liabilities

Foreign currency exchange forward contracts	$ —	$ 80	$ —	$ 80
	$ —	$ 26	$ —	$ 26

During the first quarter of 2014, there were no transfers of assets or liabilities between Level 1 and Level 2.

Investments at fair value were as follows (in thousands):

	March 29, 2014			
	Adjusted Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$33,005	$—	$—	$33,005
Certificates of deposit	3,600	—	—	3,600
Commercial paper	77,645	3	(8)	77,640
Corporate bonds	178,981	44	(117)	178,908

U.S. treasuries	4,801	4	—	4,805
Total available-for-sale investments	$298,032	$51	$(125)	$297,958

	December 28, 2013			
	Adjusted Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$51,749	$—	$—	$51,749
Certificates of deposit	3,840	—	—	3,840
Commercial paper	85,870	2	(12)	85,860
Corporate bonds	150,711	27	(143)	150,595
U.S. treasuries	4,802	2	—	4,804
Total available-for-sale investments	$296,972	$31	$(155)	$296,848

As of March 29, 2014, the Company's available-for-sale investments in certificates of deposit, commercial paper, corporate bonds, and U.S. treasuries have a contractual maturity term of no more than 16 months. Proceeds from sales and maturities of available-for-sale investments were $57.1 million for the first quarter of 2014. The Company had no net realized gains (losses) on short-term and long-term investments for the first quarter of 2014. The specific identification method is used to account for gains and losses on available-for-sale investments.

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As of March 29, 2014 and December 28, 2013, the Company held $46.8 million and $64.6 million of cash in banks, respectively.

Other-Than-Temporary Impairments

As a result of the Company's disposal of $3.1 million auction rate securities (par value) during the three months ended March 30, 2013, it recorded an approximately $0.2 million gain, which was recognized as Other gain (loss) in the Company's condensed consolidated statements of operations.

A roll-forward of amortized cost, cumulative other-than-temporary impairments ("OTTI") recognized in earnings and Accumulated other comprehensive loss is as follows (in thousands):

	Amortized Cost	Cumulative OTTI in Earnings	Unrealized Gain	OTTI Loss in Accumulated Other Comprehensive Loss	Accumulated Other Comprehensive Income (Loss)
Balance at December 29, 2012	$2,707	$(394)	$784	$(618)	$166
Call on investments	(87)	13	(25)	20	(5)
Investments sold	(2,620)	381	(759)	598	(161)
Balance at March 30, 2013	$—	$—	$—	$—	$—

4. Cost-method Investment

As of March 29, 2014, the Company's investment in a privately-held company was $9.0 million. This investment is accounted for as a cost-method investment, as the Company owns less than 20% of the voting securities and does not have the ability to exercise significant influence over operating and financial policies of the entity. The Company's cost-method investment is carried at historical cost in its condensed consolidated financial statements and measured at fair value on a nonrecurring basis. If the Company believes that the carrying value of the cost basis investment is in excess of estimated fair value, the Company's policy is to record an impairment charge in Other income (expense), net in the accompanying condensed consolidated statements of operations to adjust the carrying value to estimated fair value, when the impairment is deemed other-than-temporary. The Company regularly evaluates the carrying value of this cost-method investment for impairment. As of March 29, 2014, no event had occurred that would adversely affect the carrying value of this investment, therefore, the fair value of the cost-method investment is not estimated. The Company did not record any impairment charges for this cost-method investment during the three months ended March 29, 2014 and March 30, 2013.

5. Derivative Instruments

Foreign Currency Exchange Forward Contracts

The Company enters into foreign currency exchange forward contracts to manage its exposure to fluctuations in foreign exchange rates that arise primarily from its euro and British pound denominated receivables and euro denominated restricted cash balance amounts that are pledged as collateral for certain stand-by and commercial letters of credit. Gains and losses on these contracts are intended to offset the impact of foreign exchange rate fluctuations on the underlying foreign currency denominated accounts receivables and restricted cash, and therefore, do not subject the Company to material balance sheet risk. The forward contracts are with one high-quality institution and the Company consistently monitors the creditworthiness of the counterparty. The forward contracts entered into during the first quarter of 2014 were denominated in euros and British pound, and had maturities of no more than 35 days. The contracts are settled for U.S. dollars at maturity at rates agreed to at inception of the contracts.

As of March 29, 2014, the Company did not designate foreign currency exchange forward contracts as hedges for accounting purposes, and accordingly changes in the fair value of these instruments are included in Other gain (loss), net in the accompanying condensed consolidated statements of operations. For the first quarter of 2014, the before-tax effect of foreign currency exchange forward contracts not designated as hedging instruments was a loss of $0.4 million included in Other gain (loss), net in the condensed consolidated statements of operations.

The fair value of derivative instruments not designated as hedging instruments in the Company's condensed consolidated balance sheets was as follows (in thousands):

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	As of March 29, 2014			As of December 28, 2013		
	Gross Notional[1]	Prepaid Expenses and Other Assets	Other Accrued Liabilities	Gross Notional[1]	Prepaid Expenses and Other Assets	Other Accrued Liabilities
Foreign currency exchange forward contracts						
Related to euro denominated receivables	$20,609	—	$ (72)	$16,867	27	$ —
Related to British pound denominated receivables	912	—	(3)	—	—	(26)
Related to restricted cash	1,392	—	(5)	1,391	2	—
	$22,913	$—	$ (80)	$18,258	$29	$ (26)

(1) Represents the face amounts of forward contracts that were outstanding as of the period noted.

6. Balance Sheet Details

The following table provides details of selected balance sheet items (in thousands):

	March 29, 2014	December 28, 2013
Inventory:		
Raw materials	$13,199	$14,311
Work in process	47,746	49,172
Finished goods [1]	65,520	60,202
Total inventory	$126,465	$123,685
Property, plant and equipment, net:		
Computer hardware	$10,053	$9,692
Computer software[2]	17,236	16,988
Laboratory and manufacturing equipment	151,132	146,834
Furniture and fixtures	1,346	1,347
Leasehold improvements	36,006	35,913
Construction in progress	9,218	8,950
Subtotal	$224,991	$219,724
Less accumulated depreciation and amortization	(146,190)	(140,056)
Total property, plant and equipment, net	$78,801	$79,668
Accrued expenses:		
Loss contingency related to non-cancelable purchase commitments	$3,454	$5,120
Professional and other consulting fees	1,534	1,411
Taxes payable	2,693	2,372
Royalties	1,503	1,540
Accrued rebate and customer prepay liability	644	3,807
Accrued interest on convertible senior notes	875	219
Other accrued expenses	9,541	7,962
Total accrued expenses	$20,244	$22,431

(1) Included in finished goods inventory at March 29, 2014 and December 28, 2013 were $8.0 million and $9.2 million, respectively, of inventory at customer locations for which product acceptance had not occurred.

(2) Included in computer software at March 29, 2014 and December 28, 2013 were $7.9 million and $7.9 million, respectively, related to an enterprise resource planning ("ERP") system that the Company implemented

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during 2012. The unamortized ERP costs at March 29, 2014 and December 28, 2013 were $6.0 million and $6.3 million, respectively.

Restricted Cash

The Company's long-term restricted cash balance is primarily comprised of certificates of deposit, of which the majority is not insured by the Federal Deposit Insurance Corporation. These amounts primarily collateralize the Company's issuances of stand-by and commercial letters of credit. Additionally, the Company's restricted cash balance includes a leave encashment fund for India employees and a corporate bank card deposit for employees in the United Kingdom.

The following table sets forth the Company's outstanding standby letters of credit (in thousands):

	March 29, 2014	December 28, 2013
Value added tax license	$1,463	$1,430
Customer proposal guarantee	1,876	1,446
Property leases	699	699
Total standby letters of credit	$4,038	$3,575

7. Comprehensive Loss

Other comprehensive loss includes certain changes in equity that are excluded from net loss. The following table sets forth the changes in accumulated other comprehensive loss by component for the first quarter of 2014 (in thousands):

	Unrealized Gain on Other Available-for-Sale Securities	Foreign Currency Translation	Accumulated Tax Effect	Total
Balance at December 28, 2013	$ (124)	$ (2,602)	$ (760)	$ (3,486)
Net current-period other comprehensive loss	50	244	(20)	274
Balance at March 29, 2014	$ (74)	$ (2,358)	$ (780)	$ (3,212)

8. Basic and Diluted Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed using net loss and the weighted average number of common shares outstanding plus potentially dilutive common shares outstanding during the period. Potentially dilutive common shares include the assumed exercise of outstanding stock options, assumed vesting of outstanding restricted stock units ("RSUs") and performance stock units ("PSUs"), assumed conversion of convertible senior notes, and assumed issuance of stock under the Company's employee stock purchase plan ("ESPP") using the treasury stock method. The Company includes the common shares underlying PSUs in the calculation of diluted net income per share when they become contingently issuable and excludes such shares when they are not contingently issuable. In net loss periods, these potentially diluted common shares are anti-dilutive and therefore, excluded from the diluted net loss calculation.

The following table sets forth the computation of loss per common share – basic and diluted (in thousands, except per share amounts):

	Three Months Ended	
	March 29, 2014	March 30, 2013
Net loss	$(4,374)	$(15,279)
Weighted average common shares outstanding - basic and diluted	121,352	114,308
Net loss per common share - basic and diluted	$(0.04)	$(0.13)

The Company had the following equity awards outstanding that could potentially dilute basic net loss per common share in the future, but were excluded from the computation of diluted loss per common share in the periods presented as their effect would have been anti-dilutive under the treasury stock method (in thousands):

	Three Months Ended	
	March 29, 2014	March 30, 2013
Stock options	6,135	8,591
Restricted stock units	5,386	5,407
Performance stock units	763	553
Employee stock purchase plan shares	431	601
Total	12,715	15,152

In the first quarter of 2014, the Company excluded the potential shares issued upon early conversion of the convertible senior notes in the calculation of diluted earnings per share because the market price was below the conversion price. In the future, the Company would include these dilutive effects of the convertible senior notes in the calculation of diluted net income per common share if the market price is above the conversion price. Upon conversion of the convertible senior notes, it is the Company's intention to pay cash equal to the lesser of the aggregate principal amount or the conversion value of the Notes being converted, therefore, only the conversion spread relating to the notes would be included in the Company's diluted earnings per share calculation unless their effect is anti-dilutive.

9. Convertible Senior Notes

In May 2013, the Company issued $150.0 million of 1.75% convertible senior notes due June 1, 2018 (the "Notes"). The Notes will mature on June 1, 2018, unless earlier purchased by the Company or converted. Interest is payable semi-annually in arrears on June 1 and December 1 of each year, commencing December 1, 2013. The net proceeds to the Company were approximately $144.5 million.

The Notes are governed by an indenture dated as of May 30, 2013 (the "Indenture"), between the Company, as issuer, and U.S. Bank National Association, as trustee. The Notes are unsecured and do not contain any financial covenants or any restrictions on the payment of dividends, the incurrence of senior debt or other indebtedness, or the issuance or repurchase of securities by the Company.

Upon conversion, it is the Company's intention to pay cash equal to the lesser of the aggregate principal amount and the conversion value of the Notes being converted and cash, shares of common stock or a combination of cash and shares of common stock, at the Company's election, for any remaining conversion obligation. The initial conversion rate is 79.4834 shares of common stock per $1,000 principal amount of Notes, subject to anti-dilution adjustments. The initial conversion price is approximately $12.58 per share of common stock.

Throughout the term of the Notes, the conversion rate may be adjusted upon the occurrence of certain events, including for any cash dividends. Holders of the Notes will not receive any cash payment representing accrued and unpaid interest upon conversion of a Note. Accrued but unpaid interest will be deemed to be paid in full upon conversion rather than canceled, extinguished or forfeited. Holders may convert their Notes under the following circumstances:

- during any fiscal quarter commencing after the fiscal quarter ending on September 28, 2013 (and only during such fiscal quarter) if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last

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trading day of the immediately preceding fiscal quarter is greater than or equal to 130% of the conversion price on each applicable trading day;

- during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price per $1,000 principal amount of Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day;

- upon the occurrence of specified corporate events described under the Indenture, such as a consolidation, merger or binding share exchange; or

- at any time on or after December 1, 2017 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their Notes at any time, regardless of the foregoing circumstances.

If the Company undergoes a fundamental change as defined in the Indenture governing the Notes, holders may require the Company to repurchase for cash all or any portion of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. In addition, upon the occurrence of a "make-whole fundamental change" (as defined in the Indenture), the Company will, in certain circumstances, increase the conversion rate by a number of additional shares for a holder that elects to convert its Notes in connection with such make-whole fundamental change.

The amounts recorded in connection with the issuance of the Notes consisted of the following (in thousands):

	Other Non-Current Assets	Long-term Debt	Additional Paid-in Capital
Principal amount	$—	$150,000	$—
Debt discount	—	(45,000)	—
Equity component	—	—	45,000
Debt issuance cost	3,872	—	(1,659)
Initial transaction amounts	$3,872	$105,000	$43,341
Amortization of debt issuance cost	(518)	—	—
Amortization of debt discount	—	6,024	—
Net carrying amount at March 29, 2014	$3,354	$111,024	$43,341

In accounting for the issuance of the Notes, the Company separated the Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of a similar debt instrument that does not have an associated convertible feature. The carrying amount of the equity component representing the conversion option was determined by deducting the fair value of the liability component from the par value of the Notes. The equity component is not remeasured as long as it continues to meet the conditions for equity classification. The excess of the principal amount of the liability component over its carrying amount ("debt discount") is amortized to interest expense over the term of the Notes. The remaining debt discount amount to be amortized over the remaining five years until maturity of the Notes was $39.0 million as of March 29, 2014.

In accounting for the issuance costs of $5.5 million related to the Notes, the Company allocated the total amount incurred to the liability and equity components of the Notes based on their relative values. Issuance costs attributable to the liability component were recorded as Other non-current assets and will be amortized to interest expense over the term of the Notes. The issuance costs attributable to the equity component were netted with the equity component in stockholders' equity. Additionally, the Company initially recorded a deferred tax liability of $17.0 million in connection with the issuance of the Notes, and a corresponding reduction in valuation allowance. The impact of both was recorded to stockholders' equity.

The Company determined that the embedded conversion option in the Notes does not require separate accounting treatment as a derivative instrument because it is both indexed to the Company's own stock and would be classified in

stockholder's equity if freestanding.

The following table sets forth total interest expense recognized related to the Notes (in thousands):

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	Three Months Ended March 29, 2014
Contractual interest expense	$657
Amortization of debt issuance costs	160
Amortization of debt discount	1,860
Total interest expense	$2,677

The effective interest rate of the liability component was 1.75%. The excess of the principal amount of the liability component over its carrying amount is amortized, using an effective interest rate of 5.12%, to interest expense over the term of the Notes.

As of March 29, 2014, the fair value of the Notes was $155.4 million. The fair value was determined based on the quoted bid price of the Notes in an over-the-counter market on March 28, 2014. The Notes are classified as Level 2 of the fair value hierarchy. Based on the closing price of the Company's common stock of $8.76 on March 28, 2014, the if-converted value of the Notes was less than their principal amount.

10. Stockholders' Equity

Stock-based Compensation Plans

The Company has stock-based compensation plans pursuant to which the Company has granted stock options, RSUs and PSUs. The Company also has an ESPP for all eligible employees. As of March 29, 2014, there were a total of 19.2 million shares of common stock available for grant under the Company's 2007 Equity Incentive Plan ("2007 Plan"). The following tables summarize the Company's equity award activity and related information (in thousands, except per share data):

	Number of Options	Weighted-Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at December 28, 2013	6,367	$ 7.26	$17,452
Options granted	25	$ 9.02	
Options exercised	(227)	$ 5.85	$649
Options canceled	(30)	$ 10.30	
Outstanding at March 29, 2014	6,135	$ 7.30	$10,841
Vested and expected to vest as of March 29, 2014	6,130		$10,835
Exercisable at March 29, 2014	5,976	$ 7.29	$10,636

	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value Per Share	Aggregate Intrinsic Value
Outstanding at December 28, 2013	6,583	$7.72	$64,443
RSUs granted	490	$8.64	
RSUs released	(1,541)	$7.91	$12,981
RSUs canceled	(146)	$7.02	
Outstanding at March 29, 2014	5,386	$7.77	$47,181
Expected to vest at March 29, 2014	5,198		$45,539

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	Number of Performance Stock Units	Weighted-Average Grant Date Fair Value Per Share	Aggregate Intrinsic Value
Outstanding at December 28, 2013	721	$7.04	$7,054
PSUs granted	338	$6.62	
PSUs released	(255)	$6.36	$2,097
PSUs canceled	(41)	$7.25	
Outstanding at March 29, 2014	763	$7.04	$6,684
Expected to vest at March 29, 2014	541		$4,738

The aggregate intrinsic value of unexercised options, unreleased RSUs and unreleased PSUs is calculated as the difference between the closing price of the Company's common stock of $8.76 at March 28, 2014 and the exercise prices of the underlying equity awards. The aggregate intrinsic value of the options that have been exercised and RSUs released is calculated as the difference between the fair market value of the common stock at the date of exercise or release and the exercise price of the underlying equity awards.

The following table presents total stock-based compensation cost for instruments granted but not yet amortized, net of estimated forfeitures, of the Company's equity compensation plans as of March 29, 2014. These costs are expected to be amortized on a straight-line basis over the following weighted-average periods (in thousands, except for weighted-average period):

	Unrecognized Compensation Expense, Net	Weighted-Average Period (in years)
Stock options	543	1.7
RSUs	28,289	2.3
PSUs	2,759	1.8

Employee Stock Options

The estimated values of stock options, as well as assumptions used in calculating these values were based on estimates as follows (expense amounts in thousands):

	Three Months Ended	
Employee and Director Stock Options	March 29, 2014	March 30, 2013
Volatility	52%	N/A
Risk-free interest rate	1.30%	N/A
Expected life	4.3 years	N/A
Estimated fair value	$3.85	N/A
Total stock-based compensation expense	$388	$803

N/A Not applicable because the Company did not grant any options to employees for the periods presented.

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Employee Stock Purchase Plan

The fair value of the ESPP shares was estimated at the date of grant using the following assumptions (expense amounts in thousands):

	Three Months Ended	
Employee Stock Purchase Plan	March 29, 2014	March 30, 2013
Volatility	51%	46%
Risk-free interest rate	0.11%	0.14%
Expected life	0.5 years	0.5 years
Estimated fair value	$2.57	$1.87
Total stock-based compensation expense	$791	$708

Restricted Stock Units

During the first quarter of 2014, the Company granted RSUs to employees and members of the Company's board of directors to receive an aggregate of 0.5 million shares of the Company's common stock. The Company accounted for the fair value of the RSUs using the closing market price of the Company's common stock on the date of grant. Amortization of stock-based compensation related to RSUs in the three months ended March 29, 2014 and March 30, 2013 was approximately $5.1 million and $6.9 million, respectively.

Performance Stock Units

Pursuant to the Company's 2007 Plan, during fiscal 2012, the Company granted 0.5 million shares of PSUs to certain of its executive officers. These PSUs will only vest upon the achievement of certain specific revenue and operating profit criteria and are subject to each named executive officer's continued service to the Company. If the financial performance metrics are not met within the time limits specified in the award agreements, the PSUs will be canceled. During the first quarter of 2014, the Company did not release any shares subject to the PSUs upon achievement of the performance goals.

Pursuant to the Company's 2007 Plan, during fiscal 2013, the Company granted 0.6 million shares of PSUs to certain of its executive officers. The number of shares to be issued upon vesting of PSUs range from 0 to 1.5 times the number of PSUs granted depending on the relative performance of the Company's common stock price compared to the NASDAQ Telecom Composite Index over the span of one, two and three years of total shareholder returns. During the first quarter of 2014, the Company released 0.3 million shares of PSUs based on a payout of 1.5 times of the target number of PSUs.

The ranges of estimated values of the PSUs granted, as well as assumptions used in calculating these values were based on estimates as follows:

	Year Ended December 28, 2013
Infinera Volatility	55%
NASDAQ Telecom Composite Index Volatility	23%
Risk-free interest rate	0.42%
Correlation with NASDAQ Telecom Composite Index	0.56
Estimated fair value	$6.27 - $7.06

Pursuant to the Company's 2007 Plan, during the first quarter of 2014, the Company granted 0.3 million shares of PSUs to certain of its executive officers. The number of shares to be issued upon vesting of PSUs range from 0 to 1.5 times the number of PSUs granted depending on the relative performance of the Company's common stock price compared to the iShares North American Tech-Multimedia Networking ("IGN") Index over the span of one, two and three years of total shareholder returns.

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The ranges of estimated values of the PSUs granted, as well as assumptions used in calculating these values were based on estimates as follows:

	Three Months Ended March 29, 2014
Infinera Volatility	49%
IGN Index Volatility	25%
Risk-free interest rate	0.66%
Correlation with IGN Index	0.60
Estimated fair value	$6.61 - $7.60

Amortization of stock-based compensation related to PSUs in the first quarter of 2014 was approximately $0.4 million. Amortization of stock-based compensation related to PSUs in the first quarter of 2013 was a credit of approximately $0.8 million, including $0.6 million of expense offset by a $1.4 million decrease in fair value for one award classified as a liability award, in accordance with Accounting Standard Codification 718, "Compensation - Stock Compensation."

Stock-Based Compensation

The following tables summarize the effects of stock-based compensation on the Company’s condensed consolidated balance sheets and statements of operations for the periods presented (in thousands):

	March 29, 2014	December 28, 2013
Stock-based compensation effects in inventory	$3,219	$3,189
Stock-based compensation effects in deferred inventory cost	$14	$15
Stock-based compensation effects in fixed assets	$139	$145

	Three Months Ended	
	March 29, 2014	March 30, 2013
Stock-based compensation effects included in net loss before income taxes		
Cost of revenue	$452	$486
Research and development	2,138	3,119
Sales and marketing	1,720	1,999
General and administration	1,530	769
	5,840	6,373
Cost of revenue – amortization from balance sheet[1)]	832	1,602
Total stock-based compensation expense	$6,672	$7,975

(1) Stock-based compensation expense deferred to inventory and deferred inventory costs in prior periods and recognized in the current period.

11. Income Taxes

Provision for income taxes for the three months ended March 29, 2014 was $0.2 million, or negative 6.0%, on a pre-tax loss of $4.1 million. This compared to a tax provision of $0.3 million, or negative 2.2%, on a pre-tax loss of $14.9 million for the three months ended March 30, 2013. The difference between the Company’s effective tax rates and the federal statutory rate of 35% is primarily attributable to U.S. losses, foreign taxes provided on the income of the Company’s foreign subsidiaries, non-deductible stock-based compensation expense and various discrete items. The release of transfer pricing reserves in the future will have a beneficial impact to tax expense, but the timing of the impact depends on factors such as expiration of the statute of limitations or settlements with tax authorities. No

significant releases are expected in the near future based on information available at this time.

The realization of tax benefits of deferred tax assets is dependent upon future levels of taxable income, of an appropriate character, in the periods the items are scheduled to be deductible or taxable. Based on the available objective evidence, management believes it is more likely than not that the domestic net deferred tax assets will not be realizable. Accordingly, the Company has provided a full valuation allowance against its domestic deferred tax assets, net of deferred tax liabilities, as of March 29, 2014 and December 28, 2013. In determining future taxable income, the Company makes assumptions to forecast federal, state and international operating income, the reversal of taxable temporary differences, and the implementation of any feasible and prudent tax planning strategies. The assumptions require judgment regarding the forecasts of future taxable income and are consistent with the Company's forecasts used to manage its business. The Company intends to maintain the remaining valuation allowance until sufficient positive evidence exists to support a reversal of, or decrease, in the valuation allowance.

12. Segment Information

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker is the Company's Chief Executive Officer ("CEO"). The Company's CEO reviews financial information presented on a consolidated basis, accompanied by information about revenue by geographic region for purposes of allocating resources and evaluating financial performance. The Company has one business activity, and there are no segment managers who are held accountable for operations, operating results and plans for levels or components below the consolidated unit level. Accordingly, the Company is considered to be in a single reporting segment and operating unit structure.

Revenue by geographic region is based on the shipping address of the customer. The following tables set forth revenue and long-lived assets by geographic region (in thousands):

Revenue

	Three Months Ended	
	March 29, 2014	March 30, 2013
Americas:		
United States	$110,691	$79,073
Other Americas	3,536	718
	114,227	79,791
Europe, Middle East and Africa	25,613	38,806
Asia Pacific and Japan	2,975	6,028
Total revenue	$142,815	$124,625

Property, plant and equipment, net

	March 29, 2014	December 28, 2013
United States	$76,029	$76,850
Other Americas	275	319
Europe, Middle East and Africa	1,027	1,451
Asia Pacific and Japan	1,470	1,048
Total property, plant and equipment, net	$78,801	$79,668

13. Guarantees

Product Warranties

Upon delivery of products, the Company provides for the estimated cost to repair or replace products including the related components that may be returned under hardware warranties. In general, hardware warranty periods range from one to five years. Hardware warranties provide the purchaser with protection in the event that the product does not perform to product specifications. During the warranty period, the purchaser's sole and exclusive remedy in the event of such defect or failure to perform is limited to the correction of the defect or failure by repair or replacement. The Company estimates its hardware warranty obligations based on the Company's historical

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experience of known product failure rates, use of materials and labor to repair or replace defective products, and service delivery costs incurred in correcting product failures. In addition, from time to time, specific hardware warranty accruals may be made if unforeseen technical problems arise with specific products. Management periodically assesses the adequacy of the Company's recorded warranty liabilities and adjusts the amounts as necessary.

Activity related to product warranty was as follows (in thousands):

	Three Months Ended	
	March 29, 2014	March 30, 2013
Beginning balance	$22,908	$16,482
Charges to operations	5,561	4,168
Utilization	(3,242)	(2,083)
Change in estimate [1]	1,158	(1,895)
Balance at the end of the period	$26,385	$16,672

(1) The Company records hardware warranty liabilities based on the latest quality and cost information available as of that date. The changes in estimate shown here are due to changes in overall actual failure rates and the resulting impact of these changes on the Company's estimate of expected future returns, as well as changes in the estimated cost of replacing failed units with either repaired or new units.

14. Litigation and Contingencies

Legal Matters

From time to time, the Company is subject to various legal proceedings, claims and litigation arising in the ordinary course of business. While the outcome of these matters is currently not determinable, the Company does not expect that the ultimate costs to resolve these matters will have a material effect on its consolidated financial position, results of operations, or cash flows.

Cambrian Science Patent Infringement Litigation

On July 12, 2011, the Company was notified by Level 3 that Cambrian Science Corporation ("Cambrian") filed suit against Level 3 and six other defendants, including Cox Communications, Inc., XO Communications, LLC, Global Crossing Limited, 360Networks (USA), Inc., Integra Telecom, Inc. and IXC, Inc. dba Telekenex (collectively, the "Defendants") in the U.S. District Court for the Central District of California alleging infringement of patent no. 6,775,312 (the "'312 Patent") and requesting damages for such alleged infringement (the "Cambrian Claim"). The nature of the Cambrian Claim involves allegations of infringement of the '312 Patent resulting from the Defendants' use of certain products and systems in the Defendants' networks, including our DTN platform. On August 24, 2011, Cambrian amended the complaint to name the Company as a defendant. The Company assumed the defense of the Cambrian Claim and filed an answer to Cambrian's complaint on September 21, 2011, in which the Company denied infringement of the '312 Patent and raised other defenses. Cambrian filed a second amended complaint on October 6, 2011, which included many of the same allegations as in the original complaint. The Company filed its answer to the second amended complaint on October 21, 2011, in which the Company maintained the same denials and defenses as in the Company's initial answer. On December 23, 2011, the Company filed a motion requesting that the court stay the case with respect to each of the above-noted customer Defendants. Cambrian filed its opposition to the Company's motion on December 30, 2011. The Company's request was denied in the court's decision on March 7, 2012. The Company presented evidence on the appropriate meanings of relevant key words used in the patent claims during a claim construction hearing on November 20, 2012.

On June 17, 2013, the court issued an order regarding claim construction, in which the court agreed with almost all of the Company's proposed claim constructions. On October 17, 2013, the parties met for a court-mandated mediation. On April 14, 2014, the Company filed three motions for summary judgment relating to non-infringement and damages. The court scheduled a hearing on the summary judgment motions for June 9, 2014. The court also scheduled a pretrial conference for July 7, 2014, and the jury trial is set to begin on July 22, 2014.

Based on the information available at this time, the Company concluded that the likelihood of a loss with respect to this suit is reasonably possible. The Company has further concluded that the range of the reasonably

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possible loss is an insignificant amount and will not have a material adverse effect on the Company's business, consolidated financial position, results of operations, or cash flows. Accordingly, the Company accrued an insignificant amount during 2013, which did not have a material adverse effect on the Company's business, consolidated financial position, results of operations, or cash flows. Factors that the Company considered in the determination of the likelihood of a loss and the estimate of that loss in respect to this matter included the merits of the case, the nature of the litigation (including the complex and technical nature of patent litigation), the length of time the matter has been pending, the status of the plaintiff as a non-operating entity and the likelihood of the plaintiff accepting the estimated amount. However, the outcome of such legal matters is inherently unpredictable and subject to significant uncertainties.

Loss Contingencies

The Company is subject to the possibility of various losses arising in the ordinary course of business. These may relate to disputes, litigation and other legal actions. In the preparation of its quarterly and annual financial statements, the Company considers the likelihood of loss or the incurrence of a liability, including whether it is probable, reasonably possible or remote that a liability has been incurred, as well as the Company's ability to reasonably estimate the amount of loss, in determining loss contingencies. In accordance with U.S. GAAP, an estimated loss contingency is accrued when it is probable that a liability has been incurred and the amount of loss can be reasonably estimated. The Company regularly evaluates current information to determine whether any accruals should be adjusted and whether new accruals are required. As of March 29, 2014, the Company has not accrued or recorded any such material liabilities.

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

This quarterly report on Form 10-Q contains "forward-looking statements" that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Such forward-looking statements include our expectations regarding earnings, revenue, gross margins, expenses and other financial items; any statements of the plans, strategies and objectives of management for future operations and personnel; factors that may affect our operating results; statements concerning new products or services, including future PIC capacity and new product costs, delivery dates and revenues; statements related to capital expenditures; statements related to future economic conditions, performance, market growth or our sales cycle; statements related to our convertible senior notes issued in May 2013; statements related to the effects of litigation on our financial position, results of operations, or cash flows; statements as to industry trends and other matters that do not relate strictly to historical facts or statements of assumptions underlying any of the foregoing. These statements are often identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," or "will," and similar expressions or variations. These statements a based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Form 10-Q and in our other SEC filings, including our annual report on Form 10-K for the fiscal year ended December 28, 2013 filed on February 21, 2014. Such forward-looking statements speak only as of the date of this report. We disclaim any obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements. The following discussion and analysis should be read in conjunction with our condensed consolidated financial statements and notes thereto included elsewhere in this quarterly report on Form 10-Q.

Overview

We were founded in December 2000 with a unique vision for optical networking. Prior to us, communications service provider optical networks were built from fairly commoditized products, broadly known as wavelength division multiplexing ("WDM") systems. Recent growth in bandwidth demand has increased the need for the delivery of high-capacity low-cost bandwidth throughout the network. We believe that traditional point-to-point network architectures do not provide the required flexibility to meet this demand. It takes large amounts of low-cost bandwidth, pervasive Optical Transport Network ("OTN") switching, and the intelligence of bandwidth management to manage these larger networks and deliver high-capacity services quickly and cost-effectively. We believe this can best be achieved with photonic integrated circuits ("PICs") and that only through photonic integration can network operators efficiently scale their network bandwidth without significant increases in space, power or operational workload.

We provide optical transport networking equipment, software and services to communications service providers, internet content providers, cable operators and subsea network operators (collectively, "Service Providers") across the globe. Optical transport networks are deployed by Service Providers facing significant demands for transmission capacity prompted by increased use of high-speed Internet access, mobile broadband, high-definition video streaming services, business Ethernet services, cloud-based services and wholesale bandwidth services.

We call our solution for Service Providers the Infinera Intelligent Transport Network. The Infinera Intelligent Transport Network is an architecture for Service Providers to address the increasing demand for cloud-based services and data center connectivity. In addition, this helps Service Providers use time as a weapon to increase revenues with reliable, differentiated services while reducing operating costs through scale, multi-layer convergence and automation. The Infinera Intelligent Transport Network is based on platforms built with our unique PICs.

Traffic patterns in the optical network continue to grow to accommodate increased demands for transmission capacity prompted by increased use of high-speed Internet access, mobile broadband, streaming high-definition video services,

business Ethernet services, cloud-based services and wholesale bandwidth services. We believe that the Infinera Intelligent Transport Network architecture is uniquely enabled to deliver improvements in these areas compared to competitive WDM systems that still rely on discrete optical components rather than PICs. We also believe that this enables Service Providers to deploy reliable, high-capacity, efficient optical network solutions

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that are easy to use and to improve the integration between the layers of Service Provider networks with the lowest total cost of ownership.

Our DTN platform currently supports 10 Gigabits per second ("Gbps") and 40 Gbps WDM transmission capacity combined with integrated switching capabilities. Our DTN-X platform supports 100 Gbps WDM transmission capacity with 500 Gbps super-channels and also integrates 5 Terabits per second of OTN switching capacity in a single bay. The DTN-X platform leverages the unique capabilities of our 500 Gbps PICs to deliver high-capacity Intelligent Transport Networks that reduce power, cooling and space, while simplifying transport network operations. The ATN platform supports direct wavelength connectivity to DTN and DTN-X nodes, reducing equipment costs and providing unique network management capabilities across our Intelligent Transport Network.

As of March 29, 2014, we have sold our network systems for deployment in the optical networks of 131 customers worldwide, including CenturyLink, Colt, Cox Communications, DANTE, Deutsche Telekom, Equinix, Interoute, KDDI, Level 3, NTT, OTE, Pacnet, Rostelecom, Telefonica, TeliaSonera International and Vodafone. Since the commencement of shipping our DTN-X platform in the second quarter of 2012, we have 42 customers who have purchased our DTN-X platform.

We do not have long-term sales commitments from our customers. To date, a few of our customers have accounted for a significant portion of our revenue. Two customers accounted for over 10% of our revenue in the first quarter of 2014, and one of these customers accounted for over 10% of our revenue in the corresponding period in 2013.

We are headquartered in Sunnyvale, California, with employees located throughout the Americas, Europe and the Asia Pacific region. We expect to continue to add personnel in the United States and internationally to develop our products and provide additional geographic sales and technical support coverage. We primarily sell our products through our direct sales force, with a small portion sold indirectly through resellers. We derived 98% and 97% of our revenue from direct sales to customers in the three months ended March 29, 2014 and March 30, 2013, respectively. Our strategy is to leverage reseller channels where appropriate to expand our presence in certain geographies; however, we expect to continue generating a substantial majority of our revenue from direct sales.

In 2014, we intend to continue to leverage the DTN-X platform to increase revenue and expand our market share as customers extend deployments of 100 Gbps transport solutions in their networks. This focus on revenue growth will be balanced with overall prudent financial management and continued efforts to drive cost improvements across all of our products and services. We believe that with sustained revenue growth, we can leverage our vertically-integrated manufacturing model, which combined with selling bandwidth capacity into deployed networks, can result in improved future profitability and cash flow.

Our near-term year-over-year and quarter-over-quarter revenue will likely be volatile and may be impacted by several factors including general economic and market conditions, time-to-market development of new products, acquisitions of new customers and the timing of large product deployments.

We will continue to make significant investments in the business as we develop new capabilities in the long-haul optical transport market and adjacent markets.

Critical Accounting Policies and Estimates

Management’s Discussion and Analysis of Financial Condition and Results of Operations is based upon our condensed consolidated financial statements, which we have prepared in accordance with the United States generally accepted accounting principles ("U.S. GAAP"). The preparation of these financial statements requires management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. Management bases its estimates on historical experience and on various other assumptions that it believes 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.

An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, if different estimates reasonably could have been used, or if changes in the estimate that are reasonably likely to occur could materially impact the financial statements. Management believes that there have been no significant changes during the three months ended March

29, 2014 to the items that we disclosed as our critical accounting policies and estimates in

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Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended December 28, 2013.

Results of Operations

The following sets forth, for the periods presented, certain unaudited condensed consolidated statements of operations information (in thousands, except percentages):

	Three Months Ended March 29, 2014		March 30, 2013			
	Amount	% of total revenue	Amount	% of total revenue	Change	% Change
Revenue:						
Product	$124,242	87 %	$108,343	87 %	$15,899	15 %
Services	18,573	13 %	16,282	13 %	2,291	14 %
Total revenue	$142,815	100 %	$124,625	100 %	$18,190	15 %
Cost of revenue:						
Product	$78,438	55 %	$75,447	61 %	$2,991	4 %
Services	5,971	4 %	6,476	5 %	(505)	(8)%
Total cost of revenue	$84,409	59 %	$81,923	66 %	$2,486	3 %
Gross profit	$58,406	41 %	$42,702	34 %	$15,704	37 %

The following table summarizes our revenue by geography and sales channel for the periods presented (in thousands, except percentages):

	Three Months Ended March 29, 2014		March 30, 2013			
	Amount	% of total revenue	Amount	% of total revenue	Change	% Change
Total revenue by geography						
Domestic	$110,691	78 %	$79,073	63 %	$31,618	40 %
International	32,124	22 %	45,552	37 %	(13,428)	(29)%
	$142,815	100 %	$124,625	100 %	$18,190	15 %
Total revenue by sales channel						
Direct	$140,474	98 %	$120,848	97 %	$19,626	16 %
Indirect	2,341	2 %	3,777	3 %	(1,436)	(38)%
	$142,815	100 %	$124,625	100 %	$18,190	15 %

Revenue

Total revenue increased by $18.2 million, or 15%, during the first quarter of 2014 compared to the corresponding period in 2013. We continued to experience sales growth in our DTN-X platform during the first quarter of 2014 as demand for 100 Gbps network deployments continued to increase. This increase in DTN-X platform revenue was partially offset by a reduction in sales of our DTN platform.

Total product revenue increased by $15.9 million, or 15%, during the first quarter of 2014 compared to the corresponding period in 2013. This increase was primarily due to higher sales of our DTN-X platform to an expanded customer base during the first quarter of 2014 reflecting the benefits from the continued investment cycle in 100 Gbps network deployments.

Total services revenue increased by $2.3 million, or 14%, during the first quarter of 2014 compared to the corresponding period in 2013. This increase was due to the higher levels of deployment services revenue as we continue to expand our customer base and incremental recognition of ongoing maintenance services revenue. As our installed customer base grows, we expect to continue to grow our services revenue in future periods.

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International revenue decreased by $13.4 million and decreased to 22% of total revenue for the first quarter of 2014 from 37% of total revenue in the corresponding period in 2013. As a percentage of total revenue, international revenue decreased during the first quarter of 2014 due to strong demand within North America. In absolute dollars, international revenue decreased as a result of the timing of new deployments in Europe, Asia Pacific and Japan. While we expect international revenue to grow in absolute dollars on a long-term basis as we increase our sales activities in Europe, Asia Pacific, Japan and other regions, international revenue may fluctuate as a percentage of total revenue depending on the size and timing of deployments both internationally and in the United States.

We believe that our DTN-X platform is well positioned as existing customers continue to build out their routes and as we gain new opportunities to increase network footprint in the long-haul optical transport and adjacent markets. We currently expect that these dynamics will drive our revenue growth moderately higher in the second quarter of 2014 as compared to the first quarter of 2014.

Cost of Revenue and Gross Margin

Gross margin increased to 41% in the first quarter of 2014 from 34% in the corresponding period of 2013. This increase was primarily due to improvements in revenue mix, including an increased level of higher margin network fill revenue to an expanded customer base for the first quarter of 2014. In addition, we experienced ongoing improvements in manufacturing yields and product costs that added to the overall improvement in gross margin. Based on our current outlook, we expect that gross margin in 2014 will remain constrained in a period when we expect to deploy significant amounts of new network footprint and expanding our share in existing accounts.

Operating Expenses

The following tables summarize our operating expenses for the periods presented (in thousands, except percentages):

	Three Months Ended					
	March 29, 2014		March 30, 2013			
	Amount	% of total revenue	Amount	% of total revenue	Change	% Change
Operating expenses:						
Research and development	$29,346	21 %	$29,726	24 %	$(380)	(1) %
Sales and marketing	17,862	13 %	18,046	14 %	(184)	(1) %
General and administrative	12,254	9 %	9,872	8 %	2,382	24 %
Total operating expenses	$59,462	43 %	$57,644	46 %	$1,818	3 %

Research and Development Expenses

Research and development expenses decreased by $0.4 million, or 1%, in the first quarter of 2014 compared to the corresponding period in 2013 primarily due to a $1.9 million decrease in prototype and non-recurring engineering expense due to timing of projects, offset by $1.5 million of increased compensation and personnel-related costs due to an increase in headcount to support continued development both within the long-haul optical transport market and also adjacent markets.

Sales and Marketing Expenses

Sales and marketing expenses decreased by $0.2 million, or 1%, during the first quarter of 2014 compared to the corresponding period in 2013 primarily due to lower costs of customer lab trials and decreased commission expenses. These decreases were partially offset by increased marketing related expenses of $0.5 million due to higher headcount to support continued expansion of our business.

General and Administrative Expenses

General and administrative expenses increased by $2.4 million, or 24%, during the first quarter of 2014 compared to the corresponding period in 2013 primarily due to higher compensation and personnel-related costs of $1.5 million due to an increase in headcount along with increased costs for professional outside services of $0.8 million.

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Other Income (Expense), Net

	Three Months Ended			
	March 29, 2014	March 30, 2013	Change	% Change
	(In thousands)			
Interest income	$336	$197	$139	71 %
Interest expense	(2,677)	—	(2,677)	(100)%
Other gain (loss), net	(729)	(203)	(526)	259 %
Total other income (expense), net	$(3,070)	$(6)	$(3,064)	51,067 %

Interest income increased by $0.1 million in the first quarter of 2014 compared to the corresponding period in 2013. This small increase was primarily driven by a higher investment balance as a result of both our cash generated from operations over the past year and the proceeds from the issuance in May 2013 of $150.0 million aggregate principal amount of 1.75% convertible senior notes due June 1, 2018 (the "Notes"), partially offset by lower investment returns.

Interest expense for the first quarter of 2014 consisted of cash interest payments and amortization of discount and issuance costs related to the Notes.

Other gain (loss), net for the first quarter of 2014 consisted of $0.7 million of realized and unrealized foreign currency transaction loss, as compared to the first quarter of 2013, which consisted of $0.4 million realized and unrealized foreign currency transaction loss partially offset by $0.2 million gain from the disposal of our remaining auction rate securities.

Income Tax Provision

Provision for income taxes for the three months ended March 29, 2014 was $0.2 million on a pre-tax loss of $4.1 million. This compared to a tax provision of $0.3 million on a pre-tax loss of $14.9 million for the three months ended March 30, 2013. The difference between our effective tax rates and the federal statutory rate of 35% is primarily attributable to U.S. losses, foreign taxes provided on the income of our foreign subsidiaries, non-deductible stock-based compensation expense and various discrete items. The release of transfer pricing reserves in the future will have a beneficial impact to tax expense, but the timing of the impact depends on factors such as expiration of the statute of limitations or settlements with tax authorities. No significant releases are expected in the near future based on information available at this time.

Liquidity and Capital Resources

	Three Months Ended	
	March 29 2014	March 30, 2013
	(In thousands)	
Net cash flow provided by (used in):		
Operating activities	$(15,433)	$(21,299)
Investing activities	$(29,247)	$11,770
Financing activities	$5,435	$4,067

	March 29, 2014	December 28, 2013
	(In thousands)	
Cash and cash equivalents	$85,249	$124,330
Short-term and long-term investments	259,461	237,079
Long-term restricted cash	4,392	3,904
	$349,102	$365,313

Cash, cash equivalents and short-term investments consist of highly-liquid investments in certificates of deposits, money market funds, commercial paper, corporate bonds and U.S. treasuries. Long-term investments primarily consist of corporate bonds. The restricted cash balance amounts are primarily pledged as collateral for

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certain stand-by and commercial letters of credit related to customer proposal guarantees, value added tax licenses and property leases.

Operating Activities

Net cash used in operating activities for the first quarter of 2014 was $15.4 million as compared to $21.3 million for the corresponding period in 2013.

Net loss for the first quarter of 2014 was $4.4 million, as compared to a net loss of $15.3 million for the corresponding period in 2013. Non-cash charges were $15.8 million in the first quarter of 2014 as compared to $14.3 million in the corresponding period in 2013 driven largely by the amortization of debt discount on the Notes we issued during fiscal year 2013.

Net cash used to fund working capital was $26.9 million for the first quarter of 2014. Accounts receivables increased by $6.8 million primarily due to timing of acceptance and invoicing of DTN-X deployments during the period. Inventory increased due to increased levels of DTN-X inventory in anticipation of higher customer shipments in the second quarter of 2014. Accounts payable decreased by $2.1 million primarily reflecting timing of purchases and payments of purchases during the period. Accrued liabilities decreased $13.4 million primarily due to reduced levels of compensation related accruals and the corporate bonus payout in the first quarter of 2014.

Net cash used to fund working capital was $20.3 million for the first quarter of 2013. Inventory increased by $5.0 million primarily due to increased levels of DTN-X inventory. Accounts receivables increased $5.1 million primarily due to the timing of acceptance and invoicing of DTN-X deployments during the period. Accounts payable decreased by $8.0 million due to the timing of purchases and payments of purchases during the period. Accrued liabilities decreased by $6.3 million primarily due to timing of compensation payments.

Investing Activities

Net cash used in investing activities in the first quarter of 2014 was $29.2 million compared to net cash provided by investing activities of $11.8 million in the corresponding period of 2013. Investing activities for the first quarter of 2014 included $23.2 million of net cash used from purchases, maturities and sales of investments in the period and $5.6 million of capital expenditures. In the first quarter of 2014, we purchased more investments with longer maturities compared to the corresponding period in 2013. This was due to the proceeds from the issuance of debt in May 2013 and net cash provided by operating activities throughout 2013. Investing activities for the first quarter of 2013 included net proceeds of $16.6 million from purchases, maturities, calls and sales of investments in the period partially offset by $4.9 million of capital expenditures.

Financing Activities

Net cash provided by financing activities in the first quarter of 2014 was $5.4 million compared to $4.1 million in the corresponding period of 2013. Financing activities for the first quarter of 2014 and the corresponding period in 2013 included net proceeds from the exercise of stock options and issuance of shares under the employee stock purchase plan ("ESPP"). These proceeds were offset by the minimum tax withholdings paid on behalf of employees for net share settlements of restricted stock units.

Liquidity

We believe that our current cash, cash equivalents and investments, together with cash generated from operations, exercise of employee stock options and purchases under our ESPP will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. If these sources of cash are insufficient to satisfy our liquidity requirements beyond 12 months, we may require additional capital from equity or debt financings to fund our operations, to respond to competitive pressures or strategic opportunities, or otherwise. We may not be able to secure timely additional financing on favorable terms, or at all. The terms of any additional financing may place limits on our financial and operating flexibility. If we raise additional funds through further issuances of equity, convertible debt securities or other securities convertible into equity, our existing stockholders could suffer dilution in their percentage ownership of us, and any new securities we issue could have rights, preferences and privileges senior to those of holders of our common stock.

In May 2013, we issued the convertible senior notes. The Notes will mature on June 1, 2018, unless earlier purchased by us or converted. Interest is payable semi-annually in arrears on June 1 and December 1 of each year, commencing

December 1, 2013. The net proceeds from the Notes issuance were approximately $144.5 million and intended to be used for working capital and other general corporate purposes.

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Upon conversion, it is our intention to pay cash equal to the lesser of the aggregate principal amount and the conversion value of the Notes as cash, shares of common stock or a combination of cash and shares of common stock, at our election, for any remaining conversion obligation. The carrying value of the Notes was $111.0 million as of March 29, 2014, which represents the liability component of the $150.0 million principal balance, net of $39.0 million debt discount. The debt discount is currently being amortized over the remaining term until maturity of the Notes on June 1, 2018. Any future redemption or conversion of the Notes could impact the timing of the repayment of these Notes.

As of March 29, 2014, contractual obligations related to the Notes are payments of $2.6 million due each year from 2014 through 2017 and $151.3 million due in 2018. These amounts represent principal and interest cash payments over the term of the Notes. Any future redemption or conversion of the Notes could impact the amount or timing of our cash payments. For more information regarding the Notes, see Note 9, “Convertible Senior Notes,” to the Notes to Condensed Consolidated Financial Statements.

As of March 29, 2014, we had $312.0 million of cash, cash equivalents, and short-term investments, including $13.5 million of cash and cash equivalents held by our foreign subsidiaries. Our cash in foreign locations is used for operational and investing activities in those locations, and we do not currently have the need or the intent to repatriate those funds to the United States. Our policy with respect to undistributed foreign subsidiaries’ earnings is to consider those earnings to be indefinitely reinvested. If we were to repatriate these funds, we would be required to accrue and pay U.S. taxes on such amounts, however, due to our significant net operating loss carryforward position for both federal and state tax purposes, as well as the full valuation allowance provided against our U.S. and state net deferred tax assets, we would currently be able to offset any such tax obligations in their entirety. However, foreign withholding taxes may be applicable.

Off-Balance Sheet Arrangements

As of March 29, 2014, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

For quantitative and qualitative disclosures about market risk affecting us, see “Quantitative and Qualitative Disclosures About Market Risk” in Item 7A. of Part II of our Annual Report on Form 10-K for the fiscal year ended December 28, 2013, which is incorporated herein by reference. Our exposure to market risk has not changed materially since December 28, 2013.

Market Risk and Market Interest Risk

Holders may convert the Notes prior to maturity upon the occurrence of certain circumstances. Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election.

As of March 29, 2014, the fair value of the Notes was $155.4 million. The fair value was determined based on the quoted bid price of the Notes in an over-the-counter market on March 28, 2014. The fair value the Notes is subject to interest rate risk, market risk and other factors due to the convertible feature. The fair value of the Notes will generally increase as interest rates fall and decrease as interest rates rise. In addition, the fair value of the Notes will generally increase as our common stock price increases and will generally decrease as our common stock price declines in value. The interest and market value changes affect the fair value of the Notes but do not impact our financial position, cash flows or results of operations due to the fixed nature of the debt obligation. Additionally, we do not carry the Notes at fair value. We present the fair value of the Notes for required disclosure purposes only.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

An evaluation was performed by management, with the participation of our chief executive officer (“CEO”) and our chief financial officer (“CFO”), of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d -15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)). Disclosure controls and procedures are designed to ensure that information required to be disclosed in our reports

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filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Based on this evaluation, our CEO and CFO have concluded that, as of the end of the fiscal period covered by this quarterly report on Form 10-Q, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified by the SEC's rules and forms and that such information is accumulated and communicated to management, including the CEO and CFO, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

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

Inherent Limitations of Internal Controls

Our management, including our CEO and CFO, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within us have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a 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 management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving our stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are subject to various legal proceedings, claims and litigation arising in the ordinary course of business. While the outcome of these matters is currently not determinable, we do not expect that the ultimate costs to resolve these matters will have a material effect on our consolidated financial position, results of operations, or cash flows.

Cambrian Science Patent Infringement Litigation

On July 12, 2011, we were notified by Level 3 that Cambrian Science Corporation ("Cambrian") filed suit against Level 3 and six other defendants, including Cox Communications, Inc., XO Communications, LLC, Global Crossing Limited, 360Networks (USA), Inc., Integra Telecom, Inc. and IXC, Inc. dba Telekenex (collectively, the "Defendants") in the U.S. District Court for the Central District of California alleging infringement of patent no. 6,775,312 (the "'312 Patent") and requesting damages for such alleged infringement (the "Cambrian Claim"). The nature of the Cambrian Claim involves allegations of infringement of the '312 Patent resulting from the Defendants' use of certain products and systems in the Defendants' networks, including our DTN platform. On August 24, 2011, Cambrian amended the complaint to name us as a defendant. We assumed the defense of the Cambrian Claim and filed an answer to Cambrian's complaint on September 21, 2011, in which we denied infringement of the '312 Patent and raised other defenses. Cambrian filed a second amended complaint on October 6, 2011, which included many of the same allegations as in the original complaint. We filed our answer to the second amended complaint on October 21, 2011, in which we maintained the same denials and defenses as in our initial answer. On December 23, 2011, we filed a motion requesting that the court stay the case with respect to each of the above-noted customer Defendants. Cambrian filed its opposition to our motion on December 30, 2011. Our request was denied in the court's decision on March 7, 2012. We presented evidence on the appropriate meanings of relevant key words used in the patent claims during a claim construction hearing on November 20, 2012.

On June 17, 2013, the court issued an order regarding claim construction, in which the court agreed with almost all of our proposed claim constructions. On October 17, 2013, the parties met for a court-mandated mediation. On April 14, 2014, we filed three motions for summary judgment relating to non-infringement and damages. The court scheduled a hearing on the summary judgment motions for June 9, 2014. The court also scheduled a pretrial conference for July 7, 2014, and the jury trial is set to begin on July 22, 2014.

Based on the information available at this time, we concluded that the likelihood of a loss with respect to this suit is reasonably possible. We have further concluded that the range of the reasonably possible loss is an insignificant amount and will not have a material adverse effect on our business, consolidated financial position, results of operations, or cash flows. Accordingly, we accrued an insignificant amount during 2013, which did not have a material adverse effect on our business, consolidated financial position, results of operations, or cash flows. Factors that we considered in the determination of the likelihood of a loss and the estimate of that loss in respect to this matter included the merits of the case, the nature of the litigation (including the complex and technical nature of patent litigation), the length of time the matter has been pending, the status of the plaintiff as a non-operating entity and the likelihood of the plaintiff accepting the estimated amount. However, the outcome of such legal matters is inherently unpredictable and subject to significant uncertainties.

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Item 1A. Risk Factors

A description of the risks and uncertainties associated with our business is set forth below. This description includes any material changes to and supersedes the description of the risks and uncertainties associated with our business previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 28, 2013. You should carefully consider such risks and uncertainties, together with the other information contained in this report, our Annual Report on Form 10-K for the fiscal year ended December 28, 2013 and in our other public filings. If any of such risks and uncertainties actually occurs, our business, financial condition or operating results could differ materially from the plans, projections and other forward-looking statements included in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report and in our other public filings. In addition, if any of the following risks and uncertainties, or if any other risks and uncertainties, actually occurs, our business, financial condition or operating results could be harmed substantially, which could cause the market price of our stock to decline, perhaps significantly.

We have a history of significant operating losses and may not achieve profitability on an annual basis in the future.

For the fiscal year ended December 28, 2013, we recorded a net loss of $32.1 million, and for the quarter ended March 29, 2014, we recorded a net loss of $4.4 million. As of December 28, 2013, our accumulated deficit was $604.5 million. As of March 29, 2014, our accumulated deficit was $608.9 million. We expect to continue to make significant expenditures related to the continued development of our business. These expenditures may include the addition of personnel related to the sales, marketing and research and development of our products and other costs related to the maintenance and expansion of our manufacturing facilities and research and development operations. We may therefore sustain significant operating losses and negative cash flows in the future. We will require increased revenue and product gross margins to achieve profitability on an annual basis.

Our revenue and operating results may fluctuate significantly, which could make our future results difficult to predict and could cause our operating results to fall below investor or analyst expectations.

Our revenue and operating results may fluctuate due to a variety of factors, many of which are outside of our control. Over the past four fiscal quarters, our revenue has ranged from $138.4 million to $142.8 million and our operating income (loss) has ranged from income of $6.4 million to a loss of $8.6 million. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Our budgeted expense levels are based, in large part, on our expectations of long-term future revenue and the development efforts associated with these future revenues. As a result, fluctuations in our revenue and gross margins will have a significant impact on our operating results. Given the relatively fixed nature of our operating costs including those relating to our personnel and facilities, particularly for our engineering personnel, any substantial adjustment to our expenses to account for lower levels of revenue will be difficult and may take time. Consequently, if our revenue does not meet projected levels in the short-term, our inventory levels and operating expenses would be high relative to revenue, resulting in additional operating losses.

In addition to other risks discussed in this section, factors that may contribute to fluctuations in our revenue and our operating results include:

- fluctuations in demand, sales cycles and prices for products and services, including discounts given in response to competitive pricing pressures;
- fluctuations in our product mix, including the mix of higher and lower margin products and significant mix changes resulting from new customer deployments;
- changes in customers' budgets for optical transport network equipment purchases and changes in their purchasing cycles;
- order cancellations or reductions or delays in delivery schedules by our customers;
- the payment terms offered to our customers;

- our ability to control costs, including our operating expenses and the costs of components we purchase for our products;

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- readiness of customer sites for installation of our products;
- the timing of product releases or upgrades by us or by our competitors. In particular, if we fail to achieve targeted release dates for our future products, or convert lab trials and field evaluations by potential customers into purchase orders, our revenue and operating results may be negatively impacted;
- any significant changes in the competitive dynamics of our market, including any new entrants, technological advances or substantial discounting of products;
- availability of third-party suppliers to provide contract engineering and installation services for us;
- the timing of recognizing revenue in any given quarter, including the impact of revenue recognition standards and any future changes in U.S. GAAP or new interpretations of existing accounting rules; and
- general economic conditions in domestic and international markets.

Many factors affecting our results of operations are beyond our control and make it difficult to predict our results for a particular quarter or to accurately predict future revenue beyond a one-quarter time horizon. If our revenue or operating results fall below the expectations of investors or securities analysts or below any guidance we may in the future provide to the market, the price of our common stock may decline substantially.

Our gross margins may fluctuate from quarter-to-quarter and may be adversely affected by a number of factors, some of which are beyond our control.

Our gross margins fluctuate from period-to-period and vary by customer and by product specification. Over the past four fiscal quarters, our gross margins have ranged from 37% to 48%. Our gross margins are likely to continue to fluctuate and will be affected by a number of factors, including:

- the mix in any period of the customers purchasing our products and the product mix, including the relative mix of higher and lower margin products and services;
- significant new customer deployments, often with a higher portion of lower margin common equipment;
- price discounts negotiated by our customers;
- introduction of new products, such as the DTN-X platform, with initial sales at relatively small volumes and higher product costs;
- sales volume from each customer during the period;
- the amount of equipment we sell in any given quarter;
- increased price competition;
- charges for excess or obsolete inventory;
- changes in the price or availability of components for our products;
- changes in our manufacturing costs, including fluctuations in yields and production volumes; and
- increased warranty or repair costs.

It is likely that the average unit prices of our products will decrease over time in response to competitive pricing pressures, increased negotiated sales discounts, new product introductions by us or our competitors or other factors. In addition, some of our customer contracts contain annual technology discounts that require us to decrease the sales price of our products to these customers. In response, we will need to reduce the cost of our products through manufacturing efficiencies, design improvements and cost reductions. If these efforts are not

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successful or if we are unable to reduce our costs to a greater extent than the reduction in the price of our products, our revenue and gross margin will decline, causing our operating results to decline. Fluctuations in gross margin may make it difficult to manage our business and achieve or maintain profitability.

Aggressive business tactics by our competitors may harm our business.

The markets in which we compete are extremely competitive and have resulted in aggressive business tactics by our competitors, including:

- aggressively pricing their optical transport products and other portfolio products, including offering significant one-time discounts and guaranteed future price decreases;
- providing financing, marketing and advertising assistance to customers;
- announcing competing products prior to market availability combined with extensive marketing efforts;
- influencing customer requirements to emphasize different product capabilities, such as greater minimum bandwidth requirements or higher transport speeds;
- offering to repurchase our equipment from existing customers; and
- asserting intellectual property rights.

The level of competition and pricing pressure tend to increase when competing for larger high-profile opportunities or during periods of economic weakness when there are fewer network build-out projects. If we fail to compete successfully against our current and future competitors, or if our current or future competitors continue or expand aggressive business tactics, including those described above, demand for our products could decline, we could experience delays or cancellations of customer orders, or we could be required to reduce our prices or increase our expenses.

Our ability to increase our revenue will depend upon continued growth of demand by consumers and businesses for additional network capacity.

Our future success depends on factors that increase the amount of data transmitted over communications networks and the growth of optical transport networks to meet the increased demand for optical capacity. These factors include the growth of mobility, video, cloud-based services, increased broadband connectivity and the continuing adoption of high-capacity, revenue-generating services. If demand for such bandwidth does not continue, or slows down, the need for increased bandwidth across networks and the market for optical communications network products may not continue to grow and our product sales would be negatively impacted. In addition, if general economic conditions weaken, our customers and potential customers may slow or delay their purchase decisions, which would have an adverse effect on our business and financial condition.

Any delays in the development and introduction of our products, and any future delays in releasing new products or in releasing enhancements to our existing products may harm our business.

Because our products are based on complex technology, including, in some cases, the development of next-generation PICs and specialized ASICs, we may experience unanticipated delays in developing, improving, manufacturing or deploying these products. The development process for our PICs is lengthy, and any modifications to our PICs, including the development of our next-generation PICs, entail significant development cost and risks.

At any given time, various new product introductions and enhancements to our existing products, such as future products based on our next-generation PICs, are in the development phase and are not yet ready for commercial manufacturing or deployment. We rely on third parties, some of which are relatively early stage companies, to develop and manufacture components for our next-generation products, which can require custom development. The maturing process from laboratory prototype to customer trials, and subsequently to general availability, involves a significant number of simultaneous development efforts. These efforts often must be completed in a timely manner so that they may be introduced into the product development cycle for our systems, and include:

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- completion of product development, including the completion of any associated PIC development, such as our next-generation PICs, and the completion of associated module development, including modules developed by third parties;

- the qualification and multiple sourcing of critical components;

- validation of manufacturing methods and processes;

- extensive quality assurance and reliability testing and staffing of testing infrastructure;

- validation of software; and

- establishment of systems integration and systems test validation requirements.

Each of these steps, in turn, presents risks of failure, rework or delay, any one of which could decrease the speed and scope of product introduction and marketplace acceptance of our products. New generations of our PICs, specialized ASICs and intensive software testing are important to the timely introduction of new products and enhancements to our existing products, and are subject to these development risks. In addition, unexpected intellectual property disputes, failure of critical design elements, and a host of other development execution risks may delay, or even prevent, the introduction of new products or enhancements to our existing products. If we do not develop and successfully introduce or enhance products in a timely manner, our competitive position will suffer. In addition, if we do not develop and successfully introduce or enhance products in sufficient time so as to satisfy our customer's expectations, we may lose future business from such customers and harm our reputation and our customer relationships, either of which would harm our business and operating results.

The markets in which we compete are highly competitive and dominated by large corporations, and we may not be able to compete effectively.

Competition in the optical transport equipment market is intense, and we expect such competition to increase. A number of very large companies have historically dominated the optical transport network equipment industry. Our competitors include current WDM suppliers, such as Alcatel-Lucent, Ciena Corporation, Cisco Systems, Inc., Coriant, Huawei Technologies Co. Ltd. and ZTE Corporation. Competition in these markets is based on price, commercial terms, functionality, manufacturing capability, pre-existing installations, services, existing business and customer relationships, scalability and the ability of products and breadth and quality of services to meet our customers' immediate and future network requirements. Other companies have, or may in the future develop, products that are or could be competitive with our products. In particular, if a competitor develops a photonic integrated circuit with similar functionality to our PICs, our business could be harmed. Recent mergers from our competitors and any future acquisitions or combinations between or among our competitors may adversely affect our competitive position by strengthening our competitors.

Many of our competitors have substantially greater name recognition and technical, financial and marketing resources and better established relationships with incumbent carriers and other potential customers than we have. Many of our competitors have more resources to develop or acquire, and more experience in developing or acquiring, new products and technologies and in creating market awareness for those products and technologies. In addition, many of our competitors have the financial resources to offer competitive products at aggressive pricing levels that could prevent us from competing effectively. Further, many of our competitors have built long-standing relationships with some of our prospective customers and have the ability to provide financing to customers and could, therefore, have an inherent advantage in selling products to those customers.

We compete with low-cost producers from China that can increase pricing pressure on us and a number of smaller companies that provide competition for a specific product, customer segment or geographic market. These competitors often base their products on the latest available technologies. Due to the narrower focus of their efforts, these competitors may achieve commercial availability of their products more quickly than we can and may provide

attractive alternatives to our customers.

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Our large customers have substantial negotiating leverage, which may require that we agree to terms and conditions that result in decreased revenue due to lower average selling prices and potentially higher cost of sales leading to lower gross margins, all of which would harm our operating results.

Substantial changes in the optical transport networking industry have occurred over the last few years. Many potential customers have confronted static or declining revenue. Many of our customers have substantial debt burdens, many have experienced financial distress, and some have gone out of business, been acquired by other service providers, or announced their withdrawal from segments of the business. Consolidation in the markets in which we compete has resulted in changes in the structure of the communications networking industry, with greater concentration of purchasing power in a small number of large service providers, cable operators, internet content providers and government agencies. The increased concentration among our customer base may also lead to increased competition for new network deployments and increased negotiating power for our customers. This may require us to decrease our average selling prices, which would have an adverse impact on our operating results.

Further, many of our customers are large communications service providers that have substantial purchasing power and leverage in negotiating contractual arrangements with us. Our customers have and may continue to seek advantageous pricing, payment and other commercial terms and may require us to develop additional features in the products we sell to them. If we are required to develop additional features for our product for a customer, we may be required to defer some of our revenue for such a customer until we have developed and delivered such additional features. We have and may continue to be required to agree to unfavorable commercial terms with these customers, including reducing the average selling price of our products or agreeing to extended payment terms in response to these commercial requirements or competitive pricing pressures. To maintain acceptable operating results, we will need to comply with these commercial terms, develop and introduce new products and product enhancements on a timely basis and continue to reduce our costs.

We expect the factors described above to continue to affect our business and operating results for an indeterminate period, in several ways, including:

- overall capital expenditures by many of our customers or potential customers may be flat or reduced;
- we will continue to have only limited ability to forecast the volume and product mix of our sales;
- managing expenditures and inventory will be difficult in light of the uncertainties surrounding our business; and
- increased competition will enable customers to insist on more favorable terms and conditions for sales, including product discounts, extended payment terms or financing assistance, as a condition of procuring their business.

If we are unable to offset any reductions in our average selling prices with increased sales volumes and reduced production costs, or if we fail to develop and introduce new products and enhancements on a timely basis, or if we disagree on our interpretation and compliance with the commercial terms of our customer agreements, our relationships with our customers and our operating results would be harmed.

We must respond to rapid technological change and comply with evolving industry standards and requirements for our products to be successful.

The optical transport networking equipment market is characterized by rapid technological change, changes in customer requirements and evolving industry standards. We continually invest in research and development to sustain or enhance our existing products, but the introduction of new communications technologies and the emergence of new industry standards or requirements could render our products obsolete. Further, in developing our products, we have made, and will continue to make, assumptions with respect to which standards or requirements will be adopted by our customers and competitors. If the standards or requirements adopted by our prospective customers are different from those on which we have focused our efforts, market acceptance of our products would be reduced or delayed and our business would be harmed.

We are continuing to invest a significant portion of our research and development efforts in the development of our next-generation products. We expect our competitors to continue to improve the performance of their existing products and to introduce new products and technologies and to influence customers' buying criteria so as to emphasize product capabilities that we do not, or may not, possess. To be competitive, we must properly anticipate future customer requirements and we must continue to invest significant resources in research and development,

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sales and marketing and customer support. If we do not anticipate these future customer requirements and invest in the technologies necessary to enable us to have and to sell the appropriate solutions, it may limit our competitive position and future sales, which would have an adverse effect on our business and financial condition. We may not have sufficient resources to make these investments and we may not be able to make the technological advances necessary to be competitive.

We are dependent on sole source and limited source suppliers for several key components, and if we fail to obtain these components on a timely basis, we will not meet our customers' product delivery requirements.

We currently purchase several key components for our products from single or limited sources. In particular, we rely on our own production of certain components of our products, such as PICs, and on third parties as sole source suppliers for certain of the components of our products, including ASICs, field-programmable gate arrays, processors, and other semiconductor and optical components. We purchase these items on a purchase order basis and have no long-term contracts with many of these sole source suppliers. We have increased our reliance on third parties to develop and manufacture components for certain products, some of which require custom development. If any of our sole or limited source suppliers suffer from capacity constraints, lower than expected yields, deployment delays, work stoppages or any other reduction or disruption in output, they may be unable to meet our delivery schedule which could result in lost revenue, additional product costs and deployment delays that could harm our business and customer relationships. Further, our suppliers could enter into exclusive arrangements with our competitors, refuse to sell their products or components to us at commercially reasonable prices or at all, go out of business or discontinue their relationships with us. We may be unable to develop alternative sources for these components.

The loss of a source of supply, or lack of sufficient availability of key components, could require us to redesign products that use such components, which could result in lost revenue, additional product costs and deployment delays that could harm our business and customer relationships. If we do not receive critical components for our products in a timely manner, we will be unable to deliver those components to our contract manufacturer in a timely manner and would, therefore, be unable to meet our prospective customers' product delivery requirements. In addition, the sourcing from new suppliers may require us to re-design our products, which could cause delays in the manufacturing and delivery of our products. In the past, we have experienced delivery delays because of lack of availability of components or reliability issues with components that we were purchasing. In addition, some of our suppliers have gone out of business, limited their supply of components to us, or indicated that they may be going out of business. Historically, we have seen a tightening of supply with a number of our suppliers and we have experienced longer than normal lead times and supply delays. We may in the future experience a shortage of certain components as a result of our own manufacturing issues, manufacturing issues at our suppliers or contract manufacturers, capacity problem experiences by our suppliers or contract manufacturers, or strong demand in the industry for such components. A return to growth in the economy is likely to continue to create pressure on us and our suppliers to accurately project overall component demand and manufacturing capacity. These supplier disruptions may continue to occur in the future, which could limit our ability to produce our products and cause us to fail to meet a customer's delivery requirements. Such events could harm our reputation and our customer relationships, either of which would harm our business and operating results.

If we fail to accurately forecast demand for our products, we may have excess or insufficient inventory, which may increase our operating costs, decrease our revenue and harm our business.

We are required to generate forecasts of future demands for our products several months prior to the scheduled delivery to our prospective customers. This requires us to make significant investments before we know if corresponding revenue will be recognized. Lead times for materials and components, including ASICs, that we need to order for the manufacture of our products vary significantly and depend on factors such as the specific supplier, contract terms and demand for each component at a given time. In the past, we have experienced lengthening in lead times for certain components. If the lead times for components are lengthened, we may be required to purchase increased levels of such components to satisfy our delivery commitments to our customers.

If we overestimate market demand for our products and, as a result, increase our inventory in anticipation of customer orders that do not materialize, we will have excess inventory, which could result in increased risk of obsolescence and

significant inventory write-downs. Furthermore, this will result in reduced production volumes and our fixed costs will be spread across fewer units, increasing our per unit costs. If we underestimate demand for our products, we will have inadequate inventory, which could slow down or interrupt the manufacturing of our products and result in delays in shipments and our ability to recognize revenue. In addition, we may be unable to meet our

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supply commitments to customers, which could result in a loss of certain customer opportunities or a breach of our customer agreements resulting in payment of damages.

If our contract manufacturers do not perform as we expect, our business may be harmed.

We rely on third-party contract manufacturers to perform a significant portion of the manufacturing of our products, and our future success will depend on our ability to have sufficient volumes of our products manufactured in a cost-effective and quality-controlled manner. We have engaged third parties to manufacture certain elements of our products at multiple contract manufacturing sites located around the world but do not have long-term agreements in place with some of our manufacturers and suppliers. There are a number of risks associated with our dependence on contract manufacturers, including:

- reduced control over delivery schedules, particularly for international contract manufacturing sites;
- reliance on the quality assurance procedures of third parties;
- potential uncertainty regarding manufacturing yields and costs;
- potential lack of adequate capacity during periods of high demand;
- potential uncertainty related to the use of international contract manufacturing sites;
- limited warranties on components supplied to us;
- potential misappropriation of our intellectual property; and
- potential manufacturing disruptions (including disruptions caused by geopolitical events, military actions or natural disasters).

Any of these risks could impair our ability to fulfill orders. Our contract manufacturers may not be able to meet the delivery requirements of our customers, which could decrease customer satisfaction and harm our product sales. We do not have long-term contracts or arrangements with our contract manufacturers that will guarantee product availability, or the continuation of particular pricing or payment terms. If our contract manufacturers are unable or unwilling to continue manufacturing our products or components of our products in required volumes or our relationship with any of our contract manufacturers is discontinued for any reason, we would be required to identify and qualify alternative manufacturers, which could cause us to be unable to meet our supply requirements to our customers and result in the breach of our customer agreements. Qualifying a new contract manufacturer and commencing volume production is expensive and time-consuming and if we are required to change or qualify a new contract manufacturer, we would likely lose sales revenue and damage our existing customer relationships.

We are dependent on a small number of key customers for a significant portion of our revenue and the loss of, or a significant reduction in, orders from one or more of our key customers would reduce our revenue and harm our operating results.

A relatively small number of customers account for a large percentage of our revenue. As a result, our business will be harmed if any of our key customers do not generate as much revenue as we forecast, stop purchasing from us, or substantially reduce their orders to us. In addition, our business will be harmed if we fail to maintain our competitive advantage with our key customers.

Our ability to continue to generate revenue from our key customers will depend on our ability to maintain strong relationships with these customers and introduce new products that are desirable to these customers at competitive prices, and we may not be successful at doing so. In most cases, our sales are made to these customers pursuant to standard purchase agreements rather than long-term purchase commitments, and orders may be canceled or reduced readily. In the event of a cancellation or reduction of an order, we may not have enough time to reduce operating expenses to minimize the effect of the lost revenue on our business. Our operating results will continue to depend on

our ability to sell our products to our key customers.

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If we fail to expand sales of our products into international markets or to sell our products to new types of customers, such as U.S. regional Bell operating companies and international postal, telephone and telegraph companies, our revenue will be harmed.

We believe that, in order to grow our revenue and business and to build a large and diverse customer base, we must successfully sell our products in international markets and to new types of customers, such as U.S. regional Bell operating companies and international postal, telephone and telegraph companies. We have limited experience selling our products internationally and to U.S. regional Bell operating companies and international postal, telephone and telegraph companies. Sales cycles for these customers are often very lengthy and competition for these customers is intense. To succeed in these sales efforts, we believe we must hire additional sales personnel to develop our relationships with these potential customers and develop and manage new sales channels through resellers, distributors and systems integrators. If we do not succeed in our efforts to sell to these customers, the size of our total addressable market will be limited. This, in turn, would harm our ability to grow our customer base and revenue.

Our manufacturing process is very complex and the partial or complete loss of our manufacturing facility, or a reduction in yields or an inability to scale capacity to meet customer demands could harm our business.

The manufacturing process for certain components of our products, including our PICs, is technically challenging. In the event that any of these manufacturing facilities were fully or partially destroyed, as a result of fire, water damage, or otherwise, it would limit our ability to produce our products. Because of the complex nature of our manufacturing facilities, such loss would take a considerable amount of time to repair or rebuild. The partial or complete loss of any of our manufacturing facilities, or an event causing the interruption in our use of such facility for any extended period of time would cause our business, financial condition and operating results to be harmed.

Minor deviations in the PIC manufacturing process can cause substantial decreases in yields and, in some cases, cause production to be suspended. In the past, we have had significant variances in our PIC yields, including production interruptions and suspensions and may have continued yield variances, including additional interruptions or suspensions in the future. We expect our manufacturing yield for our next-generation PICs to be lower initially and increase as we achieve full production. Poor yields from our PIC manufacturing process or defects, integration issues or other performance problems in our products could limit our ability to satisfy customer demand requirements, and could cause us customer relations and business reputation problems, harming our business and operating results.

Our inability to obtain sufficient manufacturing capacity to meet demand, either in our own facilities or through foundry or similar arrangements with third parties, could harm our relationships with our customers, our business and our operating results.

If we fail to protect our intellectual property rights, our competitive position could be harmed or we could incur significant expense to enforce our rights.

We depend on our ability to protect our proprietary technology. We rely on a combination of methods to protect our intellectual property, including limiting access to certain information, and utilizing trade secret, patent, copyright and trademark laws and confidentiality agreements with employees and third parties, all of which offer only limited protection. The steps we have taken to protect our proprietary rights may be inadequate to preclude misappropriation or unauthorized disclosure of our proprietary information or infringement of our intellectual property rights, and our ability to police such misappropriation, unauthorized disclosure or infringement is uncertain, particularly in countries outside of the United States. This is likely to become an increasingly important issue as we expand our operations and product development into countries that provide a lower level of intellectual property protection. We do not know whether any of our pending patent applications will result in the issuance of patents or whether the examination process will require us to narrow our claims, and even if patents are issued, they may be contested, circumvented or invalidated. Moreover, the rights granted under any issued patents may not provide us with a competitive advantage, and, as with any technology, competitors may be able to develop similar or superior technologies to our own now or in the future.

Protecting against the unauthorized use of our products, trademarks and other proprietary rights is expensive, difficult, time consuming and, in some cases, impossible. Litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity or scope of the proprietary rights of others. Such litigation could result in substantial cost and diversion of management resources, either of which could

harm our business, financial condition and operating results. Furthermore, many of our current

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and potential competitors have the ability to dedicate substantially greater resources to enforce their intellectual property rights than we do. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property.

Claims by others that we infringe their intellectual property could harm our business.

Our industry is characterized by the existence of a large number of patents and frequent claims and related litigation regarding patent and other intellectual property rights. In particular, many leading companies in the optical transport networking industry, including our competitors, have extensive patent portfolios with respect to optical transport networking technology. We expect that infringement claims may increase as the number of products and competitors in our market increases and overlaps occur. From time to time, third parties may assert exclusive patent, copyright, trademark and other intellectual property rights to technologies and related standards that are important to our business or seek to invalidate the proprietary rights that we hold. Competitors or other third parties have, and may continue to assert claims or initiate litigation or other proceedings against us or our manufacturers, suppliers or customers alleging infringement of their proprietary rights, or seeking to invalidate our proprietary rights, with respect to our products and technology. In the event that we are unsuccessful in defending against any such claims, or any resulting lawsuit or proceedings, we could incur liability for damages and/or have valuable proprietary rights invalidated.

Any claim of infringement from a third party, even one without merit, could cause us to incur substantial costs defending against the claim, and could distract our management from running our business. Furthermore, a party making such a claim, if successful, could secure a judgment that requires us to pay substantial damages. A judgment could also include an injunction or other court order that could prevent us from offering our products. In addition, we might be required to seek a license for the use of such intellectual property, which may not be available on commercially reasonable terms or at all. Alternatively, we may be required to develop non-infringing technology, which would require significant effort and expense and may ultimately not be successful. Any of these events could harm our business, financial condition and operating results. Competitors and other third parties have and may continue to assert infringement claims against our customers and sales partners. Any of these claims would require us to initiate or defend potentially protracted and costly litigation on their behalf, regardless of the merits of these claims, because we generally indemnify our customers and sales partners from claims of infringement of proprietary rights of third parties. If any of these claims succeed, we may be forced to pay damages on behalf of our customers or sales partners, which could have an adverse effect on our business, financial condition and operating results.

We incorporate open source software into our products. Although we monitor our use of open source software closely, the terms of many open source licenses have not been interpreted by U.S. courts, and there is a risk that such licenses could be construed in a manner that could impose unanticipated conditions or restrictions on our ability to commercialize our products. In such event, we could be required to seek licenses from third parties in order to continue offering our products, to re-engineer our products or to discontinue the sale of our products in the event re-engineering cannot be accomplished on a timely basis, any of which could adversely affect our business, operating results and financial condition.

We are involved in litigation with Cambrian whereby Cambrian alleged that we and seven of our customers infringe one of Cambrian's patents. Information regarding this matter is set forth in Part II, Item 1. “Legal Proceedings,” and is incorporated herein by reference.

Unfavorable macroeconomic and market conditions may adversely affect our industry, business and gross margins.

Our business depends on the overall demand for additional bandwidth capacity and on the economic health and willingness of our customers and potential customers to make capital commitments to purchase our products and services. As a result of macroeconomic or market uncertainty, we may face new risks that we have not yet identified. In addition, a number of the risks associated with our business, which are disclosed in these risk factors, may increase in likelihood, magnitude or duration.

In the past, unfavorable macroeconomic and market conditions have resulted in sustained periods of decreased demand for optical communications products. These conditions may also result in the tightening of credit markets, which may limit or delay our customers’ ability to obtain necessary financing for their purchases of our products. A

lack of liquidity in the capital markets or the continued uncertainty in the global economic environment may cause our customers to delay or cancel their purchases, increase the time they take to pay or default on their payment obligations, each of which would negatively affect our business and operating results. Continued

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weakness and uncertainty in the global economy could cause some of our customers to become illiquid, delay payments or adversely affect our collection of their accounts, which could result in a higher level of bad debt expense. In addition, currency fluctuations could negatively affect our international customers' ability or desire to purchase our products.

Challenging economic conditions have from time to time contributed to slowdowns in the telecommunications industry in which we operate. Such slowdowns may result in:

- reduced demand for our products as a result of constraints on capital spending by our customers, particularly service providers;
- increased price competition for our products, not only from our competitors, but also as a result of our customer's or potential customer's utilization of inventoried or underutilized products, which could put additional downward pressure on our near term gross profits;
- risk of excess or obsolete inventories;
- excess manufacturing capacity and higher associated overhead costs as a percentage of revenue; and
- more limited ability to accurately forecast our business and future financial performance.

A lack of liquidity and economic uncertainty may adversely affect our suppliers or the terms on which we purchase products from these suppliers. It may also cause some of our suppliers to become illiquid. Any of these impacts could limit our ability to obtain components for our products from these suppliers and could adversely impact our supply chain or the delivery schedule to our customers. This also could require us to purchase more expensive components, or re-design our products, which could cause increases in the cost of our products and delays in the manufacturing and delivery of our products. Such events could harm our gross margins and harm our reputation and our customer relationships, either of which could harm our business and operating results.

Product performance problems, including undetected errors in our hardware or software, or deployment delays could harm our business and reputation.

The development and production of new products with high technology content is complicated and often involves problems with software, components and manufacturing methods. Complex hardware and software systems, such as our products, can often contain undetected errors when first introduced or as new versions are released. In addition, errors associated with components we purchase from third parties, including customized components, may be difficult to resolve. We have experienced errors in the past in connection with our DTN platform, including failures due to the receipt of faulty components from our suppliers. We suspect that errors, including potentially serious errors, will be found from time to time in our products. Our products may suffer degradation of performance and reliability over time.

If reliability, quality or network monitoring problems develop, a number of negative effects on our business could result, including:

- delays in our ability to recognize revenue;
- costs associated with fixing software or hardware defects or replacing products;
- high service and warranty expenses;
- delays in shipments;
- high inventory excess and obsolescence expense;

- high levels of product returns;
- diversion of our engineering personnel from our product development efforts;
- delays in collecting accounts receivable;

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- payment of damages for performance failures;
- reduced orders from existing customers; and
- declining interest from potential customers.

Because we outsource the manufacturing of certain components of our products, we may also be subject to product performance problems as a result of the acts or omissions of third parties.

From time to time, we encounter interruptions or delays in the activation of our products at a customer's site. These interruptions or delays may result from product performance problems or from issues with installation and activation, some of which are outside our control. If we experience significant interruptions or delays that we cannot promptly resolve, the associated revenue for these installations may be delayed or confidence in our products could be undermined, which could cause us to lose customers and fail to add new customers.

If we lose key personnel or fail to attract and retain additional qualified personnel when needed, our business may be harmed.

Our success depends to a significant degree upon the continued contributions of our key management, engineering, sales and marketing, and finance personnel, many of whom would be difficult to replace. For example, senior members of our engineering team have unique technical experience that would be difficult to replace. We do not have long-term employment contracts or key person life insurance covering any of our key personnel. Because our products are complex, we must hire and retain a large number of highly trained customer service and support personnel to ensure that the deployment of our products do not result in network disruption for our customers. We believe our future success will depend in large part upon our ability to identify, attract and retain highly skilled managerial, engineering, sales, marketing, finance and customer service and support personnel. Competition for these individuals is intense in our industry, especially in the San Francisco Bay Area where we are headquartered. We may not succeed in identifying, attracting and retaining appropriate personnel. The loss of the services of any of our key personnel, the inability to identify, attract or retain qualified personnel in the future or delays in hiring qualified personnel, particularly engineers and sales personnel, could make it difficult for us to manage our business and meet key objectives, such as timely product introductions.

Our debt obligations may adversely affect our ability to raise additional capital and will be a burden on our future cash flows and cash resources, particularly if these obligations are settled in cash upon maturity or sooner upon an event of default.

In May 2013, we issued the Notes. The degree to which we are leveraged could have important consequences, including, but not limited to, the following:

- our ability to obtain additional financing in the future for working capital, capital expenditures, acquisitions, litigation, general corporate or other purposes may be limited;
- a substantial portion of our future cash balance may be dedicated to the payment of the principal of our indebtedness as we have the intention to pay the principal amount of the Notes in cash upon conversion if specified conditions are met or when due, such that we would not have those funds available for use in our business; and
- if upon any conversion of the Notes we are required to satisfy our conversion obligation with shares of our common stock or if a make-whole fundamental change occurs, our existing stockholders' interest in us would be diluted.

Our ability to meet our payment obligations under our debt instruments depends on our future cash flow performance. This, to some extent, is subject to general economic, financial, competitive, legislative and regulatory factors, as well as other factors that may be beyond our control. There can be no assurance that our business will generate positive cash flow from operations, or that additional capital will be available to us, in an amount sufficient to enable us to meet our debt payment obligations and to fund other liquidity needs. If we are unable to generate sufficient cash flow to service our debt obligations, we may need to refinance or restructure our debt, sell assets, reduce or delay capital investments, or seek to raise additional capital. If we were unable to implement one or more of these alternatives, we

may be unable to meet our debt payment obligations. As a result, we may be more

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vulnerable to economic downturns, less able to withstand competitive pressures and less flexible in responding to changing business and economic conditions.

We may issue additional shares of our common stock in connection with the conversion of the Notes, and thereby dilute our existing stockholders and potentially adversely affect the market price of our common stock.

In the event that some or all of the Notes are converted into common stock, the ownership interests of existing stockholders will be diluted, and any sales in the public market of any shares of our common stock issuable upon such conversion of the Notes could adversely affect the prevailing market price of our common stock. In addition, the anticipated conversion of the Notes could depress the market price of our common stock.

The accounting method for convertible debt securities that may be settled in cash, such as the Notes, could have a material effect on our reported financial results.

Under Accounting Standards Codification 470-20, Debt with Conversion and Other Options ("ASC 470-20"), an entity must separately account for the liability and equity components of the convertible debt instruments (such as the Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the Notes is that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheet at the issuance date and the value of the equity component would be treated as debt discount for purposes of accounting for the debt component of the Notes. As a result, we will be required to record a greater amount of non-cash interest expense as a result of the amortization of the discounted carrying value of the Notes to their face amount over the term of the Notes.

The make-whole fundamental change provisions of the Notes may delay or prevent an otherwise beneficial takeover attempt of us.

If a make-whole fundamental change such as an acquisition of our company occurs prior to the maturity of the Notes, under certain circumstances, the conversion rate for the Notes will increase such that additional shares of our common stock will be issued upon conversion of the Notes in connection with such make-whole fundamental change. The increase in the conversion rate will be determined based on the date on which the make-whole fundamental change occurs or becomes effective and the price paid (or deemed paid) per share of our common stock in such transaction. This increase will be dilutive to our existing stockholders. Our obligation to increase the conversion rate upon the occurrence of a make-whole fundamental change may, in certain circumstances, delay or prevent a takeover of us that might otherwise be beneficial to our stockholders.

If we need additional capital in the future, it may not be available to us on favorable terms, or at all.

Our business requires significant capital. We have historically relied on significant outside debt or equity financing as well as cash flow from operations to fund our operations, capital expenditures and expansion. We may require additional capital from equity or debt financings in the future to fund our operations or respond to competitive pressures or strategic opportunities. We have a history of significant operating losses. For 2013, we had a net loss of $32.1 million. In the event that we require additional capital, we may not be able to secure timely additional financing on favorable terms, or at all. The terms of any additional financing may place limits on our financial and operating flexibility. If we raise additional funds through further issuances of equity, convertible debt securities or other securities convertible into equity, our existing stockholders could suffer dilution in their percentage ownership of our company, and any new securities we issue could have rights, preferences and privileges senior to those of holders of our common stock. If we are unable to obtain adequate financing or financing on terms satisfactory to us, if and when we require it, our ability to grow or support our business and to respond to business challenges could be limited and our business will be harmed.

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Our sales cycle can be long and unpredictable, which could result in an unexpected revenue shortfall in any given quarter.

Our products have a lengthy sales cycle, which can extend from six to twelve months and may take even longer for larger prospective customers such as U.S. regional Bell operating companies, international postal, telephone and telegraph companies and U.S. competitive local exchange carriers. Our prospective customers conduct significant evaluation, testing, implementation and acceptance procedures before they purchase our products. We incur substantial sales and marketing expenses and expend significant management effort during this time, regardless of whether we make a sale.

Because the purchase of our equipment involves substantial cost, most of our customers wait to purchase our equipment until they are ready to deploy it in their network. As a result, it is difficult for us to accurately predict the timing of future purchases by our customers. In addition, product purchases are often subject to budget constraints, multiple approvals and unplanned administrative processing and other delays. If sales expected from customers for a particular quarter are not realized in that quarter or at all, our revenue will be negatively impacted.

Our international sales and operations subject us to additional risks that may harm our operating results.

We market, sell and service our products globally. During the first quarter of 2014 and in the years 2013 and 2012, we derived approximately 22%, 36% and 32%, respectively, of our revenue from customers outside of the United States. We have sales and support personnel in numerous countries worldwide. In addition, we have a large group of development personnel located in Bangalore, India; Beijing, China; and Kanata, Canada. We expect that significant management attention and financial resources will be required for our international activities over the foreseeable future as we continue to expand our international presence. In some countries, our successes in selling our products will depend in part on our ability to form relationships with local partners. Our inability to identify appropriate partners or reach mutually satisfactory arrangements for international sales of our products could impact our ability to maintain or increase international market demand for our products.

Our international operations are subject to inherent risks, and our future results could be adversely affected by a variety of factors, many of which are outside of our control, including:

- greater difficulty in collecting accounts receivable and longer collection periods;
- difficulties of managing and staffing international offices, and the increased travel, infrastructure and legal compliance costs associated with multiple international locations;
- the impact of recessions in economies outside the United States;
- tariff and trade barriers and other regulatory requirements or contractual limitations on our ability to sell or develop our products in certain foreign markets;
- certification requirements;
- greater difficulty documenting and testing our internal controls;
- reduced protection for intellectual property rights in some countries;
- potentially adverse tax consequences;
- political and economic instability;
- effects of changes in currency exchange rates that could negatively affect our financial results and cash flows; and
- service provider and government spending patterns.

International customers may also require that we comply with certain testing or customization of our products to conform to local standards. The product development costs to test or customize our products could be extensive and a material expense for us.

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Our international operations are subject to increasingly complex foreign and U.S. laws and regulations, including but not limited to anti-corruption laws, such as the Foreign Corrupt Practices Act and the UK Bribery Act and equivalent laws in other jurisdictions, antitrust or competition laws, and data privacy laws, among others. Violations of these laws and regulations could result in fines and penalties, criminal sanctions against us, our officers, or our employees, prohibitions on the conduct of our business and on our ability to offer our products and services in one or more countries, and could also materially affect our reputation, our international expansion efforts, our ability to attract and retain employees, our business, and our operating results. Although we have implemented policies, procedures and training designed to ensure compliance with these laws and regulations, there can be no complete assurance that any individual employee, contractor, or agent will not violate our policies. Additionally, the costs of complying with these laws (including the costs of investigations, auditing and monitoring) could also adversely affect our current or future business.

As we continue to expand our business globally, our success will depend, in large part, on our ability to anticipate and effectively manage these and other risks associated with our international operations. Our failure to manage any of these risks could harm our international operations and reduce our international sales.

We may be adversely affected by fluctuations in currency exchange rates.

A portion of our sales are to countries outside of the United States, and are in currencies other than U.S. dollars, and therefore subject to foreign currency fluctuation. Accordingly, fluctuations in foreign currency rates could have a material impact on our revenue in future periods. We also have exposure to currency exchange rates as a result of the growth in our non-U.S. dollar denominated operating expense in Europe, Asia and Canada. We currently enter into foreign currency exchange forward contracts to reduce the impact of foreign currency fluctuations on accounts receivable denominated in euro and the British pound. These hedging programs reduce the impact of currency exchange rate movements on certain transactions, but do not cover all foreign-denominated transactions and therefore do not entirely eliminate the impact of fluctuations in exchange rates that could negatively affect our results of operations and financial condition.

If we fail to maintain effective internal control over financial reporting in the future, the accuracy and timing of our financial reporting may be adversely affected.

We are required to comply with Section 404 of the Sarbanes-Oxley Act of 2002. The provisions of the act require, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. Preparing our financial statements involves a number of complex processes, many of which are done manually and are dependent upon individual data input or review. These processes include, but are not limited to, calculating revenue, deferred revenue and inventory costs. While we continue to automate our processes and enhance our review and put in place controls to reduce the likelihood for errors, we expect that for the foreseeable future, many of our processes will remain manually intensive and thus subject to human error.

Any acquisitions we make could disrupt our business and harm our financial condition and operations.

We have made strategic acquisitions of businesses, technologies and other assets in the past. While we have no current agreements or commitments, we may in the future acquire businesses, product lines or technologies. In the event of any future acquisitions, we may not ultimately strengthen our competitive position or achieve our goals, or they may be viewed negatively by customers, financial markets or investors and we could:

- issue stock that would dilute our current stockholders' percentage ownership;
- incur debt and assume other liabilities; or
- incur amortization expenses related to goodwill and other intangible assets and/or incur large and immediate write-offs.

Acquisitions also involve numerous risks, including:

- problems integrating the acquired operations, technologies or products with our own;

- diversion of management's attention from our core business;
- assumption of unknown liabilities;

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- adverse effects on existing business relationships with suppliers and customers;
- increased accounting compliance risk;
- risks associated with entering new markets; and
- potential loss of key employees.

We may not be able to successfully integrate any businesses, products, technologies or personnel that we might acquire in the future. Our failure to do so could have an adverse effect on our business, financial condition and operating results.

Our use and reliance upon development resources in India, China and Canada may expose us to unanticipated costs or liabilities.

We have established development centers in India, China and Canada and expect to continue to increase hiring of personnel for these facilities. There is no assurance that our reliance upon development resources in India, China or Canada will enable us to achieve meaningful cost reductions or greater resource efficiency. Further, our development efforts and other operations in these countries involve significant risks, including:

- difficulty hiring and retaining appropriate engineering resources due to intense competition for such resources and resulting wage inflation;
- the knowledge transfer related to our technology and exposure to misappropriation of intellectual property or confidential information, including information that is proprietary to us, our customers and other third parties;
- heightened exposure to changes in the economic, security and political conditions of India, China and Canada;
- fluctuation in currency exchange rates and tax risks associated with international operations; and
- development efforts that do not meet our requirements because of language, cultural or other differences associated with international operations, resulting in errors or delays.

Difficulties resulting from the factors above and other risks related to our operations in these countries could expose us to increased expense, impair our development efforts, harm our competitive position and damage our reputation.

Unforeseen health, safety and environmental costs could harm our business.

Our manufacturing operations use substances that are regulated by various federal, state and international laws governing health, safety and the environment, including the Waste Electrical and Electronic Equipment and Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment regulations adopted by the European Union. If we experience a problem with these substances, it could cause an interruption or delay in our manufacturing operations or could cause us to incur liabilities for any costs related to health, safety or environmental remediation. We could also be subject to liability if we do not handle these substances in compliance with safety standards for storage and transportation and applicable laws. If we experience a problem or fail to comply with such safety standards, our business, financial condition and operating results may be harmed.

We are subject to governmental regulations that could adversely affect our business.

We are subject to export control laws that limit which products we sell and where and to whom we sell our products. U.S. export control laws also limit our ability to conduct product development activities in certain countries. In addition, various countries regulate the import of certain technologies and have enacted laws that could limit our ability to distribute our products or could limit our customers' ability to implement our products in those countries. Changes in our products or changes in import and export regulations may create delays in the introduction of our products in international markets, prevent our customers with international operations from deploying our products

throughout their global systems or, in some cases, prevent the import and export of our

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products to certain countries altogether. Any change in import and export regulations or related legislation, shift in approach to the enforcement or scope of existing regulations, or change in the countries, persons or technologies targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export or sell our products to, existing or potential customers with international operations. Failure to comply with these and similar laws on a timely basis, or at all, decreased use of our products or any limitation on our ability to export or sell our products would adversely affect our business, financial condition and operating results.

Our product or manufacturing standards could also be impacted by new or revised environmental rules and regulations or other social initiatives. For instance, the SEC adopted new disclosure requirements in 2012 relating to the sourcing of certain minerals from the Democratic Republic of Congo and certain other adjoining countries. Those rules, which will require reporting in calendar 2014, could adversely affect our costs, the availability of minerals used in our products and our relationships with customers and suppliers.

The Federal Communications Commission ("FCC") has jurisdiction over the entire U.S. communications industry and, as a result, our products and our U.S. customers are subject to FCC rules and regulations. Current and future FCC regulations affecting communications services, our products or our customers' businesses could negatively affect our business. In addition, international regulatory standards could impair our ability to develop products for international customers in the future. Moreover, many jurisdictions are evaluating or implementing regulations relating to cyber security, privacy and data protection, which can affect the market and requirements for networking and communications equipment. Delays caused by our compliance with regulatory requirements could result in postponements or cancellations of product orders. Further, we may not be successful in obtaining or maintaining any regulatory approvals that may, in the future, be required to operate our business. Any failure to obtain such approvals could harm our business and operating results.

Natural disasters, terrorist attacks or other catastrophic events could harm our operations.

Our headquarters and the majority of our infrastructure, including our PIC fabrication manufacturing facility, are located in Northern California, an area that is susceptible to earthquakes and other natural disasters. Further, a terrorist attack aimed at Northern California or at our nation's energy or telecommunications infrastructure could hinder or delay the development and sale of our products. In the event that an earthquake, terrorist attack or other man-made or natural catastrophe were to destroy any part of our facilities, or certain of our contract manufacturers' facilities, destroy or disrupt vital infrastructure systems or interrupt our operations for any extended period of time, our business, financial condition and operating results would be harmed.

Security incidents, such as data breaches and cyber-attacks, could compromise our intellectual property and proprietary or confidential information and cause significant damage to our business and reputation.

In the ordinary course of our business, we maintain sensitive data on our networks, including data related to our intellectual property and data related to our business and that of our customers and business partners that is considered proprietary or confidential information. We believe that companies in the technology industry have been increasingly subject to a wide variety of security incidents, cyber-attacks and other attempts to gain unauthorized access. While the secure maintenance of this information is critical to our business and reputation, our network and storage applications may be subject to unauthorized access by hackers or breached due to operator error, malfeasance or other system disruptions. It may be difficult to anticipate or immediately detect such security incidents or data breaches and the damage caused as a result. Accordingly, a data breach, cyber-attack, or unauthorized access or disclosure of our information, could compromise our intellectual property and reveal proprietary or confidential business information. In addition, these security incidents could also cause us to incur significant remediation costs and expenses, disrupt key business operations, subject us to liability and divert attention of management and key information technology resources, any of which could cause significant harm to our business and reputation.

The trading price of our common stock has been volatile and is likely to be volatile in the future.

The trading prices of our common stock and the securities of other technology companies have been and may continue to be highly volatile. Further, our common stock has limited prior trading history. Factors affecting the trading price of our common stock include:

•variations in our operating results;

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- announcements of technological innovations, new services or service enhancements, strategic alliances or agreements by us or by our competitors;
- the gain or loss of customers;
- recruitment or departure of key personnel;
- changes in the estimates of our future operating results or external guidance on those results or changes in recommendations by any securities analysts that elect to follow our common stock;
- market conditions in our industry, the industries of our customers and the economy as a whole; and
- adoption or modification of regulations, policies, procedures or programs applicable to our business.

In addition, if the market for technology stocks or the stock market in general experiences loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition or operating results. The trading price of our common stock might also decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. Each of these factors, among others, could harm the value of your investment in our common stock. Some companies that have had volatile market prices for their securities have had securities class action lawsuits filed against them. If a suit were filed against us, regardless of its merits or outcome, it could result in substantial costs and divert management's attention and resources.

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

We are a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law, which apply to us, may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our amended and restated certificate of incorporation and amended and restated bylaws:

- authorize the issuance of "blank check" convertible preferred stock that could be issued by our board of directors to thwart a takeover attempt;
- establish a classified board of directors, as a result of which the successors to the directors whose terms have expired will be elected to serve from the time of election and qualification until the third annual meeting following their election;
- require that directors only be removed from office for cause and only upon a supermajority stockholder vote;
- provide that vacancies on the board of directors, including newly-created directorships, may be filled only by a majority vote of directors then in office rather than by stockholders;
- prevent stockholders from calling special meetings; and
- prohibit stockholder action by written consent, requiring all actions to be taken at a meeting of the stockholders.

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Item 6. Exhibits

Exhibit No.	Description
10.1	Consulting Agreement between Ita Brennan and the Company dated February 28, 2014, incorporated by reference to Exhibit 10.1 of the registrant's Current Report on Form 8-K as filed on March 3, 2014
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the SEC and is not to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

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SIGNATURES

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

Infinera Corporation

By:	/s/ BRAD FELLER Brad Feller Chief Financial Officer (Duly Authorized Officer and Principal Financial Officer)
Date:	April 30, 2014