

NUPATHE INC.  
Form 10-K  
March 27, 2013

Use these links to rapidly review the document

[Table of Contents](#)

[ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA](#)

[ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES](#)

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM 10-K**

---

(Mark One)

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

For the fiscal year ended December 31, 2012

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934  
Commission file number 001-34836

---

**NuPathe Inc.**

(Exact name of registrant as specified in its charter)

---

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**20-2218246**  
(IRS Employer  
Identification number)

**227 Washington Street**  
**Suite 200**  
**Conshohocken, Pennsylvania**  
(Address of principal executive offices)

**19428**  
(Zip Code)

Registrant's telephone number, including area code: **(484) 567-0130**

---

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

**Title of each class**  
Common Stock, \$0.001 par value per share

**Name of each exchange on which registered**  
The NASDAQ Stock Market LLC  
(The NASDAQ Global Market)

Securities registered pursuant to Section 12(g) of the Securities Exchange Act of 1934: **None**

# Edgar Filing: NUPATHE INC. - Form 10-K

---

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, 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  No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a  
smaller reporting company)

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, was \$28,866,044 as of June 30, 2012, the last day of the registrant's second fiscal quarter for the year ended December 31, 2012, based upon the closing sale price on The NASDAQ Global Market reported for such date. Shares of common stock held by the registrant's officers and directors and by each other person who may be deemed to be an affiliate have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 25, 2013, there were 29,071,164 shares of the registrant's common stock, \$0.001 par value per share, outstanding.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2013 annual meeting of stockholders are incorporated by reference into Part III of this Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days after the fiscal year ended December 31, 2012.

---

Table of Contents

NUPATHE INC.

Annual Report on Form 10-K for the Fiscal Year Ended December 31, 2012

Table of Contents

|   |            |
|---|------------|
| <u>CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>   | i          |
| <u>PART I</u>   |            |
| <u>Item 1. Business</u>   | <u>1</u>   |
| <u>Item 1A. Risk Factors</u>  | <u>27</u>  |
| <u>Item 1B. Unresolved Staff Comments</u>   | <u>52</u>  |
| <u>Item 2. Properties</u>   | <u>52</u>  |
| <u>Item 3. Legal Proceedings</u>  | <u>52</u>  |
| <u>Item 4. Mine Safety Disclosures</u>  | <u>52</u>  |
| <u>PART II</u>  |            |
| <u>Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> | <u>53</u>  |
| <u>Item 6. Selected Financial Data</u>  | <u>53</u>  |
| <u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                        | <u>55</u>  |
| <u>Item 7A. Quantitative and Qualitative Disclosures About Market Risk</u>  | <u>69</u>  |
| <u>Item 8. Financial Statements and Supplementary Data</u>  | <u>70</u>  |
| <u>Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>                         | <u>100</u> |
| <u>Item 9A. Controls and Procedures</u>   | <u>100</u> |
| <u>Item 9B. Other Information</u>   | <u>101</u> |
| <u>PART III</u>   |            |
| <u>Item 10. Directors, Executive Officers and Corporate Governance</u>  | <u>102</u> |
| <u>Item 11. Executive Compensation</u>  | <u>102</u> |
| <u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>              | <u>102</u> |
| <u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>                                   | <u>102</u> |
| <u>Item 14. Principal Accountant Fees and Services.</u>   | <u>102</u> |
| <u>PART IV</u>  |            |
| <u>Item 15. Exhibits, Financial Statement Schedules</u>   | <u>103</u> |
| <u>SIGNATURES</u>   | <u>104</u> |
| <u>EXHIBIT INDEX</u>  | <u>106</u> |

Unless the context otherwise indicates, references in this Form 10-K to "NuPathe," "the Company," "we," "us" and "our" refer to NuPathe Inc.

NuPathe®, Zecuity , SmartRelief and LAD are trademarks of NuPathe Inc. All other trademarks, trade names and service marks appearing in this Form 10-K are the property of their respective owners.

Table of Contents

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

All statements contained in, or incorporated by reference into, this Form 10-K that are not historical facts are hereby identified as "forward-looking statements" and include, among others, statements relating to:

the sufficiency of our cash and cash equivalents to fund our operations and debt service obligations into the fourth quarter of 2013;

our ability to obtain additional capital in sufficient amounts and on terms acceptable to us, and the consequences of failing to do so;

future expenses and capital requirements;

the expected launch of Zecuity in the fourth quarter of 2013;

our plans to obtain commercial and development partners for Zecuity and our other product candidates, and the timing of any such partnerships;

our commercialization plans regarding Zecuity and our other product candidates;

our development, manufacturing and commercialization capabilities;

our ability to establish and effectively manage our supply chain;

the performance of our partners and other third parties;

the rate and degree of market acceptance of Zecuity and any other future products;

our ability to obtain adequate reimbursement from government and other third party payors for Zecuity;

the size of the potential markets for Zecuity and our other product candidates and our ability to serve those markets;

our development plans and ability to obtain marketing approval of NP201 and NP202;

our ongoing and planned preclinical studies, clinical trials and regulatory submissions (including post-marketing requirements for Zecuity);

the implication of results from clinical trials and other research activities;

## Edgar Filing: NUPATHE INC. - Form 10-K

our ability to acquire or license suitable product candidates or technologies from third parties;

our ability to obtain and maintain intellectual property protection and the scope of such protection; and

the effect of legal and regulatory developments in the U.S. and foreign countries;

as well as other statements relating to our expectations, plans and beliefs regarding our future operations, financial performance or financial condition or other future events (including assumptions underlying or relating to any of the foregoing). Forward-looking statements appear primarily in the sections of this Form 10-K entitled "Item 1 Business," "Item 1A Risk Factors," "Item 2 Properties", "Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations", "Item 7A Quantitative and Qualitative Disclosures About Market Risk," and "Item 8 Financial Statements and Supplementary Data." In some cases, you can identify forward-looking statements by words such as "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing," "scheduled" and similar expressions, although not all forward-looking statements contain these identifying words.

## Edgar Filing: NUPATHE INC. - Form 10-K

### Table of Contents

Forward-looking statements are based upon our current expectations, plans and beliefs and are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results to differ materially and adversely from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this Form 10-K and in particular the risks and uncertainties discussed under Item 1A "Risk Factors" of this Form 10-K and those discussed in other documents we file with the Securities and Exchange Commission (SEC). As a result, you should not place undue reliance on forward-looking statements.

The forward-looking statements contained in this Form 10-K represent our views only as of the date of this Form 10-K (or any earlier date indicated in such statement). While we may update certain forward-looking statements from time to time, we specifically disclaim any obligation to do so, whether as a result of new information, future developments or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in the periodic and current reports that we file with the SEC. Our SEC filings are available free of charge through the "Investor Relations SEC filings" page of our website at [www.nupathe.com](http://www.nupathe.com) and through the SEC's website at [www.sec.gov](http://www.sec.gov). The information contained on our website, or accessible thereby, is not a part of this Form 10-K.

The foregoing cautionary statements are intended to qualify all forward-looking statements wherever they may appear in this Form 10-K. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Table of Contents

**PART I**

**ITEM 1. BUSINESS**

**Overview**

We are a specialty pharmaceutical company focused on the development and commercialization of branded therapeutics for diseases of the central nervous system, including neurological and psychiatric disorders. Our lead product, Zecuity (sumatriptan iontophoretic transdermal system), was approved by the FDA on January 17, 2013 for the acute treatment of migraine, with or without aura, in adults. In addition to Zecuity, we have two pipeline product candidates, NP201 for the continuous symptomatic treatment of Parkinson's disease, and NP202 for the long-term treatment of schizophrenia and bipolar disorder use our proprietary LAD biodegradable implant technology.

Zecuity is a single-use, battery-powered patch that actively delivers sumatriptan, the most prescribed migraine medication in the U.S., through the skin. Zecuity is the first patch approved by the FDA for the acute treatment of migraine. We expect to make Zecuity available by prescription in the fourth quarter of 2013 and are actively seeking partnerships to maximize the commercial potential for Zecuity in the U.S. and territories throughout the world.

Zecuity is designed to overcome limitations of current migraine treatments that are related to route of administration and peak plasma concentrations, and in particular, to address the unmet needs of patients who experience migraine-related nausea (MRN) as part of their attacks. While migraine is commonly associated with a debilitating headache that is the hallmark of a migraine, migraine-related nausea can be a significant source of disability. According to an article by Dr. Richard Lipton in 2013 in *Headache*, a peer-reviewed medical journal, and based upon an analysis of the American Migraine Prevalence and Prevention (AMPP) Study, 49.5% of migraine patients experience MRN in at least half of their migraine attacks. In this analysis, the patients who frequently experience migraine-related nausea reported more migraine disease burden and impairment to work and life including increased odds of being on medical leave, and reported higher headache pain severity and headache impact compared with patients who infrequently or never experience MRN.

According to a survey conducted by the National Headache Foundation in 2008, 48% of respondents who ever experienced nausea or vomiting with a migraine reported that the nausea or vomiting had a moderate to major impact on when or how they take their migraine medication. In the same survey, some migraineurs reported they delay taking migraine medication until nausea subsides, while others reported they avoid taking their migraine medication altogether because of nausea and expectation or fear of vomiting. Because Zecuity is administered transdermally, we believe that it will be an attractive treatment option for migraine patients suffering from nausea or vomiting who might otherwise delay or avoid taking oral medication.

Many patients also avoid or delay treatment because they fear triptan sensation adverse events, which include chest tightness, chest heaviness, numbness of the extremities, paresthesias (or tingling), and panic. According to U.S. prescribing information, the incidence of triptan sensation adverse events referred to as atypical sensations is 42% for subcutaneous injection. For oral sumatriptan, the incidence of triptan sensation adverse events referred to as atypical sensations is up to 6% and those referred to as pain and pressure sensations is up to 8%, depending upon the dose. We developed Zecuity to deliver therapeutic sumatriptan plasma levels without reaching levels commonly associated with an increased prevalence of triptan sensation adverse events. As a result, there was a low incidence of triptan sensation adverse events reported by patients in our clinical trials for Zecuity. In our pivotal Phase III trial, the incidence of atypical sensations was 1.7% and the incidence of pain and pressure sensations was 1.7%.

According to a 2001 article by Dr. Michel Ferrari published in *The Lancet*, a peer-reviewed medical journal, clinical trials have demonstrated that at least 40% of migraine patients fail to respond

Table of Contents

consistently to oral triptans. Based on data from multiple published third party clinical trials, including those described in a 2005 article by Dr. David Dodick published in *Headache*, a peer-reviewed medical journal, we believe patients' failure to respond consistently results from a variety of causes, including low and inconsistent absorption of oral medication because of reduced gastric motility in migraine patients. Because Zecuity does not depend on gastrointestinal absorption, its absorption is not compromised by reduced gastric motility. As a result, we believe that Zecuity has the potential to provide more consistent relief than oral medications for certain patients that experience reduced gastric motility during their migraine.

Both of our pipeline product candidates, NP201 and NP202, are designed to deliver therapeutic levels of medication over a period of months with a single dose. NP201, for the continuous symptomatic treatment of Parkinson's disease, utilizes ropinirole, an FDA-approved dopamine agonist, and is designed to provide up to two months of continuous delivery. NP202, for the long-term treatment of schizophrenia and bipolar disorder, is designed to help address the long-standing problem of patient noncompliance by providing three months of continuous delivery of risperidone, an FDA-approved atypical antipsychotic. NuPathe is actively seeking partnerships to maximize the commercial potential for NP201 and NP202 in the U.S. and territories throughout the world, and intends to limit spending on these programs until a development partner is obtained.

**Our Strategy**

Our strategy is to develop and commercialize therapeutics for diseases of the central nervous system that can address significant unmet medical needs and overcome limitations of existing products. Key elements of our strategy include:

preparing for an expected fourth quarter of 2013 launch of Zecuity, the first and only patch approved by the FDA for the acute treatment of migraine;

securing a commercial partner in advance of the U.S launch of Zecuity, and building a commercial infrastructure to complement that of the partner;

maximizing the commercial potential of Zecuity, our product candidates and our proprietary technologies in the U.S. and territories throughout the world through partnerships, collaborations, licensing and other strategic transactions; and

advancing the development of NP201 and NP202 once development partners are obtained.



Table of Contents**Our Product and Product Candidates**

The following table summarizes key information about our Zecuity and our product candidates. We hold worldwide commercialization rights to Zecuity and our product candidates.

| <b>Product/<br/>Product<br/>Candidate</b> | <b>Indication/<br/>Indications(s) Sought</b> | <b>Description</b>                                   | <b>Development Status</b>  |
|---|--|--|--|
| Zecuity                                   | Acute treatment of migraine                  | Sumatriptan iontophoretic transdermal system (patch) | Approved by the FDA on January 17, 2013<br><br>Launch expected in 4Q13   |
| NP201                                     | Parkinson's disease                          | Ropinirole two-month implant                         | Preclinical proof of concept and pre-IND toxicology studies completed<br><br>IND prepared<br><br>Seeking development partner |
| NP202                                     | Schizophrenia and bipolar disorder           | Risperidone three-month implant                      | Prototype development in progress<br><br>Seeking development partner   |

**Migraine Market****Overview**

Migraine is a debilitating neurological disease that affects approximately 31 million adults in the U.S. Symptoms of migraine include moderate to severe headache pain, nausea and vomiting, photophobia (abnormal sensitivity to light), and phonophobia (abnormal sensitivity to sound). Most migraines last between four and 24 hours, but some last as long as three days. According to an article by Dr. Richard Lipton published in 2007 in *Neurology*, a peer-reviewed medical journal, 63% of migraine patients experience between one and four migraines per month, and 31% of migraine patients experience three or more migraines per month. Migraine patients are limited in their daily function during a migraine and often seek dark, quiet surroundings until the migraine has passed.

According to another article by Dr. Lipton, published in 2001 in *Headache*, over 18% of women and over 6% of men in the U.S. experience migraines. Lipton further reported that migraines are most common in the working population, from 25 to 55 years old, and can be sufficiently serious to cause migraine patients to miss work or school.

## Edgar Filing: NUPATHE INC. - Form 10-K

Over 13 million prescriptions for medications indicated for acute migraine were filled in the U.S. in the twelve months ended June 2011, according to IMS Health, Incorporated, a pharmaceutical market research firm (IMS). More than 90% of these prescriptions, or approximately 130 million individual units, were for triptans.

### ***Migraine-Related Nausea and Vomiting***

According to an article by Dr. Richard Lipton published in 2013 in *Headache*, and based upon an analysis of the AMPP Study, approximately half of migraine patients experience MRN in at least half of their migraine attacks. Additionally, according to an article by Dr. Stephen Silberstein published in 1995 in *Headache*, approximately 32% of patients who had ever experienced MRN, experienced MRN during every migraine attack, approximately 32% of patients who ever vomit do so in at least half of their migraine attacks and approximately 13% vomit in all of their attacks.

Table of Contents

According to an article Dr. Richard Lipton published in 2013 the *Journal of Medical Economics*, a peer-reviewed journal, patients who frequently experience migraine-related nausea report more migraine disease burden and impairment to work and life, are less satisfied with their current migraine medications and account for higher headache-related healthcare utilization and costs compared with patients who infrequently or never experience migraine-related nausea. This includes a 2.1 times higher direct care costs for neurologists and headache specialists, 5.7 times higher emergency or urgent care use and 8.3 times higher overnight hospital stay costs.

Additionally, Dr. Hans Christoph-Diener authored two articles that conclude that the presence of migraine-related nausea at the time of migraine treatment with oral triptans reduced the likelihood that patients achieved headache pain relief with such medications. The first article, published in 2004 in *Neurology*, was based on a retrospective analysis of data from 128 clinical trials including 28,407 migraine patients treated with either oral sumatriptan (generics and Imitrex®) or naratriptan (generics and Amerge®). The second trial, published in 2007 in *Cephalalgia*, a peer-reviewed medical journal, was based on a retrospective analysis of data from 10 placebo-controlled trials including 8,473 migraine patients treated with oral eletriptan (Relpax®).

***Migraine-Associated Gastroparesis***

According to an article by Dr. Sheena Aurora, published in 2006 in *Headache*, which details a study conducted in 10 subjects with migraine and 10 subjects with no history of migraine, migraine patients experience, to varying degrees, paralysis of the muscles of the stomach, or gastroparesis. Aurora reported that this gastroparesis can result in up to an 80% slower rate of digestion, or gastric motility, in migraine patients. We believe that reduced gastric motility experienced by migraine patients during a migraine may result in low and inconsistent absorption of oral medications and is one of a variety of factors that may cause patients to fail to respond consistently or adequately to such medications.

***Triptan Sensation Adverse Events***

Many patients also avoid or delay treatment because they fear triptan sensations adverse, which are adverse events associated with triptan medications. Triptan sensation adverse events include "atypical sensations" and "pain and pressure sensations," which include chest tightness, chest heaviness, numbness of the extremities, paresthesias (or tingling), and panic. According to U.S. prescribing information, the incidence of atypical sensations is 42% for subcutaneous injection. For oral sumatriptan, the incidence of atypical sensations is up to 6% and the incidence of pain and pressure sensations is up to 8%, depending upon the dose.

***Acute Treatment of Migraine***

The FDA has approved acute migraine prescription medications in four classes:

Triptans, including a triptan combination;

Ergotamines, including dihydroergotamine (DHE);

Analgesic combinations; and

A non-steroidal anti-inflammatory drug (NSAID).

Currently, triptans constitute the most prescribed class of medication for the acute treatment of migraine in the U.S. Sumatriptan, approved by the FDA in 1992, is the most prescribed triptan, according to IMS. There are seven commercially available triptan medications in the U.S. utilizing a variety of routes of administration: tablet, orally disintegrating tablet, nasal spray and subcutaneous injection. Zecuity is the first and only patch approved by the FDA for the acute treatment of migraine.

## Edgar Filing: NUPATHE INC. - Form 10-K

### Table of Contents

According to IMS, oral triptans, in tablet and orally disintegrating tablet formulations, accounted for 95% of triptan units sold in the U.S. in the twelve months ended June 2011. Non-oral triptans, in nasal spray and subcutaneous injection formulations, accounted for only 5% of such triptan units.

The following table summarizes U.S. unit information for the twelve months ended June 2011, by product class, for prescription products indicated for the treatment of acute migraine, based on IMS data:

| Product Class         | Key Product Brands (Drug)  | Route of Administration   | Twelve Months Ended June 2011 Units Sold(1) (% Total) |
|-----------------------|--|---|---|
| Triptan               | Generic sumatriptan and Imitrex®   | Tablet, orally disintegrating tablet, nasal spray, subcutaneous injection | 128.6 million (88.2)%                                 |
|                       | Generic rizatriptan and Maxalt®  |   |   |
|                       | Zomig® (zolmitriptan)  |   |   |
|                       | Relpax® (eletriptan)   |   |   |
|                       | Treximet® (sumatriptan/naproxen)   |   |   |
| Analgesic Combination | Sumavel DosePro® (subcutaneous sumatriptan)  |   |   |
|                       | Epidrin®, Midrin®, Migrazone® and generics (isometheptene mucate, dichloralphenazone, acetaminophen) | Capsule   | 13.7 million (9.4)%                                   |
| Ergotamine            | Prodrin® (acetaminophen, caffeine, isometheptene)  |   |   |
|                       | Migranal® (dihydroergotamine)  | Nasal spray, injection, tablet suppository                                | 3.4 million (2.4)%                                    |
|                       | DHE-45 and generics (dihydroergotamine)  |   |   |

Cafergot® and generics (dihydroergotamine, caffeine)

---

- (1) A unit represents a single dose of each medication.

**Our Solution: Zecuity**

Zecuity (sumatriptan iontophoretic transdermal system) is indicated for the acute treatment of migraine with or without aura in adults. Zecuity is a single-use, battery-powered patch applied to the upper arm or thigh during a migraine. Following application and with a press of a button, Zecuity initiates transdermal delivery (through the skin), bypassing the gastrointestinal tract. Throughout the four-hour dosing period, the microprocessor within Zecuity monitors skin resistance every 20 milliseconds and adjusts drug delivery accordingly to ensure delivery of 6.5 mg of sumatriptan, the most prescribed migraine medication, with minimal patient-to-patient variability.

Zecuity utilizes our proprietary active transdermal delivery technology that delivers medication through the skin using a process called iontophoresis. We designed Zecuity to overcome the limitations of current migraine treatments that are related to route of administration and peak plasma concentration levels and, in particular, to address the unmet needs of patients who experience MRN as

Table of Contents

part of their attacks. We believe Zecuity provides patients with the following benefits when compared to alternative migraine therapies:

*Route of administration that circumvents nausea and vomiting.* Because Zecuity is administered transdermally, we believe that it will be an attractive treatment option for migraine patients suffering from nausea or vomiting who might otherwise delay or avoid taking medication. This approach is consistent with the American Academy of Neurology guidelines that recommend non-oral therapies for migraine patients who experience nausea or vomiting as significant migraine symptoms.

*Low incidence of triptan sensation adverse events.* Zecuity delivers therapeutic sumatriptan plasma levels without reaching levels that are commonly associated with an increased prevalence of triptan sensation adverse events. As a result, there was a low incidence of triptan sensation adverse events reported in our clinical trials for Zecuity. In our pivotal Phase III trial, the incidence of atypical sensations was 1.7% and the incidence of pain and pressure sensations was 1.7%. According to U.S. prescribing information, the incidence of atypical sensations is 42% for subcutaneous injection. For oral sumatriptan, the incidence of atypical sensations is up to 6% and the incidence of pain and pressure sensations is up to 8%, depending upon the dose.

*Consistent delivery.* Because Zecuity does not depend on gastrointestinal absorption, its absorption is not compromised by reduced gastric motility, which may present in certain migraine patients. As a result, Zecuity provides consistent drug delivery with low patient-to-patient variability. As a result, we believe that Zecuity may provide for consistent relief than oral medications for certain patients that experience reduced gastric motility during their migraines.

***Zecuity Commercial Strategy***

We expect to make Zecuity available by prescription in the U.S. in the fourth quarter of 2013 and are actively seeking partnerships to maximize the commercial potential for Zecuity. Our goal is to secure a commercial partner prior to the launch of Zecuity and to build our commercial infrastructure to complement that of our partner, which may include the hiring and deployment of our own specialty sales force. We expect marketing efforts to be directed at high potential prescribers of Zecuity, primarily consisting of neurologists, headache specialists and those primary care physicians who most frequently treat migraine. We believe these efforts will enable the realization of a significant portion of the commercial opportunity for Zecuity.

If we hire our own specialty sales force, we may seek to acquire complementary products to market and sell or collaborate with pharmaceutical or biotechnology companies to market and sell their products. We may also seek to commercialize Zecuity outside the U.S., although we currently plan to do so only with a partner.

***Zecuity Clinical Program and Post-Marketing Requirements***

Zecuity was approved by the FDA on January 17, 2013 for the acute treatment of migraine with or without aura in adults. Zecuity was approved based upon an extensive development program with phase 3 trials that included 800 patients using more than 10,000 Zecuity patches. In these trials, Zecuity was proven safe and effective at treating migraine and relieving its cardinal symptoms (headache pain, migraine-related nausea and sensitivity to light and sound) two hours after patch activation.

*Pivotal Phase III Clinical Trial*

In the phase 3 pivotal study involving 469 patients, twice as many patients treated with Zecuity achieved freedom from headache pain at two hours compared with placebo (18% and 9%,

Table of Contents

respectively). Additionally, 53% of patients treated with Zecuity achieved relief from headache pain and 84% were nausea free at two hours (29% and 63%, respectively, with placebo). Approximately 50% of patients receiving Zecuity (compared to 44% receiving a placebo patch) experienced at least one treatment-emergent adverse event, which is an event that was not present prior to patch application or a worsening of either the intensity or frequency of a symptom following patch application. The most common (greater than 5%) side effects of Zecuity were application site pain, tingling, itching, warmth and discomfort. The incidence of triptan sensation adverse events was low with 1.7% experiencing "atypical sensations" and 1.7% experiencing "pain and other pressure sensations". Most patients experienced some skin redness after removing Zecuity which typically resolved in 24 hours.

*12-Month, Repeat-Use Phase III Trials*

We also completed two 12-month, repeat-use Phase III trials. Zecuity was well tolerated in both of these open label trials by the 662 patients who applied a total of 9,744 patches. The most frequently reported adverse events were application site conditions (44%), primarily application site pain, application site pruritus, application site tingling and application site discoloration. The incidence of triptan sensation adverse events was very low (0.9%).

Approximately 4% of patients in the repeat-use trials experienced allergic contact dermatitis (ACD). ACD is caused by exposure to a substance or material to which a person has become especially sensitive or allergic. Compared to transdermal delivery systems of currently marketed products, the incidence of ACD with the use of Zecuity is low. Patients who develop ACD from use of Zecuity may have systemic sensitization or other systemic reactions if any sumatriptan-containing product is used and, as a result, may no longer be able to take sumatriptan in any form.

*Post-Marketing Requirements*

As a condition to approval, we agreed to conduct the following post-marketing clinical and non-clinical studies:

| <b>Study Description</b>   | <b>Expected Start Date</b> | <b>Required Completion Date</b> |
|--|----------------------------|---------------------------------|
| Phase I: Open label, single-dose safety, PK and tolerability study of Zecuity in pediatric migraine patients (12 - 17 years)                     | August 2013                | July 2014                       |
| Phase III: Efficacy and tolerability of Zecuity in the treatment of acute migraine in adolescents (randomized, double-blind, placebo controlled) | September 2014             | December 2015                   |
| Phase III: 12 month safety study in the treatment of acute migraine in adolescents (open label)  | September 2014             | December 2016                   |
| Non-clinical: 7 day dermal painting study (mice) using various penetration enhancers to access the dermal carcinogenicity of sumatriptan         | May 2013                   | November 2013                   |
| Non-clinical: A dermal carcinogenicity study of sumatriptan succinate in mice to access the dermal carcinogenicity of sumatriptan                | May 2014                   | December 2016                   |

Table of Contents

**Pipeline Products**

In addition to Zecuity, our current research and development pipeline consists of two preclinical product candidates, NP201 for the treatment of Parkinson's disease, and NP202 for the treatment of schizophrenia and bipolar disorder. We are actively seeking partnerships to maximize the commercial potential of these product candidates in the U.S. and throughout the world, and intend to limit spending on these programs until a development partner is obtained.

***NP201: Product candidate for the continuous symptomatic treatment of Parkinson's disease***

Parkinson's disease is a progressive, degenerative disease characterized by movement symptoms such as tremor or trembling in the hands, arms, and legs; rigidity of the limbs and trunk; slowness of movement; and impaired balance and coordination. According to the Parkinson's Disease Foundation, Parkinson's disease affects about one million people in the U.S. and more than four million people worldwide. Although symptoms of Parkinson's disease can appear at any age, the average age of onset is 60.

The loss of neurons in the brain that help to control movement causes Parkinson's disease. These neurons produce dopamine, a neurotransmitter that transmits signals that control movement. Currently, no cure exists for Parkinson's disease. Symptomatic treatments rely on the replacement of dopamine through either levodopa, which the brain converts to dopamine, or dopamine agonists, which mimic dopamine.

Multiple challenges complicate the treatment of Parkinson's disease. Intermittent dosing of oral medications leads to periods of "on" after dosing and periods of "off" as the medication wears off. During "on" periods, excessive levels of medication can produce adverse events, primarily abnormal movements. During "off" periods, low levels of medication lead to poor efficacy. In addition, Parkinson's disease is a progressive disease, which causes patients to become less responsive to their medication over time and more sensitive to excessive drug levels.

The majority of Parkinson's disease patients currently use oral medications that require administration one to three times per day, exposing the patient to varying medication levels. The intermittent dosing of oral medications further complicates treatment, as patients experience periods of "on" after dosing and periods of "off" as the medication wears off. According to a 2009 article by Dr. Fabrizio Stocchi published in *Parkinsonism and Related Disorders*, a peer-reviewed medical journal, some experts believe that intermittent dosing may result in more frequent and serious adverse events and may hasten the progression of Parkinson's disease by causing harm to the remaining dopamine receptors. As Dr. Stocchi reported, studies suggest that continuous medication delivery may alleviate the symptoms of Parkinson's disease without inducing the abnormal movements caused by too much medication.

Only two Parkinson's disease medications currently provide for continuous delivery, and neither is approved in the U.S. Duodopa® is a levodopa/carbidopa gel marketed by Abbott Laboratories that requires the surgical insertion of a tube into the patient's small intestine. APO-go® is an injectable apomorphine marketed by Britannia Pharmaceuticals Limited that requires the patient to wear a pump around his or her waist. Because both APO-go and Duodopa are difficult to administer, they are generally reserved for complicated and difficult to control patients.

NP201 is designed to provide continuous delivery of Parkinson's disease medication in an easy to administer and tolerable dose formulation. NP201 consists of our Long Acting Delivery (LAD) technology combined with ropinirole, a generic, FDA-approved dopamine agonist also known as Requip®. After administration, NP201 is designed to slowly dissolve while releasing ropinirole.

We have studied NP201 in several animal models. We believe the data from these studies suggest that NP201 can provide continuous, stable medication levels for up to two months. In addition, we



Table of Contents

completed a proof of concept study in a well-accepted animal model of Parkinson's disease that we believe suggests NP201 has the potential to provide continuous symptomatic relief for up to two months per dose and to decrease the incidence of "on" and "off" adverse events associated with current treatments.

In March 2010, we met with the FDA to discuss our development plan for NP201. Based on this meeting, we believe that we can submit an NDA for NP201 under Section 505(b)(2) of the FDCA and that the FDA may require only a single successful pivotal Phase III clinical trial for approval.

We have completed a toxicology study and all activities required for an IND filing for NP201, however, we are seeking a development partner prior to submitting the IND for NP201.

***NP202: Product candidate for the long-term treatment of schizophrenia and bipolar disorder***

Schizophrenia is a life-long serious psychiatric illness that causes people to lose touch with reality and often interferes with their ability to think clearly, manage emotions, make decisions and relate to others. Bipolar disorder, or manic depression, is another life-long psychiatric illness that causes extreme shifts in mood, energy and functioning. These changes may be subtle or dramatic and typically vary greatly over the course of a person's life as well as among individuals.

According to the National Alliance on Mental Illness, schizophrenia affects over two million adults in the U.S., while bipolar disorder affects over ten million adults in the U.S. According to an article by Dr. Eric Wu published in 2005 in *The Journal of Clinical Psychiatry*, a peer-reviewed medical journal, as of 2002 the estimated direct healthcare costs of schizophrenia in the U.S. were \$22.7 billion, including outpatient care, medications and long-term care.

Patient compliance with medication has been a long-standing problem in the treatment of schizophrenia. As reported in an article by Dr. Jeffrey Lieberman published in 2005 in *The New England Journal of Medicine*, a peer-reviewed medical journal, the Clinical Antipsychotic Trials in Intervention Effectiveness, or CATIE, study, conducted between 2001 and 2004, indicated that 74% of schizophrenia patients become non-compliant with their medication within 18 months of commencing the use of medication. According to an article by Patricia Thieda published in 2003 in *Psychiatric Services*, a peer-reviewed medical journal, schizophrenia patients with poor compliance are more than twice as likely to experience relapse than patients with good compliance. We believe medication compliance represents a significant opportunity for improved treatments.

In an attempt to improve patient compliance, physicians administer antipsychotic drugs through depot injections. Depot injections release medication over a longer period than conventional injections or oral medications. Depot injection products include Risperdal Consta® and Invega Sustenna®, both marketed by Johnson & Johnson, and Zyprexa Relprew®, marketed by Eli Lilly & Co. These drugs provide two to four weeks of therapy per dose.

We believe that NP202 has the potential to provide a significant improvement over existing treatment options for patients suffering from schizophrenia or bipolar disorder because:

NP202 is designed to provide three months of continuous delivery of risperidone with a single dose. Currently available products provide therapy for only two to four weeks, resulting in frequent physician visits and increasing the risk of non-compliance;

NP202 is designed to allow a physician to remove the implant at any time during the dosing period. With currently available injectable products, physicians and patients cannot stop therapy, which may discourage some physicians and patients concerned about adverse events; and

NP202 is designed to be an easy to administer, pre-loaded injectable product that can be stored at room temperature. Risperdal Consta®, an FDA-approved depot injectable product, must be prepared and mixed prior to administration.

Table of Contents

We have developed prototype products and initiated pre-IND activities for NP202.

**Our Proprietary Delivery Technologies**

Our current drug development activities use two proprietary medication delivery technologies: SmartRelief and LAD. Zecuity incorporates SmartRelief, while NP201 and NP202 both incorporate LAD. We have certain exclusive worldwide rights to both technologies.

***SmartRelief Technology***

SmartRelief is our proprietary transdermal medication delivery technology based on iontophoresis, a non-invasive method of actively transporting molecules, such as sumatriptan, that are not able to be delivered passively through the skin. Iontophoresis involves the application of a mild electrical current to the skin through two reservoirs. One reservoir contains ionized (or charged) medication. The other reservoir contains a counter ion, commonly sodium chloride (or salt). When a current is applied, medication molecules travel out of the reservoir into the skin, where blood vessels absorb and disburse them throughout the body.

Unlike passive transdermal technologies, which rely on diffusion for medication delivery, iontophoresis controls the amount and rate of medication delivery. Iontophoresis also enables transdermal delivery of a variety of medications that cannot be delivered passively through the skin. It is possible to deliver a variety of different medications, including proteins and peptides, using iontophoresis. Our SmartRelief technology positions us to capitalize on the expanding global transdermal market, which, according to *PharmaLive Special Reports*, September 2011, a pharmaceutical industry publication, is expected to grow from \$21.5 billion in 2010 to \$31.5 billion by 2015.

***Long-Acting Delivery Technology***

Our LAD technology is designed to improve the control, consistency and convenience of medication delivery. LAD is comprised of a biodegradable polymer matrix using commonly available medical polymers and an active drug, combined to form a small implant for injection just below the skin. The implant may be removed by a physician using a minor surgical procedure if a decision is made to stop therapy.

To date, we have tested several neuropsychiatric compounds formulated with LAD in multiple animal models. Based on these studies, we believe LAD has the potential to treat patients for one to three months with a single dose of a therapy. As a result, we believe LAD has the potential, to improve medication efficacy and compliance and reduce the incidence of certain adverse events. We have not yet tested LAD in humans.

**Competition**

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. Our major competitors include organizations such as major multinational pharmaceutical companies, established biotechnology companies and specialty pharmaceutical and generic drug companies. Many of our competitors have greater financial and other resources than we have, such as larger research and development staffs and more extensive marketing and manufacturing organizations. As a result, these companies may obtain marketing approval more rapidly than we are able and may be more effective in selling and marketing their products. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our competitors may succeed in developing, acquiring or licensing on an exclusive basis technologies and drug products that are more effective or less costly than Zecuity or any other product

Table of Contents

candidate that we are currently developing or that we may develop, which could render our products obsolete and noncompetitive. We expect Zecuity and other products that we commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, the level of generic competition and the availability of reimbursement from government and other third party payors. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize our product candidates in our target commercial markets.

**Zecuity**

Zecuity will compete with currently marketed triptans, including Imitrex® (sumatriptan), Maxalt® (rizatriptan), Zomig® (zolmitriptan), Relpax® (eletriptan), Axert® (almotriptan), Frova® (frovatriptan), Amerge® (naratriptan), Treximet® (sumatriptan/naproxen) and Sumavel DosePro® (sumatriptan), as well as generic sumatriptan, the active ingredient in Imitrex, and generic versions of other branded triptans that have lost or will lose their patent exclusivity. Because of the low cost, health insurers may require or encourage use of, and consumers may use, a generic triptan prior to trying Zecuity. Zecuity will also compete with other approved products, including analgesic combinations, NSAIDs and ergotamines, including DHE.

We believe that Zecuity's features, including its convenient, non-oral route of administration, controlled delivery of medication and consistent dosing, differentiates it from other migraine treatments, particularly for migraine patients suffering from nausea or vomiting.

In addition to marketed migraine medications, both large and small companies have migraine product candidates in various stages of clinical development. These include Levadex® from MAP Pharmaceuticals, Inc., an inhaled formulation of DHE, and an intranasal powder formulation of sumatriptan from Optinose, both for the treatment of acute migraine. Optinose announced results from a 200 patient Phase III trial in November 2012 and MAP Pharmaceuticals re-submitted its NDA for Levadex to the FDA in 4Q 2011 with a PDUFA date of April 15, 2013. In March 2013, Allergan acquired MAP Pharmaceuticals. . Allergan also markets Botox, which is marketed for the treatment of chronic migraine.

Our strategy to compete in the migraine market includes:

Elevating physician awareness of migraine related nausea and its disease burden;

Highlighting low incidence of triptan sensation adverse events associated with Zecuity;

Emphasizing consistent delivery of medication with low patient-to-patient variability; and

Building on physician experience with sumatriptan, the most prescribed migraine medication in the U.S.

**NP201 and NP202**

As with Zecuity, each of NP201 and NP202, if approved, will face competition from generic and branded products. Specifically, NP201 will face competition from generic immediate release and extended release versions of ropinirole and the dopamine agonist pramipexole, as well as from two continuous delivery medications, a levodopa gel and an injectable apomorphine. NP202 will face competition from a variety of branded and generic versions of antipsychotic medications, in addition to several other sustained delivery depot formulations of atypical antipsychotics.

**Manufacturing**

We have no manufacturing facilities. All of our manufacturing processes are outsourced to third parties with oversight by our internal managers. We rely on third party contract manufacturers, component fabricators and secondary service providers to manufacture Zecuity and our product

Table of Contents

candidates. We believe this practice helps us control our expenses, as the construction, maintenance and insurance of pharmaceutical manufacturing facilities requires significant capital.

We intend to manage our supply chain for Zecuity internally. FDA regulations require that materials be produced under current Good Manufacturing Practices (cGMP). We have established an internal quality control and quality assurance program, including a set of standard operating procedures and specifications that we believe are consistent with cGMP. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. We depend on our third party contract manufacturers and suppliers for continued compliance with cGMP requirements.

We expect to enter into a commercial manufacturing agreement for Zecuity with a U.S. subsidiary of LTS Lohmann Therapie-Systeme AG (LTS). LTS manufactured our clinical supplies of Zecuity under the terms of a development and license agreement. See "License and Development" section below for additional information. To that end, we funded the purchase by LTS of the machinery that LTS will use to produce the commercial supply of Zecuity. The machinery is customized to the particular manufacturing specifications of Zecuity and is owned by LTS. In order for LTS to produce commercial supply of Zecuity, it must successfully qualify and validate this machinery and the production processes. If we are unable to enter into a commercial manufacturing agreement with LTS in a timely manner, or on acceptable terms, or LTS is unable to qualify and validate the machinery and production processes, our ability to launch and commercialize Zecuity will be delayed, prevented or impaired.

In addition, we are developing other customized machinery to assemble a key component of Zecuity. Upon completion, the equipment will be installed at a designated third party manufacturer. If we are unable to get this equipment fabricated or the equipment cannot be installed and validated at our third party manufacturer in a timely manner, our ability to launch and commercialize Zecuity will be adversely affected. If this customized equipment or the LTS machinery malfunctions at any time during the production process, the time it may take to secure replacement parts, to undertake repairs and to revalidate the equipment and process could adversely affect our ability to commercially launch Zecuity and meet the commercial demand for Zecuity.

We also intend to enter into supply agreements with our other critical contract manufacturers, component fabricators and secondary service providers to secure commercial supply for Zecuity, although not all of our suppliers and service providers will be under contract. LTS and some of these suppliers, fabricators and providers will be the sole qualified source of their respective components.

Supplies for our NP201 and NP202 clinical programs, consisting of LAD and the active ingredients, ropinirole and risperidone, are currently manufactured for us by Evonik Industries AG, Inc. Ropinirole and risperidone are generic and available from multiple sources.

### **Distribution**

We expect to sell Zecuity to wholesale pharmaceutical distributors, who, in turn, will sell Zecuity to pharmacies, hospitals and other customers. We expect to use a third-party logistics provider for key services related to logistics, warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management and will seek to leverage the distribution capabilities of any commercial partner that we obtain for Zecuity.

### **License and Development**

The following are the license and development agreements that we believe are material to the ongoing operations of our business.

Table of Contents

***Travanti Pharma Inc.***

In July 2008, we entered into an asset purchase and license agreement with Travanti Pharma Inc. (Travanti) pursuant to which we acquired from Travanti a patent application, including all supporting documentation and priority documents, that is directed to transdermal delivery of anti-migraine medications using an active delivery patch. Under the agreement, we granted Travanti a nonexclusive, royalty-free, perpetual, worldwide license to use the purchased patent application, and the invention covered by such patent application, outside the field of migraine. In May 2009, Teikoku Pharma USA, Inc. acquired Travanti.

In addition, under the Travanti agreement, we obtained a perpetual, worldwide, exclusive, royalty-free license, with the right to grant sublicenses, under Travanti's patent rights, including issued U.S. Patent No. 6,745,071, as described in more detail under " Intellectual Property and Exclusivity," and know-how that relate generally to specified iontophoresis technology to develop, make and commercialize migraine products. If we make improvements that directly relate to such Travanti patents and patent applications, Travanti will hold a nonexclusive, royalty-free, perpetual, worldwide license to use such improvements outside the field of migraine. The Travanti agreement does not contain any termination provisions under which our license rights would terminate.

***LTS Lohmann Therapie-Systeme AG***

In September 2007, we entered into a development and license agreement with LTS, which was amended as of April 2008, February 2009 and May 2010. Under the development and license agreement, LTS agreed to perform development activities relating to Zecuity in accordance with an agreed upon development plan and to use commercially reasonable efforts to provide us with supplies for our clinical trials. LTS also has provided us with supplies for our non-clinical use.

Pursuant to the terms of the development and license agreement, each party exclusively owns any inventions related to such party's existing intellectual property that arise out of the development program. The parties jointly own any joint inventions that arise out of the development program not solely based on one party's existing intellectual property. Each party grants to the other a non-exclusive, royalty-free license under its respective intellectual property for the sole purpose of developing Zecuity. If we execute a commercial manufacturing agreement for Zecuity with LTS, LTS will have the exclusive right to manufacture Zecuity and LTS will grant us an exclusive, worldwide, royalty-free license under LTS's intellectual property to use, import, sell, market and distribute, or have imported, sold, marketed or distributed, Zecuity. If we do not execute a commercial manufacturing agreement with LTS, we may not have access to LTS's proprietary technology and know-how necessary to develop, manufacture or commercialize Zecuity.

The development and license agreement remains in effect until the parties execute a commercial manufacturing agreement or until either party terminates the agreement by its terms. We may terminate the development and license agreement at any time upon 60 days' notice to LTS. In addition, either party may terminate the agreement if the other party materially breaches the agreement and fails to cure the breach during a 60-day cure period. Either party may terminate the agreement if the development committee established under the agreement determines that it is not feasible to develop a product as anticipated under the development plan.

In June 2010, we entered into an equipment funding agreement with LTS under which we funded the purchase by LTS of manufacturing equipment for Zecuity. Throughout 2010 and 2011, we funded the purchase of the equipment by making payments to LTS in the aggregate amount of \$6.8 million based on exchange rates at the time the payments were made. In the first quarter of 2013, we entered into an amendment to this funding agreement pursuant to which we agreed to fund the purchase of additional manufacturing equipment for Zecuity to increase commercial capacity. We expect to make total payments under this amendment of \$0.8 million based on exchange rates in effect at March 1, 2013.

Table of Contents

LTS owns the equipment purchased pursuant to the funding agreement and related amendment and is responsible for its routine and scheduled maintenance and repair. LTS is required to use the purchased equipment solely for fulfilling its obligations to manufacture Zecuity. In addition, LTS is prohibited from encumbering the purchased equipment and may not sell or dispose of such equipment, except that LTS may transfer ownership of it to its affiliate, LTS Lohmann Therapy Systems Partnership L.P. Moreover, if we do not enter into a commercial manufacturing agreement with LTS, LTS must, at its option, either transfer ownership of the equipment to us or refund to us the purchase price of the equipment, less depreciation.

***University of Pennsylvania***

We entered into a patent license agreement with the University of Pennsylvania (Penn), which became effective in July 2006 and was amended in May 2007. Under the patent license agreement, Penn granted to us exclusive, worldwide rights under specified Penn patent applications, and patents issuing therefrom, to make, use and sell products using LAD. Under the agreement, we have the right to sublicense, subject to specified conditions, including the payment of sublicense fees. The agreement currently covers NP201 and NP202.

The patent license agreement requires that we use commercially reasonable efforts to develop and commercialize licensed products. We must submit development plans annually for products we intend to develop. We must also commit at least \$250,000 annually towards the development and commercialization of licensed products, until the first commercial sale of the first licensed product.

Under the patent license agreement, we pay Penn annual license maintenance fees of up to \$50,000 until the first commercial sale of the first licensed product. In addition, we have agreed to pay Penn aggregate milestone payments of up to \$950,000 upon the achievement of specified development and regulatory milestones related to each licensed product that contains ropinirole or other specified active ingredients, including the active ingredients in NP201 and NP202, and royalties in the low single digits on worldwide net sales of such licensed products. We and Penn have agreed to negotiate the milestone payments and royalties payable for each licensed product that contains an active ingredient other than those currently specified in the agreement. If we grant a sublicense of our rights under the Penn patent rights to a third party, we must pay Penn a specified portion of certain income received from such third party sublicensee.

The patent license agreement, and our obligation to pay royalties to Penn, will terminate, on a product by product basis, on the later of the expiration or abandonment of the last Penn patent, which we expect will occur in April 2027, or ten years after the first commercial sale of a licensed product if no patent issues from the patent applications licensed from Penn under the agreement. We may terminate the agreement at any time upon 60 days' notice to Penn. Penn may terminate the agreement in connection with our uncured breach, bankruptcy or insolvency.

***Evonik Industries AG, Inc.***

In March 2007, we entered into a feasibility evaluation agreement with SurModics Pharmaceuticals, Inc., which was amended in December 2007, April 2008, July 2008, October 2008, March 2009 and May 2010. SurModics Pharmaceuticals was acquired by Evonik Industries AG, Inc. in 2011. All references to Evonik Industries contained in this Form 10-K shall be deemed to refer to SurModics Pharmaceuticals prior to such acquisition. Under the feasibility evaluation agreement, we and Evonik Industries, from time to time, enter into plans of work whereby Evonik Industries performs evaluation, development and formulation work for NP201 and provides us with preclinical supplies of NP201.

Pursuant to the feasibility evaluation agreement, each party owns exclusively any inventions arising out of the development program if they are based solely on that party's existing intellectual property.

Table of Contents

Any inventions under the development program based on both parties' intellectual property are jointly owned. Evonik Industries has the right to practice aspects of joint research inventions developed under the feasibility agreement that do not relate to our product or use our technology or confidential information. We received an option to obtain an exclusive, royalty bearing license under Evonik Industries' technology and intellectual property necessary to make, have made, use and sell NP201. We agreed to pay Evonik Industries for its services and supplies on a time and materials basis. The feasibility evaluation agreement will remain effective until mutually agreed upon by the parties or until terminated by us upon at least two weeks' advanced written notice to Evonik Industries.

In September 2009, upon our exercise of the option under the feasibility evaluation agreement, we entered into a license agreement with Evonik Industries, pursuant to which we received an exclusive worldwide license, with the right to sublicense, under Evonik Industries' intellectual property, including its interest in joint inventions developed under the feasibility agreement, to make, have made, use, sell, import and export products covered by the license agreement, comprised of a biodegradable, preformed, macroscopic implant device consisting of ropinirole, as the sole active pharmaceutical ingredient, incorporated into the controlled delivery system developed or optimized under the feasibility agreement. The license agreement currently covers NP201. We granted Evonik Industries an exclusive, perpetual, worldwide, royalty-free license under our interest in joint inventions for uses that do not relate to products covered by the license agreement or include any of our existing technology or confidential information. We also granted Evonik Industries a right of first negotiation to manufacture clinical supplies of covered products. If we and Evonik Industries enter into such clinical manufacturing agreement, Evonik Industries has a right of first negotiation to manufacture commercial supplies of covered products.

Under the license agreement, we have agreed to pay Evonik Industries aggregate milestone payments of up to \$4.75 million upon the first achievement of specified development, regulatory and sales level milestones related to the first clinical indication approved by a regulatory authority for covered products. We must also pay an additional milestone payment upon regulatory approval of each additional clinical indication for covered products and royalties in the low single digits on worldwide net sales of commercial product. In countries where a valid Evonik Industries patent claim does not cover the product, the applicable royalty rate decreases. If we do not enter into a commercial manufacturing agreement with Evonik Industries, the applicable royalty rate will increase, though it will remain in the low single digits.

Under the license agreement we are responsible for developing and obtaining regulatory approval for covered products. We have agreed to use commercially reasonable efforts to actively develop and obtain regulatory approvals to market a covered product, including NP201, in major markets throughout the world. In addition, we have agreed to comply with specific diligence milestones to obtain such regulatory approval and to develop and commercialize a covered product in the U.S.

The license agreement and our obligation to pay Evonik Industries royalties will terminate on a country by country basis on the later of the date on which a valid Evonik Industries patent claim no longer covers the product or an agreed period after the first commercial sale of the product in such country. Thereafter the license will become an exclusive, perpetual fully paid-up license.

We have the right to terminate the license agreement for any reason at any time upon 90 days' notice to Evonik Industries. Either party has the right to terminate the agreement in connection with the other party's uncured material breach, bankruptcy or insolvency. Evonik Industries may either terminate the license agreement or make it non-exclusive if we fail to meet the agreed upon diligence milestones or otherwise fail to use commercially reasonable efforts to develop and obtain regulatory approval for a covered product.

Table of Contents

**Intellectual Property**

Our success will depend, in part, on our ability to protect our product candidates and technology through patents, trade secrets, proprietary know-how, FDA exclusivity and contractual restrictions on disclosure.

***Patents and Patent Applications***

We seek to protect the proprietary position of our product candidates by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to our business. U.S. patents generally have a term of 20 years from the date of filing. Because patent protection is not available for the active pharmaceutical ingredient compounds included in Zecuity, NP201 or NP202, we will need to rely primarily on the protections afforded by device, formulation and method of use patents.

***Zecuity***

We exclusively license one issued U.S. patent and its foreign counterparts, and own three issued U.S. patents and six U.S. patent applications and their foreign counterparts. In connection with the FDA's approval of Zecuity, the issued U.S. patent that we license and the three issued U.S. patents that we own were listed in the FDA's Orange Book. See "Section 505(b)(2) New Drug Applications" below for additional information regarding the FDA's Orange Book.

Our licensed *U.S. Patent No. 6,745,071*, owned by Travanti, is generally directed towards wearable iontophoretic devices, including Zecuity, that are prepackaged as complete self-contained units that include an active pharmaceutical ingredient to be administered, a provision for isolating moisture sources from the electrodes and from the power source during storage to optimize shelf stability, and a simple, user-friendly mechanism to transfer the active pharmaceutical ingredient and counter ion reservoirs to the electrodes. The expiration date for this patent is in 2023. There are corresponding patents in Australia, Canada and Korea which will also expire in 2023 and corresponding patent applications pending in certain other countries which will expire in 2023 if issued. Under the Travanti asset purchase and license agreement, we have a perpetual, worldwide, exclusive, royalty-free license, in the field of migraine, to Travanti patents, patent applications and know-how that relate generally to iontophoresis.

Our issued patents include:

*U.S. Patent No. 7,973,058* which is generally directed to methods of treating migraine using an iontophoretic patch containing a triptan. This patent expires in 2027 and there are corresponding patent applications pending in certain select foreign countries which will also expire in 2027, if issued.

*U.S. Patent No. 8,155,737* which is generally directed to methods of treating migraine using an iontophoretic patch by administering sumatriptan to achieve consistent plasma levels with low patient to patient variability. This patent expires in 2028 and there are corresponding patent applications pending in certain select foreign countries which will also expire in 2028, if issued.

*U.S. Patent No. 8,366,600* which is generally directed to methods of treating migraine using an iontophoretic patch by administering a triptan comprising our proprietary hydrogel polyamine formulation. This patent expires in 2029 and there are corresponding patent applications pending in certain select foreign countries which will expire in 2028, if issued.

Our pending patent applications are generally directed to:

Methods and devices for treating migraine and migraine related nausea using integrated iontophoretic patches, including Zecuity;



Table of Contents

Active ingredient reservoir formulations, including the Zecuity formulation;

Electronic control systems and methods for use of the same in delivering an active pharmaceutical ingredient for an integrated iontophoretic patch, including Zecuity; and

Methods and systems for testing iontophoretic drug delivery systems, including Zecuity.

If these U.S. applications and their foreign corresponding applications that we have filed in select countries issue, we generally expect these patents to expire between 2027 and 2032.

***LAD Technology***

We own or exclusively license three issued U.S. patents and seven U.S. patent applications, as well as corresponding foreign patent applications filed in select countries, relating to our LAD product candidates, NP201 and NP202. The U.S. patents and patent applications, and their corresponding foreign applications, if issued, are generally expected to expire between 2021 and 2030. These patents and patent applications include claims generally directed to the LAD technology, as well as the use of the LAD technology in conjunction with various medications in the treatment of certain neurological and psychiatric diseases, including Parkinson's disease, schizophrenia and bipolar disorder.

***FDA Marketing Exclusivity***

Under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, newly approved drugs and indications benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides three years of U.S. marketing exclusivity for the approval of new NDAs with new clinical trials for previously approved drugs and supplemental NDAs, for example, for new indications or new dosages or dosage forms of an existing drug, if new clinical investigations are essential to the approval. This three-year exclusivity covers only the new changes associated with the NDA and does not prohibit the FDA from approving ANDAs for drugs containing the original active ingredient. Based on its clinical trial program, Zecuity qualifies for this three-year exclusivity under the Hatch-Waxman Act, which will expire on January 17, 2016.

Additionally, six months of U.S. marketing exclusivity is available under Section 505A of the FDCA if, in response to a written request from the FDA, a sponsor submits and the agency accepts requested information relating to the use of the approved drug in the pediatric population. This six month pediatric exclusivity period is not a standalone exclusivity period, but rather is added to any existing patent or non-patent exclusivity period for which the drug product is eligible. We intend to seek this additional period of six months exclusivity from the FDA once we successfully complete pediatric clinical trials for Zecuity.

***Proprietary Information***

We seek to protect our proprietary information, including our trade secrets and proprietary know-how, by requiring our employees, consultants and other advisors to execute confidentiality agreements upon the commencement of their employment or engagement. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not be disclosed to third parties except in specific circumstances. In the case of our employees, the agreements also typically provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed during employment shall be our exclusive property to the extent permitted by law. Where appropriate, agreements we obtain with our consultants also typically contain similar assignment of invention provisions. Further, we generally require confidentiality agreements from business partners and other third parties that receive our confidential information.

Table of Contents

We also have rights to certain third party proprietary processing and manufacturing technologies related to our product candidates. See the section above entitled "License and Development Agreements" for additional information.

**Government Regulation**

***Federal Food, Drug and Cosmetic Act***

Prescription drug products are subject to extensive pre- and post-market regulation by the FDA, including regulations that govern the testing, manufacturing, distribution, safety, efficacy, approval, labeling, storage, record keeping, reporting, advertising and promotion of such products under the FDCA, and its implementing regulations, and by comparable agencies and laws in foreign countries. Failure to comply with applicable FDA or other regulatory requirements may result in civil or criminal penalties, debarment, recall or seizure of products, partial or total suspension of production or withdrawal of the product from the market. The FDA must approve any new unapproved drug or dosage form, including a new use of a previously approved drug, prior to marketing in the U.S. All applications for FDA approval must contain, among other things, information relating to safety and efficacy, pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling and quality control.

***New Drug Applications***

Generally, the FDA must approve any new drug before marketing of the drug occurs in the U.S. This process generally involves:

Completion of preclinical laboratory and animal testing in compliance with the FDA's Good Laboratory Practice (cGLP), regulations;

Submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin in the U.S.;

Performance of human clinical trials, including adequate and well-controlled clinical trials, in compliance with Good Clinical Practice (cGCP) requirements and regulations to establish the safety and efficacy of the proposed drug product for each intended use;

Satisfactory completion of an FDA pre-approval inspection of the product's manufacturing facility or facilities to assess compliance with the FDA's cGMP regulations; and

Submission to, and approval by, the FDA of an NDA application.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that the FDA will grant approvals for any of our product candidates on a timely basis, if at all. Preclinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. The results of preclinical tests, together with manufacturing information and analytical data, comprise a part of an IND application submission 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 concerns or questions about the conduct of the clinical trial, including concerns regarding exposure of human research subjects to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND may not result in FDA authorization to commence a clinical trial. In addition, the FDA requires a separate submission to an existing IND for each successive clinical trial conducted during product development. Further, an independent institutional review board (IRB), covering each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the clinical trial until completed. The FDA, the IRB or the sponsor may suspend a

Table of Contents

clinical trial at any time, or from time to time, on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. As a separate amendment to an IND, a sponsor may submit a request for a special protocol assessment (SPA), from the FDA. Under the SPA procedure, a sponsor may seek the FDA's agreement on the design, conduct and analyses of, among other things, a clinical trial intended to form the primary basis of an efficacy claim. If the FDA agrees in writing, it may not change its agreement after the clinical trial begins, except in limited circumstances, such as upon identification of a substantial scientific issue essential to determining the safety and effectiveness of a product candidate after commencement of a Phase III clinical trial. If the clinical trial succeeds, the sponsor can ordinarily rely on it as the primary basis for approval with respect to effectiveness. Clinical testing also must satisfy extensive cGCP, regulations, including regulations for informed consent, IRB review and approval, retention of records, submission of clinical data and IND submission.

For purposes of an NDA submission and approval, typically, the conduct of human clinical trials occurs in the following three pre-market sequential phases, which may overlap:

*Phase I:* Sponsors initially conduct clinical trials in a limited population to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients.

*Phase II:* Sponsors conduct clinical trials generally in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. Sponsors may conduct multiple Phase II clinical trials to obtain information prior to beginning larger and more extensive Phase III clinical trials.

*Phase III:* These include expanded controlled and uncontrolled trials, including pivotal clinical trials. When Phase II evaluations suggest the effectiveness of a dose range of the product and acceptability of such product's safety profile, sponsors undertake Phase III clinical trials in larger patient populations to obtain additional information needed to evaluate the overall benefit and risk balance of the drug and to provide an adequate basis to develop labeling.

In addition, sponsors may conduct Phase IV clinical trials after the FDA approves a drug. In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety or effectiveness after NDA approval. Such post approval trials are typically referred to as Phase IV clinical trials.

Sponsors submit the results of product development, preclinical studies and clinical trials to the FDA as part of an NDA. NDAs must also contain extensive manufacturing information and proposed labeling. Upon receipt, the FDA initially reviews the NDA to determine whether it is sufficiently complete to initiate a substantive review. If the FDA identifies deficiencies that would preclude substantive review, the FDA will refuse to accept the NDA and will inform the sponsor of the deficiencies that must be corrected prior to resubmission. If the FDA accepts the submission for substantive review, the FDA typically reviews the NDA in accordance with established time frames. Under the Prescription Drug User Fee Act (PDUFA), the FDA agrees to specific goals for NDA review time through a two-tiered classification system, Priority Review and Standard Review. For a Priority Review application, the FDA aims to complete the initial review cycle in six to eight months. Standard Review applies to all applications that are not eligible for Priority Review. The FDA aims to complete Standard Review NDAs within a ten to twelve month timeframe. We anticipate that any NDA that we may file for our product candidates would receive Standard Review. Review processes often extend significantly beyond anticipated completion dates due to FDA requests for additional information or clarification, difficulties scheduling an advisory committee meeting or FDA workload issues. The FDA may refer the application to an advisory committee for review, evaluation and

Table of Contents

recommendation as to the application's approval. The recommendations of an advisory committee do not bind the FDA, but the FDA generally follows such recommendations.

If an NDA does not satisfy applicable regulatory criteria, the FDA may deny approval of an NDA or may require, among other things, additional clinical data or an additional pivotal Phase III clinical trial. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we do. The FDA could also require a risk evaluation and mitigation strategy (REMS) plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, a commitment to conduct one or more post-market studies or clinical trials and the correction of identified manufacturing deficiencies, including the development of adequate controls and specifications.

After approval, the NDA sponsor must comply with comprehensive requirements governing, among other things, manufacturing, marketing activities, distribution, annual reporting and adverse event reporting. If new safety issues are identified following approval, the FDA can require the NDA sponsor to revise the approved labeling to reflect the new safety information; conduct post-market studies or clinical trials to assess the new safety information; and implement a REMS program to mitigate newly-identified risks. In addition, if after approval the FDA determines that the product does not meet applicable regulatory requirements or poses unacceptable safety risks, the FDA may take other regulatory actions, including requesting a product recall or initiating suspension or withdrawal of the NDA approval.

Drugs may be marketed only for approved indications and in accordance with the provisions of the approved label. Further, if we modify a drug, including any changes in indications, labeling or manufacturing processes or facilities, the FDA may require us to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials.

Under PDUFA, NDA applicants must pay significant NDA user fees upon submission. In addition, manufacturers of approved prescription drug products must pay annual establishment and product user fees.

***Section 505(b)(2) New Drug Applications***

As an alternate path to FDA approval, particularly for modifications to drug products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Act, and permits the submission of an NDA where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and effectiveness for an approved product. The FDA may also require companies to perform additional clinical trials, measurements, or other types of studies or assessments (e.g., bridging studies) to support any change from the previously approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, the 505(b)(2) applicant must submit patent certifications in its 505(b)(2) application with respect to any patents listed for the approved product on which the application relies in the FDA's

Table of Contents

publication, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the Orange Book). Specifically, the applicant must certify for each listed patent that (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA application until all the unchallenged listed patents claiming the referenced product have expired. Further, the FDA will also not accept or approve, as applicable, a Section 505(b)(2) NDA application until any non-patent exclusivity, such as exclusivity for obtaining approval of a New Chemical Entity, listed in the Orange Book for the referenced product, has expired.

If the 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the 505(b)(2) NDA has been accepted for submission by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months, or until a court deems the patent unenforceable, invalid or not infringed, whichever is earlier. Moreover, in cases where a 505(b)(2) application containing a Paragraph IV certification is submitted during a previously approved drug's five year exclusivity period, the 30-month period is automatically extended to prevent approval of the 505(b)(2) application until the date that is seven and one-half years after approval of the previously approved reference product. The court also has the ability to shorten or lengthen either the 30 month or the seven and one-half year period if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized. Alternatively, if the NDA applicant or relevant patent holder does not file a patent infringement lawsuit within the specified 45 day period, the 30 month stay will not prevent approval of the 505(b)(2) application.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) NDAs that we submit.

In the NDA submissions for our product candidates, we intend to follow the development and approval pathway permitted under the FDCA that we believe will maximize the commercial opportunities for these product candidates.

***International Regulation***

In addition to regulations in the U.S., we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of any future products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Table of Contents

For example, under European Union (EU), regulatory systems, sponsors may submit marketing authorizations either under a centralized or mutual recognition procedure. Under the centralized procedure, a single application to the European Medicines Agency (EMA), leads to an approval granted by the European Commission which permits the marketing of a product throughout the EU. The centralized procedure is mandatory for certain classes of medicinal products, but optional for others. For example, all medicinal products developed by certain biotechnological means, and those developed for cancer and other specified diseases and disorders including neurodegenerative disorders, must be authorized via the centralized procedure. The national procedure is used for products that are not required to be authorized by the centralized procedure. Under the national procedure, an application for a marketing authorization is submitted to the competent authority of one member state of the EU. The holders of a national marketing authorization may submit further applications to the competent authorities of the remaining member states via either the decentralized or mutual recognition procedure. The decentralized procedure enables applicants to submit an identical application to the competent authorities of all member states where approval is sought at the same time as the first application, while under the mutual recognition procedure, products are authorized initially in one member state, and other member states where approval is sought are then requested to recognize the original authorization based upon an assessment report prepared by the original authorizing competent authority. Both the decentralized and mutual recognition procedures should take no longer than 90 days, but if one member state makes an objection, which under the legislation can only be based on a possible risk to human health, the application will be automatically referred to the Committee for Medicinal Products for Human Use (the CHMP), of the EMA. If a referral for arbitration is made, the procedure is suspended. However, member states that have already approved the application may, at the request of the applicant, authorize the product in question without waiting for the result of the arbitration. Such authorizations will be without prejudice to the outcome of the arbitration. For all other concerned member states, the opinion of the CHMP, which is binding, could support or reject the objection or alternatively could reach a compromise position acceptable to all EU countries concerned. The arbitration procedure may take an additional year before a final decision is reached and may require the delivery of additional data.

As with FDA approval we may not be able to secure regulatory approvals in Europe in a timely manner, if at all. Additionally, as in the U.S., post-approval regulatory requirements, such as those regarding product manufactures, marketing, or distribution, would apply to any product that is approved in Europe, and failure to comply with such obligations could have a material adverse effect on our ability to successfully commercialize any product.

The conduct of clinical trials in the EU is governed by the European Clinical Trials Directive (2001/20/EC), which was implemented in May 2004. This directive governs how regulatory bodies in member states control clinical trials. No clinical trial may be started without a clinical trial authorization granted by the national competent authority and favorable ethics approval. Accordingly, there is a marked degree of change and uncertainty both in the regulation of clinical trials and in respect of marketing authorizations which face us for our products in Europe.

In addition to regulations in Europe and the U.S., we will be subject to a variety of foreign regulations governing clinical trials and commercial distribution of our products and product candidates.

***Third Party Payor Coverage and Reimbursement***

The commercial success of Zecuity and, if and when commercialized, our product candidates will depend, in part, upon the availability of coverage and reimbursement from third party payors at the federal, state and private levels, including U.S. Government payor programs, including Medicare and Medicaid, private health care insurance companies and managed care plans have attempted to control costs by limiting coverage and the amount of reimbursement for particular procedures or drug

Table of Contents

treatments. The United States Congress and state legislatures from time to time propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our products profitably. Ongoing federal and state government initiatives directed at lowering the total cost of health care will likely continue to focus on healthcare reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid payment systems.

We expect that the pharmaceutical industry will continue to experience pricing pressures due to these initiatives and the trend toward managed healthcare and the increasing influence of managed care organizations. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for Zecuity and operate profitably.

***Manufacturing Requirements***

We and our third party manufacturers must comply with applicable FDA regulations relating to FDA's cGMP regulations. 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, extensive records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP requirements to the satisfaction of the FDA pursuant to a pre-approval inspection before we can use them to manufacture our products. We and our third party manufacturers and certain key component suppliers 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 untitled letters, warning letters, determinations of product adulteration, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restrictions through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval. Such perceived problems concerning safety or efficacy may arise in the context of clinical studies continued as a result of our post-marketing obligations, reports we or FDA receive from patients and healthcare providers, or literature published by third parties regarding our products or similar products.

***Healthcare Fraud and Abuse Laws***

We are subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws, false claims laws and physician self-referral laws. Violations of these laws are punishable by criminal, civil and/or administrative sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state health care programs, including Medicare, Medicaid and veterans' health programs. Because of the far-reaching nature of these laws, there can be no assurance that the occurrence of one or more violations of these laws would not result in a material adverse effect on our business, financial condition and results of operations. In recent years, federal and state enforcement authorities, including the Justice Department and the Office of Inspector General for the U.S. Department of Health and Human Services, have increased the resources devoted to investigating potential violations of these laws.

Table of Contents

*Anti-Kickback Laws.* Our operations are subject to federal and state anti-kickback laws. Certain provisions of the Social Security Act prohibit entities such as us from knowingly and willingly offering, paying, soliciting or receiving any form of remuneration (including any kickbacks, bribes or rebates) in return for the referral of items or services for which payment may be made under a federal health care program, or in return for the recommendation, arrangement, purchase, lease or order of items or services for which payment may be made under a federal health care program. Violation of the federal anti-kickback law is a felony, punishable by criminal fines and imprisonment for up to five years or both. In addition, the Department of Health and Human Services may impose civil penalties and exclude violators from participation in federal health care programs such as Medicare and Medicaid. Violations of the federal anti-kickback law may be used as the basis for claims under the False Claims Act. Many states have adopted similar prohibitions against payments intended to induce referrals of products or services paid by Medicaid or other third party payors, although the specific prohibitions vary from state-to-state.

*Physician Self-Referral Laws.* We also may be subject to federal and/or state physician self-referral laws. Federal physician self-referral legislation (the "Stark law") prohibits, subject to certain exceptions, a physician from referring Medicare or Medicaid patients to an entity to provide designated health services, including, among other things, durable medical equipment and outpatient prescription drugs, when the physician or a member of his immediate family has an ownership or investment interest in or has entered into a compensation arrangement. The Stark law also prohibits the entity receiving the improper referral from billing Medicare for any covered good or service furnished pursuant to an improper referral. The penalties for violations include a prohibition on payment by these government programs and civil penalties for participation in a circumvention scheme. Violations of the Stark Laws may be used as the basis for claims under the False Claims Act. Various states have adopted comparable self-referral laws that have a diverse range of prohibition and exception criteria, and which also contain similar provisions and penalties.

*False Claims.* The federal False Claims Act imposes civil and criminal liability on individuals or entities that submit, cause the submission of, or conspire to file false or fraudulent claims for payment to the government. Violations of the federal False Claims Act may result in penalties equal to three times the damages that the government sustained, civil monetary penalties and exclusion from participation in the federal healthcare programs.

The federal False Claims Act also allows a private individual to bring a qui tam whistleblower suit on behalf of the government against an individual or entity for violations of the False Claims Act. In a qui tam suit, the private plaintiff is responsible for initiating a lawsuit that may eventually lead to the government recovering money of which it was defrauded. After the private plaintiff has initiated the lawsuit, the government must decide whether to intervene in the lawsuit and become the primary prosecutor. In the event the government declines to join the lawsuit, the private plaintiff may choose to pursue the case alone, in which case the private plaintiff's counsel will have primary control over the prosecution (although the government must be kept apprised of the progress of the lawsuit). In return for bringing the suit on the government's behalf, the statute provides that the private plaintiff is entitled to receive up to 30% of the recovered amount from the litigation proceeds if the litigation is successful plus reasonable expenses and attorneys' fees. Recently, the number of qui tam suits in the health care industry has increased dramatically. In addition, a number of states have enacted laws modeled after the False Claims Act that allow those states to recover money which was fraudulently obtained from the state.

*Other Fraud and Abuse Laws.* The Health Insurance Portability and Accountability Act of 1996 created, in part, two new federal crimes: Health Care Fraud and False Statements Relating to Health Care Matters. The Health Care Fraud statute prohibits the knowing and willful execution



Table of Contents

of a scheme or artifice to defraud any health care benefit program. A violation of the statute is a felony and may result in fines and/or imprisonment. The False Statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact by any trick, scheme or device or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. A violation of this statute is a felony and may result in fines and/or imprisonment.

An increasing number of states are passing legislation requiring the reporting and disclosure of gifts or other value given to health care providers, the disclosure of certain advertising and promotion expenditures, the disclosure of product pricing information, the licensing of sales representatives, the adoption of codes of conduct that meet state requirements and the posting of our compliance plan on our Web site.

The federal Physician Payment Sunshine Act was passed as part of PPACA. The act requires manufacturers of pharmaceuticals and medical devices to report certain payments or transfer of value to a physician or teaching hospital to the federal government. This includes the cost of meals provided to a physician. It also includes fees and reimbursed expenses associated with contracted services such as speaker programs, advisory boards, and consulting and research related payments. The act also requires that companies report on drug samples distributed by the company. The first report is due on March 31, 2014. This report must capture all reportable physician and teaching hospital spending from August 1, 2013 through December 31, 2013. The statute requires the federal government to make reported information available to the public by September 30, 2014.

We are required to report pricing information to the Federal and state governments as part of our participation in programs such as the Medicaid Drug Rebate Program, Medicare Part B, and programs run by the Public Health Service, and the Department of Defense. If these reports are not filed in a timely and accurate fashion, we could be subjected to fines and liability.

***Other Regulatory Requirements***

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among other things, standards for direct-to-consumer advertising, industry-sponsored scientific and educational activities and promotional activities involving the Internet, as well as prohibitions on off-label promotion. The FDA has very broad enforcement authority under the FDCA, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing entities to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, civil money penalties and state and federal civil and criminal investigations and prosecutions. Product promotion is often scrutinized in connection with actions and investigations brought under the federal and/or state False Claims Acts; entities investigating in connection with such matters (such as the Justice Department and the Office of Inspector General for the U.S. Department of Health and Human Services) will routinely work with the FDA and/or will consider FDA's regulations regarding product promotion and intended use in determining whether off-label promotion has occurred.

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, government agencies have broad regulatory and enforcement powers, including the ability to levy fines and civil penalties.

In addition, drug manufacturers also are subject to federal and state requirements and restrictions concerning interactions with physicians and other healthcare professionals, internal compliance programs, and transparency reporting requirements, including, for example, reporting of physician

Table of Contents

payments and other transfers of value, reporting of physician ownership or investment interests, reporting of marketing expenditures and clinical trial registration and reporting of clinical trial results on the publicly available clinical trial databank maintained by the National Institutes of Health at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov).

**Research and Development**

For the years ended December 31, 2012, 2011 and 2010, we spent \$10.1 million, \$12.4 million and \$17.1 million, respectively, on research and development expenses, of which \$5.9 million, \$7.1 million and \$12.2 million, respectively, was for the development of Zecuity, \$0.004 million, \$0.6 million and \$1.1 million, respectively, was for the development of NP201, and \$0.1 million, \$0.5 million and \$0.3, respectively, was for the development of NP202. The remaining research and development expenses are for amounts incurred that we do not allocate to specific programs, such as personnel related expenses, including salaries and benefits, as well as general fixed costs for our facility and related expenses.

**Employees**

As of December 31, 2012, we employed 14 full-time employee equivalents, of which 8 were engaged in research and development and clinical trials and 6 were engaged in administration, finance, commercial, business development and legal. None of our employees is represented by a labor union. Our employees are at-will employees, however, we have entered into agreements with certain of our officers and employees that provide for severance benefits in the event we terminate the individual's employment without cause or the individual resigns for good reason, as defined in such agreements.

**Corporate Information**

We were incorporated under the laws of the State of Delaware in January 2005. Our principal executive offices are located at 227 Washington Street, Suite 200, Conshohocken, Pennsylvania 19428 and our telephone number is (484) 567-0130.

**Available Information**

We maintain a corporate website at [www.nupathe.com](http://www.nupathe.com). We make available free of charge through our website's "Investor Relations SEC Filings" page most of our filings with the SEC, including our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. These materials are available as soon as reasonably practicable after such material is filed with or furnished to the SEC. The public can also obtain these materials from the SEC's website at [www.sec.gov](http://www.sec.gov) and at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

Also available through our website's "Investor Relations Corporate Governance" page are charters for the audit, compensation and nominating and corporate governance committees of our board of directors, our corporate governance guidelines and our code of business conduct and ethics.

The references to our website and the SEC's website in this Form 10-K are intended to be inactive textual references only. Neither the contents of our website, nor the contents of the SEC's website, are incorporated by reference herein.

Table of Contents

**ITEM 1A. RISK FACTORS**

*Our business is subject to substantial risks and uncertainties. Any of the risks and uncertainties described below, either alone or taken together, could materially and adversely affect our business, financial condition, results of operations or prospects. These risks and uncertainties could also cause actual results to differ materially from those expressed or implied by forward-looking statements that we make from time to time (please read the "Cautionary Note Regarding Forward-Looking Statements" appearing at the beginning of this Form 10-K). The risks and uncertainties described below are not the only ones we face. Risks and uncertainties of general applicability and additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business, financial condition, results of operations or prospects and could cause actual results to differ materially from those expressed or implied by our forward-looking statements.*

**Risks Related to Our Financial Condition and Capital Requirements**

*We need to obtain additional capital to continue as a going concern; failure to obtain such capital may cause us to delay the launch of Zecuity, to curtail and reduce our operations and costs, and to modify our business strategy.*

Our principal sources of liquidity are cash and cash equivalents of \$22.6 million as of December 31, 2012. As of December 31, 2012, we had working capital of \$19.8 million. During 2012, we used \$20.6 million of cash for operating activities and \$0.5 million for investing activities, which were partially funded from \$20.6 million of net cash provided by financing activities (primarily from the \$26.3 million of net proceeds from the October 2012 Financing).

We believe that our existing cash and cash equivalents will be sufficient to fund our operations, debt service and interest obligations into the fourth quarter of 2013. However, changing circumstances may cause us to consume capital faster than we currently anticipate, and we may need to spend more money than currently expected because of such circumstances. The additional capital that we will require to launch Zecuity and fund our operations and debt service obligations beyond the fourth quarter of 2013 will depend largely upon the timing, scope, terms and structure of any commercial partnership that we are able to enter into for Zecuity because we intend to build our commercial infrastructure to complement that of our partner. There is no assurance that we will be able to secure a commercial partner on acceptable terms or otherwise.

To meet our capital needs, we intend to raise additional capital through corporate collaborations, partnerships or other strategic transactions, debt or equity financings or other funding opportunities. There can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise. Furthermore, the covenants and the pledge of our assets as collateral under the 2012 Term Loan limit our ability to obtain additional debt financing. Until such time as we are able to secure the necessary capital, we intend to limit and delay certain expenditures required for commercialization of Zecuity.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, will result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, which are not favorable to us or our stockholders. If we raise additional funds through corporate collaboration, partnership or other strategic transactions, it may be necessary to relinquish valuable rights to Zecuity, our product candidates, our technologies or future revenue streams or to grant licenses or sell assets on terms that may not be favorable to us.

Table of Contents

If we are unable to raise the necessary capital on terms acceptable to us, as and when needed, we will be required to delay the launch of Zecuity and to curtail and reduce our operations and costs and modify our business strategy, and we may be unable to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the year ended December 31, 2012 related to our ability to continue as a going concern.

We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence.

***Our indebtedness may limit cash flow available to invest in the ongoing needs of our business and our inability to meet our payment obligations may permit our lender to proceed against the collateral granted pursuant to our 2012 Term Loan.***

Our indebtedness, combined with our other financial obligations and contractual commitments, could have significant adverse consequences, including:

Requiring us to dedicate a substantial portion of our cash resources to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;

Increasing our vulnerability to adverse changes in interest rates, currency exchange rates, general economic, industry and competitive conditions and adverse changes in government regulation;

Limiting our flexibility in planning for, or reacting to, changes in our business and our industry; and

Placing us at a competitive disadvantage compared to our competitors that have less debt.

As of December 31, 2012, we had \$8.7 million of principal indebtedness, which is shown on our balance sheet net of \$0.2 million of debt discount, of which \$0.4 million is current and due in 2013, as well as \$0.08 million of accrued and unpaid interest outstanding under our loan and security agreement (2012 Term Loan). We may not have sufficient capital or may be unable to arrange for additional capital to pay the amounts due under our 2012 Term Loan or any other borrowings.

Our obligations under our 2012 Term Loan are secured by a lien on all of our assets, excluding intellectual property, which is subject to a negative pledge. In addition, our cash and investment accounts are subject to account control agreements with the lender that gives them the right to assume control of the account in the event of a default under the 2012 Term Loan. The 2012 Term Loan contains operating covenants including, among others, covenants restricting our ability to incur additional indebtedness, pay dividends or other distributions, effect a sale of any part of our business and merge with or acquire another company. The 2012 Term Loan also includes customary events of default including upon the occurrence of a payment default, a covenant default, a material adverse change (as defined therein) and insolvency. Upon the occurrence of an event of default, the interest on the 2012 Term Loan will be increased by 3% over the rate that would otherwise be applicable. In addition, the occurrence of an event of default could result in the acceleration of our obligations under the 2012 Term Loan as well as grant the lender the right to exercise remedies with respect to the collateral.

Table of Contents

***We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future. We may never become profitable.***

As of December 31, 2012, we had an accumulated deficit of \$140.8 million. We are a development-stage specialty pharmaceutical company. Our lead product, Zecuity, was approved by the FDA on January 17, 2013 for the acute treatment of migraine with or without aura in adults. We expect to make Zecuity available by prescription in the fourth quarter of 2013 and, to date, have not generated any revenues. We have funded our operations to date primarily with the proceeds of the sale of common stock, convertible preferred stock, warrants, convertible notes and borrowings under debt facilities. We expect to continue to incur substantial additional operating losses for at least the next several years as we commercialize Zecuity and continue to develop and seek marketing approval for our product candidates. As a result, we expect to continue to incur significant and increasing losses for the foreseeable future.

To achieve and maintain profitability, we need to generate significant revenues from future product sales. This will require us to be successful in a range of challenging activities, including:

Commercializing Zecuity and any other product candidates for which we obtain marketing approval; and

Achieving market acceptance of Zecuity and any other product candidates for which we obtain marketing approval in the medical community and with patients and third party payors.

Because of the numerous risks and uncertainties associated with commercialization, we are unable to predict the amount of future revenues from Zecuity and extent of any future losses. We may never generate significant future revenues or achieve and sustain profitability.

***The sale of our common stock to Aspire Capital may cause dilution to our existing stockholders and the sale of the shares of common stock acquired by Aspire Capital could cause the price of our common stock to decline.***

We have registered 2,901,734 shares of common stock that we may sell to Aspire Capital under our common stock purchase agreement with Aspire Capital (Purchase Agreement), of which 84,866 shares have been issued to Aspire Capital as a commitment fee in consideration for entering into the Purchase Agreement (the Commitment Shares), 70,721 shares were sold to Aspire Capital upon execution of the Purchase Agreement (the Initial Purchase Shares) and 2,746,147 shares that we may elect to sell to Aspire Capital under the Purchase Agreement. It is anticipated that shares registered will be sold over the term of the Purchase Agreement, which ends on August 15, 2013. The number of shares ultimately offered for sale by Aspire Capital is dependent upon the number of shares we elect to sell to Aspire Capital under the Purchase Agreement. Depending upon market liquidity at the time, sales of shares of our common stock under the Purchase Agreement may cause the trading price of our common stock to decline.

In addition, sales by Aspire Capital of shares acquired pursuant to the Purchase Agreement may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Aspire Capital or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

***We have a limited operating history, which makes it difficult to evaluate our business and growth prospects.***

We were incorporated in Delaware in January 2005. Our operations to date have been limited to organizing and staffing our company, conducting product development activities for Zecuity and

Table of Contents

performing preclinical development of our other product candidates. As a company, we have not yet demonstrated an ability to commercialize a product. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully commercializing pharmaceutical products as a company.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

**Risks Related to Development and Commercialization of Our Product and Product Candidates**

*We are largely dependent on the commercial success of Zecuity.*

As a company, Zecuity will be the first product that we commercialize. Our ability to generate revenues and become profitable will depend in large part on the commercial success of Zecuity. If Zecuity or any other product that we commercialize in the future does not gain an adequate level of acceptance among physicians, patients and third parties, we may not generate significant product revenues or become profitable. Market acceptance of Zecuity, and any other product that we commercialize, by physicians, patients and third party payors will depend on a number of factors, some of which are beyond our control, including:

The efficacy, safety and other potential advantages in relation to alternative treatments;

The relative convenience and ease of administration;

The availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;

The prevalence and severity of adverse events;

The cost of treatment in relation to alternative treatments, including generic products;

The extent and strength of our third party manufacturer and supplier support;

The extent and strength of marketing and distribution support;

The limitations or warnings contained in a product's FDA approved labeling; and

Distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory risk evaluation and mitigation strategy or voluntary risk management plan.

For example, even though Zecuity has been approved by the FDA for the acute treatment of migraine with or without aura in adults, physicians and patients may not immediately be receptive to Zecuity and may be slow to adopt it as an accepted treatment for acute migraine. In addition, even though we believe Zecuity has significant advantages to other treatment options, because no head-to-head trials comparing Zecuity to competing products have been conducted, the prescribing information approved by the FDA does not contain claims that Zecuity is safer or more effective than competitive products. Accordingly, promotion of Zecuity will not reflect any comparative advantages that may exist. Further, the availability of numerous inexpensive generic forms of migraine therapy products may also limit acceptance of Zecuity among physicians, patients and third party payors. If Zecuity does not achieve an adequate level of acceptance among physicians, patients and third party payors, we may not generate meaningful revenues from Zecuity and we may not become profitable.



Table of Contents

***It will be difficult for us to profitably sell Zecuity or any other product that we obtain marketing approval for in the future if reimbursement for such product is limited.***

Market acceptance and sales of Zecuity or any other product that we obtain marketing approval for in the future will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for Zecuity or any other product that we obtain marketing approval for in the future and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, Zecuity and any other products that we commercialize. Numerous generic products may be available at lower prices than branded therapy products, such as Zecuity, which may also reduce the likelihood and level of reimbursement for Zecuity. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize Zecuity or any other product for which we obtain marketing approval. The active ingredient in Zecuity, sumatriptan, is available as a generic, as are other triptans. Because of the low cost, health insurers may require or encourage use of, and consumers may use, a generic triptan prior to trying Zecuity.

***If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell Zecuity, we may be unable to generate product revenues.***

Zecuity was approved by the FDA for the acute treatment of migraine with and without aura in adults on January 17, 2013. We expect to make Zecuity available by prescription in the U.S. in the fourth quarter of 2013. Our goal is to secure a commercial partner prior to the launch of Zecuity and to build our commercial infrastructure to complement that of our partner, which may include the hiring and deployment of our own specialty sales force. In the event we hire our own specialty sales force, we may seek to acquire complementary products to market and sell or collaborate with pharmaceutical or biotechnology companies to market and sell their products. We may also seek to commercialize Zecuity outside the U.S., although we currently plan to do so only with a partner.

The establishment of our own sales force, commercial infrastructure and related compliance plans to market Zecuity is expensive and time consuming and could delay product launch, and we may not be able to successfully develop this capability. We, or our future collaborators, will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. In the event we are unable to develop the necessary sales and marketing infrastructure, we will not be able to commercialize Zecuity or any other product, which would limit our ability to generate product revenues. Even if we are able to build marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing Zecuity or any other product for which we obtain marketing approval in the future.

To the extent we rely on or partner with third parties to commercialize Zecuity or any other product for which we obtain marketing approval in the future, we may receive less revenue than if we commercialized these products ourselves. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts. In the event we are unable to partner with a third party marketing and sales organization, our ability to generate product revenues may be limited either in the U.S. or internationally.



Table of Contents

***We face significant competition from other pharmaceutical and biotechnology companies and from inexpensive generic migraine therapies, as well as branded products. Our operating results will suffer if we fail to compete effectively.***

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. Our major competitors include organizations such as major multinational pharmaceutical companies, established biotechnology companies and specialty pharmaceutical and generic drug companies. Many of our competitors have greater financial and other resources than we have, such as larger research and development staff and more extensive marketing and manufacturing organizations. As a result, these companies may obtain marketing approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our competitors may succeed in developing, acquiring or licensing on an exclusive basis technologies and drug products that are more effective or less costly than Zecuity or any other drug candidate that we develop, which could render our products obsolete and noncompetitive. We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, the level of generic competition and the availability of reimbursement from government and other third party payors. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize our product candidates in our target commercial markets.

The majority of marketed prescription products for treatment of acute migraine in the U.S. are in the triptan class in tablet, orally-disintegrating tablet, nasal spray and injectable formulations. The largest selling triptan in units is sumatriptan, with approximately 75.6 million individual units sold in the U.S. during the twelve months ended June 2011, including approximately 9.2 million units attributable to GlaxoSmithKline plc's (GSK), branded sumatriptan products, Imitrex® and Treximet®. There are at least six other branded triptan therapies being sold by pharmaceutical and biotechnology companies.

Zecuity will face intense competition from inexpensive generic versions of sumatriptan and generic versions of other branded products of competitors that have lost or will lose their patent exclusivity. In addition, we expect other triptan patents to expire between 2013 and 2017. Many of these products are manufactured and marketed by large pharmaceutical companies and are well accepted by physicians, patients and third party payors. Because of the low cost, health insurers likely would require or encourage use of, a generic triptan prior to trying Zecuity.

In addition to marketed migraine medications, both large and small companies have migraine product candidates in various stages of clinical development. These include Levadex from MAP Pharmaceuticals, Inc., an inhaled formulation of DHE, and an intranasal powder formulation of sumatriptan from Optinose, both for the treatment of acute migraine. Optinose announced positive results from a 200 patient Phase III trial in November 2012 and MAP Pharmaceuticals re-submitted its NDA for Levadex to the FDA in 4Q 2011 with a PDUFA date of April 15, 2013. On March 1, 2013, MAP Pharmaceuticals was acquired by Allergan. Allergan also markets Botox, which is marketed for the treatment of chronic migraine.

As with Zecuity, each of NP201 and NP202, if approved, will face competition from generic and branded products. Specifically, NP201, a biodegradable, subcutaneous, injectable polymer implant combined with ropinirole, will face competition from generic immediate release and extended release versions of ropinirole and the dopamine agonist pramipexole, as well as from two continuous delivery medications, a levodopa gel and an injectable apomorphine. NP202, a biodegradable, subcutaneous, injectable polymer implant combined with risperidone will face competition from a variety of branded and generic versions of antipsychotic medications, in addition to several other sustained delivery depot formulations of atypical antipsychotics.

Table of Contents

As a result of all of these factors, our operating results will suffer if we fail to compete effectively.

***Any failure or delay in preclinical studies or clinical trials for our product candidates may cause us to incur additional costs or delay or prevent the commercialization of our product candidates and could severely harm our business.***

Before obtaining marketing approval for the sale of our product candidates, we must conduct, at our own expense, extensive preclinical tests and then clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing, in particular, is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Even if preclinical studies and early phase clinical trials succeed, it is necessary to conduct additional clinical trials in larger numbers of subjects taking the medication for longer periods before seeking FDA approval to market and sell a medication in the U.S. Clinical data is often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products. A failure of one or more of our clinical trials can occur at any stage of testing.

We may experience numerous unforeseen events during, or as a result of, the clinical trial process, which could delay or prevent us from receiving marketing approval or commercializing our product candidates, including the following:

Regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site, or may not permit changes to a clinical trial protocol once the clinical trial has been initiated;

Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional pre-clinical and/or clinical trials or we may abandon projects that we expect to be promising;

The number of subjects required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower than we anticipate, or participants may drop out of, or be ineligible for participation in, our clinical trials at a higher rate than we anticipate;

We might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;

Regulators or institutional review boards may require that we halt, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or our clinical protocols;

Regulators may refuse to accept or consider data from clinical trials for various reasons, including noncompliance with regulatory requirements or our clinical protocols;

Meetings with regulators may be a significant expenditure of resources and funding, and may cause delays in or changes to our clinical development programs;

The cost of our preclinical or clinical trials may be greater than we anticipate;

We may be required to conduct additional preclinical or clinical trials, or to expand existing trials;

The supply or quality of our product candidates or other materials necessary to conduct our clinical trials may be insufficient or inadequate; and



Table of Contents

The effects of our product candidates may not be the desired effects or the desired level of effect or may include undesirable side effects or the product candidates may have other unexpected characteristics.

We expect to conduct additional clinical trials in the future for Zecuity and our other product candidates. Subject enrollment, which is a significant factor in the timing of clinical trials, is affected by a variety of factors, including the following:

The size and nature of the subject population;

The proximity of subjects to clinical sites;

The effectiveness of publicity by clinical trials sites regarding the trial;

The eligibility criteria for the trial, including factors such as frequency of required assessments, length of the study, and ongoing monitoring requirements;

The design of the clinical trial;

Competing clinical trials; and

Clinicians' and subjects' perceptions as to the potential advantages of the medication being studied in relation to other available therapies, including any new medications that may be approved for the indications we are investigating.

Furthermore, we plan to rely on clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance. Any delays or unanticipated problems during clinical testing, such as additional monitoring of clinical trials sites, enrollment in our clinical trials being slower than we anticipate or participants dropping out of or being excluded from participation in our clinical trials at a higher rate than we anticipate, could increase our costs, slow down our product development and approval process and harm our business.

***Serious adverse events or other safety risks could require us to abandon development and preclude or limit approval of our product candidates.***

We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. In addition, regulatory agencies or institutional review boards may at any time order the temporary or permanent discontinuation of our clinical trials or of investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate a clinical trial of any product candidates, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates, if at all, will be delayed or eliminated.

Clinical trials for our product candidates involve testing in large subject populations, which could reveal a high prevalence of adverse events. If these effects include undesirable serious adverse events or have unexpected characteristics, we may need to abandon our development of these product candidates. Alternatively, the identification of serious adverse events or other significant safety risks could result in the imposition of approval requirements, such as labeling or distribution and use restrictions that limit the available market for our product candidates.

***If we fail to acquire, develop and commercialize additional product candidates, our prospects for future growth and our ability to sustain profitability may be limited.***

A key element of our strategy is to develop and commercialize a portfolio of product candidates in addition to Zecuity. To do so, we plan to obtain additional product candidates or technologies primarily



Table of Contents

through acquisitions or licenses. We may not be successful in our efforts to identify and develop additional product candidates, and any product candidates we do identify may not produce commercially viable drugs that safely and effectively treat their indicated conditions. To date, our efforts have yielded two product candidates in addition to Zecuity, both of which are in preclinical development.

Our development programs may initially show promise in identifying potential product leads, yet fail to produce product candidates for clinical development. In addition, identifying new treatment needs and product candidates requires substantial technical, financial and human resources on our part. If we are unable to obtain development partners or additional development program funding or continue to devote substantial technical and human resources to such programs, we may have to delay or abandon these programs. Any product candidate that we successfully identify may require substantial additional development efforts prior to commercial sale, including preclinical studies, extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are susceptible to the risks of failure that are inherent in pharmaceutical product development.

We may be unable to license or acquire suitable product candidates or technologies from third parties for a number of reasons. In particular, the licensing and acquisition of pharmaceutical products is competitive. A number of more established companies are also pursuing strategies to license or acquire products. These established companies may have a competitive advantage over us due to their size, cash resources or greater clinical development and commercialization capabilities. In addition, we expect competition in acquiring product candidates to increase, which may lead to fewer suitable acquisition opportunities for us as well as higher acquisition prices.

Other factors that may prevent us from licensing or otherwise acquiring suitable product candidates include the following:

We may be unable to license or acquire the relevant technology on terms that would allow us to make an appropriate return from such product;

Companies that perceive us to be their competitors may be unwilling to assign or license their product rights to us; or

We may be unable to identify suitable products or product candidates within our areas of expertise; or

We may not have sufficient funds to acquire, develop or commercialize additional products or technologies.

***Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of Zecuity or any other products that we commercialize.***

The risk that we may be sued on product liability claims is inherent in the development of pharmaceutical products. We will face an even greater risk as we commercialize Zecuity. If we cannot successfully defend ourselves against claims that our products or our product candidates, cause injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, these lawsuits may:

Expose us to adverse publicity;

Decrease demand for any products that we successfully develop;

Cause clinical trial participants to withdraw from clinical trials or be reluctant to enroll;

Divert our management or partners from pursuing our business strategy;

Increase warnings on our product label;

Be costly to defend; and



Table of Contents

Force us to limit or forgo further development and commercialization of these products.

Although we maintain general liability and product liability insurance with limits, subject to deductibles, of \$2.0 million in the aggregate for general liability, \$10.0 million in the aggregate for umbrella liability coverage for payments that exceed the general liability limits and \$5.0 million in the aggregate for product liability, this insurance may not fully cover potential liabilities. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial. In addition, inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the development and commercial production and sale of our products, which could adversely affect our business, operating results and financial condition.

*A variety of risks associated with our planned international business relationships could materially adversely affect our business.*

We may enter into agreements with third parties for the development and commercialization of Zecuity and possibly other products in international markets. If we do so, we would be subject to additional risks related to entering into international business relationships, including:

Differing regulatory requirements in foreign countries including, among others, requirements relating to drug approvals, reimbursement and sales and marketing practices;

Potentially reduced protection for intellectual property rights;

The potential for so-called parallel importing, which is what happens when a local seller, faced with higher local prices, opts to import goods from a foreign market, with lower prices, rather than buying them locally;

Unexpected changes in tariffs, trade barriers and regulatory requirements;

Economic weakness, including inflation, or political instability in particular foreign economies and markets;

Compliance with tax, employment, immigration and labor laws for employees traveling abroad;

Foreign taxes;

Foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;

Workforce uncertainty in countries where labor unrest is more common than in the U.S.;

Production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

Business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

These and other risks may materially adversely affect our ability to develop and commercialize products in international markets and may harm our business.





Table of Contents

**Risks Related to Our Dependence on Third Parties**

*We use third parties to manufacture Zecuity and our product candidates, and the machinery to produce the commercial supply of Zecuity must be designed, built and validated. This may increase the risk that we will not have sufficient quantities of Zecuity or our product candidates or such quantities at an acceptable cost, which could result in the commercialization of Zecuity and the development of our product candidates being delayed, prevented or impaired.*

We do not own or operate, and have no plans to establish, any manufacturing facilities for our product candidates. We lack the resources and the capabilities to manufacture Zecuity or any of our product candidates on a clinical or commercial scale. If we are unable to enter into commercial manufacturing agreements with LTS and certain other third party manufacturers and suppliers for the commercial supply of Zecuity in a timely manner, or on acceptable terms, our ability to commercialize Zecuity will be delayed, prevented or impaired. Even if we enter into these agreements, LTS and several of our other manufacturers and suppliers will be single source suppliers to us for a significant period of time. In particular, LTS manufactures Zecuity using sumatriptan and components that we purchase from third parties. Although LTS has considerable experience in the manufacture of passive transdermal drug patches, it has not manufactured active transdermal patches other than Zecuity.

Because we outsource all of our manufacturing processes, there is no guarantee that there will be sufficient supplies to fulfill our requirements or that we may obtain such supplies on acceptable terms. Although we intend to enter into agreements with our critical manufacturers, component fabricators and secondary service providers to secure commercial supply of Zecuity, not all of our suppliers and service providers will be under contract. Any delays in obtaining adequate supplies of our product candidates could limit our ability to meet commercial demand for Zecuity

The machinery that LTS will use to produce the commercial supply of Zecuity is customized to the particular manufacturing specifications of Zecuity. If LTS is unable to qualify and validate this equipment in a timely manner, our ability to launch and commercialize Zecuity will be compromised significantly. If this customized equipment malfunctions at any time during the production process, the time it may take LTS to secure replacement parts, to undertake repairs and to revalidate the equipment and process could limit our ability to meet the commercial demand for Zecuity.

In addition, we are developing another customized piece of machinery to assemble a key component of Zecuity. Upon completion, the equipment will be installed at a designated third party manufacturer. If we are unable to get this equipment fabricated or the equipment cannot be validated at our third party manufacturer in a timely manner, our ability to launch and commercialize Zecuity will be adversely affected. If this customized equipment malfunctions at any time during the production process, the time it may take to secure replacement parts, to undertake repairs and to revalidate the equipment and process could adversely affect our ability to commercially launch Zecuity and meet the commercial demand for Zecuity.

Reliance on third party manufacturers subjects us to risks that would not affect us if we manufactured the product candidates ourselves, including:

Reliance on the third parties for regulatory compliance and quality assurance;

The possible breach of the manufacturing agreements by the third parties because of factors beyond our control;

The possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on their own business priorities; and

The disruption and costs associated with changing suppliers.

Table of Contents

Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. If our existing third party manufacturers, or the third parties that we engage in the future to manufacture a product for commercial sale or for our clinical trials, should cease to continue to do so for any reason, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Our suppliers are subject to regulatory requirements, covering manufacturing, testing, quality control, and record keeping relating to our product candidates, and subject to ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another supplier that meets all regulatory requirements.

***We rely on third parties to conduct aspects of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed in obtaining or ultimately not be able to obtain marketing approval for our product candidates.***

We currently rely on contract research organizations (CROs) for some aspects of our clinical trials, including data management, statistical analysis and electronic compilation of our NDA. We may enter into additional agreements with CROs to obtain additional resources and expertise in an attempt to accelerate our progress with regard to ongoing clinical and preclinical programs. Entering into relationships with CROs involves substantial cost and requires extensive management time and focus. In addition, typically there is a transition period when a CRO commences work. As a result, delays may occur, which may materially impact our ability to meet our desired clinical development timelines and ultimately have a material adverse impact on our operating results, financial condition or future prospects.

As CROs are not our employees, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and preclinical programs in which they are engaged to perform. If the CROs we engage do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the data they provide is compromised due to the failure to adhere to regulatory requirements or for other reasons, then our development programs may be extended, delayed or terminated, or we may not be able to obtain marketing approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed and our costs could increase.

***Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.***

We are actively seeking partnerships, collaborations and other strategic transactions to maximize the commercial potential of Zecuity, our product candidates and our proprietary technologies in the U.S. and territories throughout the world. We may enter into such arrangements on a selective basis depending on the merits of retaining commercialization rights for ourselves as compared to entering into selective collaboration arrangements with leading pharmaceutical or biotechnology companies for Zecuity and each of our product candidates and technologies, both in the U.S. and internationally. We face competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose

Table of Contents

to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercialization and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision making authority.

Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

**Risks Related to Regulatory Matters**

*If we are unable to obtain marketing approval for NP201 and NP202, we will not be able to commercialize such product candidates and our business may be harmed.*

Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA to establish the product candidate's safety and efficacy. Securing FDA approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA. Our other product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals is expensive and often takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved and the nature of the disease or condition to be treated. We may fail to obtain marketing approval for our product candidates for many reasons, including the following:

We may not be able to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for any indication;

The results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for approval;

The FDA or comparable foreign regulatory authorities may disagree with the number, design, conduct or implementation of our clinical trials;

We may not be able to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

We may not be able to demonstrate that a product candidate provides an advantage over current standard of care or future competitive therapies in development;

Table of Contents

The FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

The FDA or comparable foreign regulatory authorities may not accept data generated at our clinical trial sites;

The data collected from clinical trials of any product candidates that we develop may not be sufficient to support the submission of an NDA or other submission or to obtain marketing approval in the U.S. or elsewhere; and

The FDA or comparable foreign regulatory authorities may identify deficiencies in the manufacturing or testing processes or facilities of third party manufacturers with which we enter into agreements for clinical and commercial supplies.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain marketing approval to market our product candidates, which could harm our business, results of operations and prospects.

***We will continue to face extensive regulatory requirements and our products may face future development and regulatory difficulties.***

FDA may impose significant restrictions on a product's indicated uses or marketing, including risk evaluation and mitigation strategies, or impose ongoing requirements, including with respect to:

Post-market surveillance, post-market studies or post-market clinical trials;

Labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of safety and other post-market information;

Monitoring and reporting adverse events and instances of the failure of a product to meet the specifications in the NDA;

Changes to the approved product, product labeling or manufacturing process;

Advertising and other promotional material; and

Disclosure of clinical trial results on publicly available databases.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. The distribution, sale and marketing of our products are subject to a number of additional requirements, including:

State wholesale drug distribution laws and the distribution of our product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act;

Sales, marketing and scientific or educational grant programs must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act, the transparency provision of the Patient Protection and Affordable Care Act and an associated reconciliation bill that became law in March 2010, which we refer to collectively as the Health Care Reform Law, the False Claims Act and similar state laws;

## Edgar Filing: NUPATHE INC. - Form 10-K

Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veteran's Health Care Act of 1992; and

If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply.

## Edgar Filing: NUPATHE INC. - Form 10-K

### Table of Contents

All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

If we or any third parties involved in our commercialization efforts fail to comply with applicable regulatory requirements, a regulatory agency may:

Issue warning letters or untitled letters asserting that we are in violation of the law;

Seek an injunction or impose civil or criminal penalties or monetary fines;

Suspend or withdraw marketing approval;

Suspend any ongoing clinical trials;

Refuse to approve pending applications or supplements to applications submitted by us;

Suspend or impose restrictions on operations, including costly new manufacturing requirements;

Seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall;

Refuse to allow us to enter into supply contracts, including government contracts;

Impose civil monetary penalties; or

Pursue civil or criminal prosecutions and fines against our company or responsible officers.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenues.

***Although we have obtained marketing approval for Zecuity, adverse effects discovered after approval could limit the commercial profile of Zecuity or any other product we develop.***

Although we have obtained marketing approval for Zecuity, we or others may later discover, after use in a larger number of subjects for longer periods of time than in clinical trials, that Zecuity or any other product that we commercialize could have adverse effect profiles that limit their usefulness or require their withdrawal. This discovery could have a number of potentially significant negative consequences, including:

Regulatory authorities may withdraw their approval of the product;

Regulatory authorities may require the addition of labeling statements, such as black box or other warnings or contraindications, or may expand our post-marketing obligations;

Regulatory authorities may require us to issue specific communications to healthcare professionals, such as "Dear Doctor Letters;"

Regulatory authorities may impose additional restrictions on marketing and distribution of the products;

Regulatory authorities may issue negative publicity regarding the product, including safety communications;

We may be required to change the way the product is administered, conduct additional clinical studies or restrict the distribution of the product;

We could be sued and held liable for harm caused to subjects; and

Our reputation may suffer.



Table of Contents

Any of these events could prevent us from maintaining market acceptance of the affected product and could substantially increase the costs of commercializing such product.

***If the manufacturing facilities of our third party manufacturers and suppliers are not maintained in a manner that is compliant with cGMP requirements, we may need to find alternative manufacturers and suppliers which could result in Zecuity supply interruptions, additional costs and lost revenues.***

The facilities of our manufacturers must be maintained in a manner compliant with cGMP requirements, including favorable inspection reports. We do not control the manufacturing process of Zecuity and are dependent on third party manufacturers for compliance with the FDA's requirements for manufacture of Zecuity. If our manufacturers cannot successfully manufacture material components and finished products that conform to our specifications and the FDA's strict regulatory requirements, they may not be able to maintain FDA approval for their manufacturing facilities. If these facilities cannot maintain compliance with FDA requirements, we may need to find alternative manufacturing facilities, which could result in Zecuity supply interruptions and substantial additional costs as a result of such delays, including costs with respect to finding alternative manufacturing facilities, and lost revenues.

***Even though Zecuity has received marketing approval by the FDA in the U.S., we may never receive marketing approval or commercialize Zecuity or any other products outside the U.S.***

In order to market Zecuity or any other product candidate outside the U.S., we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. The marketing approval process in other countries may include all of the risks associated with obtaining FDA approval in the U.S., as well as other risks. For example, legislation analogous to Section 505(b)(2) of the FDCA in the U.S., which relates to the ability of an NDA applicant to use published data not developed by such applicant, does not exist in other countries. In territories where data is not freely available, we may not have the ability to commercialize our products without negotiating rights from third parties to refer to their clinical data in our regulatory applications, which could require the expenditure of significant additional funds. Further, we may be unable to obtain rights to the necessary clinical data and may be required to develop our own proprietary safety and effectiveness dossiers. In addition, in many countries outside the U.S., it is required that a product receives pricing and reimbursement approval before the product can be commercialized. This can result in substantial delays in such countries.

Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. In addition, we may be subject to fines, suspension or withdrawal of marketing approvals, product recalls, seizure of products, operating restrictions and criminal prosecution if we fail to comply with applicable foreign regulatory requirements. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

***Our relationships with physicians, customers and payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any product that we commercialize. Our arrangements with third party payors and

Table of Contents

customers will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute Zecuity and any other product we commercialize. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

The federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;

The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

The federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and

Analogous state laws and regulations, such as state anti-kickback and false claims laws and transparency laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations are costly. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities conducted by our sales team in the sale of Zecuity, are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Table of Contents

***Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.***

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell Zecuity or any other product that we commercialize.

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Modernization Act) changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

Additionally, in March 2010, President Obama signed into law the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revised the definition of "average manufacturer price" for reporting purposes, which increased the amount of Medicaid drug rebates to states. Further, beginning in 2011, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

More recently, in July 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA), which, in addition to reauthorizing PDUFA and amending other provisions that were scheduled to sunset, established new user fee statutes for generic drugs and biosimilars, including a new fee for Drug Master Files and product and establishment fees for manufacturers of generic drugs. These fees may impact our manufacturers and/or suppliers, potentially resulting in increased costs to manufacture our products. FDASIA also emphasizes drug safety, such as enhancing FDA's inspection authority and oversight of the drug supply chain. This renewed focus on drug safety and enhanced authority to inspect and enforce cGMP requirements may result in additional regulatory burdens and operating costs, and may also impact timelines for product production, marketing, distribution, and availability, to the extent that any concerns are detected during FDA's inspections of our manufacturers.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. Litigation involving the regulation and marketing of pharmaceutical products also could impact promotional activities and labeling. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed (whether as a result of legislation or litigation), or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In

Table of Contents

addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

***Our development and commercialization strategy for NP201 and NP202 depends, in part, upon the FDA's prior findings of safety and effectiveness of ropinirole and risperidone based on data not developed by us, but which the FDA may rely upon in reviewing our NDA.***

The Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA, for purposes of approving an NDA, to permit the applicant to rely upon the FDA's previous findings of safety and effectiveness for an approved product. The FDA may also require companies to perform additional clinical trials or measurements to support any change from the previously approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. Similar to Zecuity, we intend to submit the NDA for NP201 and NP202 under Section 505(b)(2), and as such the NDA will rely, in part, on the FDA's previous findings of safety and effectiveness for ropinirole and risperidone. Even though we may be able to take advantage of Section 505(b)(2) to support potential U.S. approval for NP201 and NP202, the FDA may require us, to perform additional clinical trials or measurements to support approval. In addition, notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) NDAs that we submit. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of our products.

**Risks Related to Intellectual Property**

***We may not be able to rely on our intellectual property to protect our products in the marketplace.***

Our success depends, in large part, on our ability to protect our competitive position through patents, trade secrets, trademarks and other intellectual property rights. The patent positions of pharmaceutical and biotechnology companies, including our company, are uncertain and involve complex questions of law and fact for which important legal issues remain unresolved or may change. As a result of recent court decisions, the requirements for patentability of inventions in the U.S. have become more stringent, including stricter requirements that inventions be non-obvious and that patent applications provide an adequate written description of the invention. These court decisions may have the effect of narrowing the types of medical treatments that are patentable.

We exclusively license one issued U.S. patent, and its foreign counterparts, and own three issued U.S. patents. Our licensed *U.S. Patent No. 6,745,071*, owned by Travanti, is generally directed towards wearable iontophoretic devices, including Zecuity, that are prepackaged as complete self-contained units that include an active pharmaceutical ingredient to be administered, a provision for isolating moisture sources from the electrodes and from the power source during storage to optimize shelf stability, and a simple, user-friendly mechanism to transfer the active pharmaceutical ingredient and counter ion reservoirs to the electrodes. Our issued patents include:

*U.S. Patent No. 7,973,058* which is generally directed to methods of treating migraine using an iontophoretic patch containing a triptan.

Table of Contents

*U.S. Patent No. 8,155,737* which is generally directed to methods of treating migraine using an iontophoretic patch by administering sumatriptan to achieve consistent plasma levels with low patient to patient variability.

*U.S. Patent No. 8,366,600* which is generally directed to methods of treating migraine using an iontophoretic patch by administering a triptan comprising our proprietary hydrogel polyamine formulation.

The issued patents that we own and license or that may be issued to or licensed by us in the future may not provide us with any competitive advantage. Our patents may be challenged by third parties in patent litigation, or in patent reexamination or opposition proceedings, which are becoming widespread in the pharmaceutical industry. In particular, it is not uncommon for potential competitors to challenge the validity of patents protecting new pharmaceutical products shortly after the products receive FDA approval. Alternatively, it is possible that third parties with products that are very similar to ours will circumvent our issued patents by purposely developing products or processes that avoid our patent claims. Our patent protection may be limited because of any of the following:

Our patents may not be broad or strong enough to prevent competition from identical or similar products;

We may be required to disclaim part of the term of some patents;

There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;

There may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a claim, but which, nonetheless ultimately may be found to affect the validity or enforceability of a claim;

If challenged, a court could determine that our patents are not valid or enforceable;

A court could determine that a competitor's technology or product does not infringe our patents; and

Our patents and patent applications could irretrievably lapse due to failure to pay fees or otherwise comply with regulations, or could be subject to compulsory licensing.

We and our licensors have filed and are actively pursuing applications for additional patents in the U.S. and in foreign jurisdictions. However, pending patent applications may not result in the issuance of patents or the scope of patent protection that we have requested, and we may not develop additional proprietary products which are patentable. Further, if we encounter delays in our development or clinical trials, the period of time during which we could market our products under patent protection would be reduced.

Because the composition of matter patent covering the active pharmaceutical ingredient of Zecuity has expired, competitors will be able to offer and sell products with the same active pharmaceutical ingredient as Zecuity so long as these competitors do not infringe any other patents that may be issued to or licensed by us, or violate any marketing exclusivity period that may be granted. Similarly, the composition of matter patents covering the active ingredients of our NP201 and NP202 product candidates have expired, and competitors will be able to offer and sell products with the same active pharmaceutical ingredients as these product candidates products so long as these competitors do not infringe any other patents that we hold or may obtain in the future, including any product, formulation and method of use patents, or violate any marketing exclusivity period that may be granted.

Patents covering new products or formulations incorporating a generic active pharmaceutical ingredient cannot prevent competitors from commercializing the original products and formulations. In addition, method-of-use patents, in particular, are more difficult to enforce than composition of matter

Table of Contents

patents because of the risk of off label sale or use of the subject compounds. Physicians are permitted to prescribe an approved product for uses that are not described in the product's labeling. Although off label prescriptions may infringe our method of use patents, if issued, the practice is common across medical specialties and such infringement is difficult to prevent or prosecute. Off label sales would limit our ability to generate revenue from the sale of our product candidates, if approved for commercial sale. In addition, if a third party were able to design around any issued product, method, formulation or other patent and create a different product not covered by our patents, if issued, we would likely be unable to prevent that third party from manufacturing and marketing its product.

We rely on third parties to protect the intellectual property we license, including trade secrets, patents, and know-how, and we may not have any input or control over the filing, prosecution or enforcement of such intellectual property rights. Any resulting patents may be invalid or unenforceable. Any enforcement of intellectual property rights, or defense of any claims asserting the invalidity thereof, may be subject to the cooperation of the third parties.

***If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.***

We are a party to a number of license agreements and may enter into additional licenses in the future. If we fail to comply with the obligations under a license agreement or otherwise breach the license agreement, the licensor may have the right to terminate the license, in which event we might not be able to market any product that is covered by any previously licensed patents.

For example, we are party to a license agreement with the University of Pennsylvania (Penn), pursuant to which we license from Penn patent applications and other intellectual property related to the LAD technology to develop and commercialize licensed products, including NP201 and NP202, and a license agreement with Evonik Industries AG, Inc. (as successor to SurModics Pharmaceuticals), pursuant to which we license from Evonik Industries intellectual property to make, have made, use, sell, import and export NP201.

We are obligated to pay milestone and royalty payments under each agreement in addition to other obligations. The triggering of milestone payments to Penn or Evonik Industries depends on factors relating to the clinical and regulatory development and commercialization of NP201 and NP202, many of which are beyond our control.

In addition, we are required to pay Penn annual license maintenance fees of up to \$50,000 and to commit at least \$250,000 annually towards the development and commercialization of licensed products, until the first commercial sale of the first licensed product.

We may become obligated to make a milestone payment, maintenance fee or other payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical trials, curtail our operations, scale back our commercialization and marketing efforts or seek additional capital to meet these obligations on terms unfavorable to us.

Our failure to comply with the requirements of these license agreements, including our milestone payment, maintenance fees and other obligations, could result in the termination of such agreements, in which case we might not be able to develop or market any product that is covered by the license. Even if we contest any such termination and are ultimately successful, our results of operations and stock price could suffer.

***Our ability to pursue the development and commercialization of Zecuity is significantly dependent upon obtaining a license of LTS's intellectual property.***

Our development and license agreement with LTS provides that if we enter into a commercial manufacturing agreement with LTS, LTS will have the exclusive right to manufacture Zecuity and LTS

Table of Contents

will grant us an exclusive, worldwide, royalty-free license under LTS's intellectual property to use, import, sell, market and distribute Zecuity. We may not enter into a commercial manufacturing agreement with LTS on commercially reasonable terms, if at all. If we do not enter into a commercial manufacturing agreement with LTS, we may not have access to LTS's proprietary technology and know-how to manufacture Zecuity. In this situation, we would need to develop equivalent or alternative intellectual property, which will significantly delay our commercialization of Zecuity and entail significant additional cost.

***We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our products.***

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. There could be issued patents of which we are not aware that our products infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe. Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our products infringe. For example, pending applications may exist that provide support or can be amended to provide support for a claim that results in an issued patent that our product infringes.

Third parties may assert that we are employing their proprietary technology without authorization. If a court held that any third party patents cover our products, the holders of any such patents may be able to block our ability to commercialize our products unless we obtained a license under the applicable patent or patents, or until such patents expire. We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us.

***If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be significantly diminished.***

In addition to patents, we rely on trade secrets and proprietary know-how to protect our intellectual property. We generally require our employees, consultants, outside scientific collaborators and sponsored researchers and other advisors to enter into confidentiality agreements. These agreements typically provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of our employees, the agreements also typically provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed during employment are our exclusive property to the extent permitted by law. Where appropriate, agreements we obtain with our consultants also typically contain similar assignment of invention provisions.

These agreements may not provide meaningful protection or adequate remedies in the event of unauthorized use or disclosure of our proprietary information. Involuntary disclosure or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position. In addition, it is possible that third parties could independently develop proprietary information and techniques substantially similar to ours or otherwise gain access to our trade secrets.

Table of Contents

**Risks Related to Employee Matters and Managing Growth**

*If we are not successful in attracting and retaining highly qualified personnel, including our current senior executive team, we may not be able to successfully implement our business strategy.*

Our ability to compete in the highly competitive pharmaceutical and biotechnology industries depends in large part upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. Competition for skilled personnel in our market is very intense because of the numerous pharmaceutical and biotechnology companies that seek similar personnel. These companies may have greater financial and other resources, offer a greater opportunity for career advancement and have a longer history in the industry than we do. We also experience competition for the hiring of our scientific and clinical personnel from universities and research institutions. We do not maintain "key person" insurance for any of our employees. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results or financial condition.

*We will need to grow our organization to commercialize Zecuity, and we may experience difficulties in managing this growth, which could disrupt our operations.*

As of December 31, 2012, we employed 14 full-time employee equivalents. We expect to make Zecuity available by prescription in the U.S. in the fourth quarter of 2013. We expect to expand our employee base for managerial, operational, sales, marketing, financial and other personnel as we prepare to commercialize Zecuity. Our goal is to secure a commercial partner prior to the launch of Zecuity and to build our commercial infrastructure to complement that of our partner, which may include the hiring and deployment of our own specialty sales force. Future growth will likely impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the commercialization of Zecuity or development of additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate or increase our revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize Zecuity and our other product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

**Risks Related to Ownership of Our Common Stock**

*The market price of our common stock has been, and may continue to be, highly volatile.*

The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including the following:

Our ability to secure a commercialization partner on favorable terms for Zecuity;

Our ability to raise additional capital on favorable terms to launch Zecuity and continue as a going concern;

Our ability to manufacture commercial supply and launch Zecuity;

Our ability to obtain adequate reimbursement from government and other third party payors for Zecuity;



Table of Contents

The commercial success of Zecuity;

Results of clinical trials of our product candidates or those of our competitors;

Changes or developments in laws or regulations applicable to our product candidates;

Introduction of competitive products or technologies;

Failure to meet or exceed financial or operational projections we provide to the public;

Actual or anticipated variations in quarterly operating results;

Failure to meet or exceed the estimates and projections of the investment community;

The perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;

General economic and market conditions and overall fluctuations in U.S. equity markets;

Developments concerning our sources of manufacturing supply;

Disputes or other developments relating to patents or other proprietary rights;

Additions or departures of key scientific or management personnel;

Issuances of debt, equity or convertible securities;

Changes in the market valuations of similar companies; and

The other factors described in this "Risk Factors" section.

In addition, the stock market in general, and the market for small pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.***

## Edgar Filing: NUPATHE INC. - Form 10-K

To our knowledge, as of January 31, 2013, our executive officers, directors and 5% stockholders and their affiliates owned approximately 59% of our outstanding voting stock. As a result, these stockholders will have significant influence and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of ownership could delay or prevent any acquisition of our company on terms that other stockholders may desire.

*Future sales of shares of our common stock, including shares issued upon the exercise of currently outstanding options and warrants could negatively affect our stock price.*

A substantial portion of our outstanding common stock can be traded without restriction at any time. The sale of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of our common stock. In addition, we have 14,403,716 shares that are subject to outstanding warrants and 1,289,843 shares that are subject to outstanding options that were

Table of Contents

in-the-money on January 31, 2013. The exercise of these warrants and options and the subsequent sale of the underlying common stock could cause a decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

***Because we do not intend to pay dividends on our common stock, your returns will be limited to any increase in the value of our stock.***

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business and do not anticipate declaring or paying any cash dividends on our common stock for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

***Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our restated certificate of incorporation and our bylaws, as well as provisions of the Delaware General Corporation Law (the DGCL) could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions include:

the ability of our Board of Directors to authorize the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

the prohibition of stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

the inability of stockholders to call a special meeting of stockholders; and

advance notice requirements for nominations for election to the board of directors and for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing our officers. In addition, we are subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

***Our business could be negatively affected as a result of the actions of activist stockholders.***

Proxy contests have been waged against many companies in the pharmaceutical industry over the last few years. If faced with a proxy contest, we may not be able to successfully respond to the contest, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest because:

Responding to proxy contests and other actions by activist stockholders may be costly and time-consuming, and may disrupt our operations and divert the attention of management and our employees;

Table of Contents

Perceived uncertainties as to the potential outcome of any proxy contest may result in our inability to consummate potential acquisitions, collaborations or licensing opportunities and may make it more difficult to attract and retain qualified personnel and business partners; and

If individuals that have a specific agenda different from that of our management or other members of our board of directors are elected to our board as a result of any proxy contest, such an election may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

We do not have any unresolved SEC staff comments relating to our periodic or current reports.

**ITEM 2. PROPERTIES**

Our principal executive offices are located in Conshohocken, Pennsylvania, where we occupy approximately 11,075 square feet of office space and 240 square feet of storage space pursuant to a lease that ends on June 30, 2013. We believe this facility is adequate and suitable for our current needs, however, we may obtain additional space in connection with the commercial launch of Zecuity.

**ITEM 3. LEGAL PROCEEDINGS**

We are not a party to any pending legal proceedings.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

Table of Contents**PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES***Market Information*

Our common stock is listed on The NASDAQ Global Market under the symbol "PATH". The following table sets forth the high and low closing sales prices per share for our common stock for the periods indicated, as reported by The NASDAQ Global Market:

| <b>Year Ended December 31, 2012:</b> | <b>High</b> | <b>Low</b> |
|--------------------------------------|-------------|------------|
| First Quarter                        | \$ 4.84     | \$ 1.87    |
| Second Quarter                       | \$ 4.09     | \$ 3.03    |
| Third Quarter                        | \$ 4.42     | \$ 3.23    |
| Fourth Quarter                       | \$ 3.71     | \$ 2.57    |

| <b>Year Ended December 31, 2011:</b> | <b>High</b> | <b>Low</b> |
|--------------------------------------|-------------|------------|
| First Quarter                        | \$ 9.09     | \$ 7.21    |
| Second Quarter                       | \$ 8.60     | \$ 6.65    |
| Third Quarter                        | \$ 7.57     | \$ 2.02    |
| Fourth Quarter                       | \$ 3.12     | \$ 1.60    |

*Holder of Record*

As of February 28, 2013, there were approximately 57 holders of record of our common stock. Because many of such shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

*Dividends*

We have never paid or declared any cash dividends on our common stock. We currently intend to retain any future earnings and do not expect to pay cash dividends in the foreseeable future.

**ITEM 6. SELECTED FINANCIAL DATA**

The following selected financial data should be read in conjunction with, and is qualified by reference to, our audited financial statements and related notes thereto and Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Form 10-K. The statement of operations data and statement of cash flows data for the years ended December 31, 2012, 2011 and 2010 and the balance sheet data as of December 31, 2012 and 2011 have been derived from our audited financial statements and related notes, which are included elsewhere in this Form 10-K. The statement of operations data and statement of cash flows data for the years ended December 31, 2009 and 2008 and the balance sheet data as of December 31, 2010, 2009 and 2008 have been derived from audited financial statements which do not appear in this Form 10-K. Our historical

Edgar Filing: NUPATHE INC. - Form 10-K

Table of Contents

results and financial condition are not necessarily indicative of the results or financial condition that may be expected in the future.

| Statement of operations data:                                | Years Ended December 31,                        |             |             |             |             |
|--|---|-------------|-------------|-------------|-------------|
|  | 2012  | 2011        | 2010        | 2009        | 2008        |
|  | (in thousands, except share and per share data) |             |             |             |             |
| Revenue  | \$  | \$          | \$          | 650         | \$          |
| Operating expenses:  |   |             |             |             |             |
| Research and development                                     | 10,149  | 12,407      | 17,064      | 11,310      | 8,815       |
| Acquired in-process research and development                 |   |             |             |             | 5,500       |
| Selling, general and administrative                          | 10,884  | 9,416       | 4,772       | 3,142       | 3,075       |
| Total operating expenses                                     | 21,033  | 21,823      | 21,836      | 14,452      | 17,390      |
| Loss from operations   | (21,033)  | (21,823)    | (21,186)    | (14,452)    | (17,390)    |
| Interest income(expense), net                                | (1,556)   | (1,411)     | (3,671)     | (1,290)     | (121)       |
| Change in fair value of warrants                             | (1,287)   |             |             |             |             |
| Loss on debt extinguishment                                  | (799)   |             |             |             |             |
| Loss before tax benefit                                      | (24,675)  | (23,234)    | (24,857)    | (15,742)    | (17,511)    |
| Income tax benefit   | 141   | 47          | 500         | 151         |             |
| Net loss   | (24,534)  | (23,187)    | (24,357)    | (15,591)    | (17,511)    |
| Deemed dividend  | (13,250)  |             |             |             |             |
| Accretion of redeemable convertible preferred stock          |   |             | (2,533)     | (3,617)     | (2,330)     |
| Net loss applicable to common stockholders                   | \$ (37,784)                                     | \$ (23,187) | \$ (26,890) | \$ (19,208) | \$ (19,841) |
| Basic and diluted net loss per common share                  | \$ (2.48)                                       | \$ (1.58)   | \$ (4.39)   | \$ (50.31)  | \$ (51.98)  |
| Weighted average basic and diluted common shares outstanding | 15,210,047                                      | 14,630,125  | 6,126,123   | 381,789     | 381,681     |

| Balance sheet data:                    | As of December 31, |           |           |          |          |
|--|--------------------|-----------|-----------|----------|----------|
|  | 2012               | 2011      | 2010      | 2009     | 2008     |
|  | (in thousands)     |           |           |          |          |
| Cash and cash equivalents              | \$ 22,570          | \$ 23,059 | \$ 38,918 | \$ 3,927 | \$ 8,368 |
| Working capital                        | 19,847             | 10,995    | 34,142    | 1,527    | 6,285    |
| Total assets                           | 30,607             | 30,849    | 43,753    | 5,009    | 9,776    |
| Long-term debt                         | 8,102              | 5,481     | 3,704     |          | 782      |
| Redeemable convertible preferred stock |                    |           |           | 55,538   | 41,809   |
| Convertible preferred stock            | 7,255              |           |           |          |          |
| Total stockholders' equity (deficit)   | 3,013              | 12,971    | 34,265    | (54,474) | (36,141) |

| Statement of cash flows data:             | Years Ended December 31,                        |             |             |             |             |
|---|---|-------------|-------------|-------------|-------------|
|   | 2012  | 2011        | 2010        | 2009        | 2008        |
|   | (in thousands, except share and per share data) |             |             |             |             |
| Net cash used in operating activities     | \$ (20,614)                                     | \$ (20,917) | \$ (18,404) | \$ (13,567) | \$ (12,274) |
| Net cash used in investing activities     | (477)   | (3,546)     | (3,485)     | (29)        | (5,627)     |
| Net cash provided by financing activities | 20,602  | 8,604       | 56,880      | 9,155       | 22,439      |

Table of Contents

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

*The following discussion and analysis should be read together with our audited financial statements and related notes appearing elsewhere in this Form 10-K.*

**Overview**

We are a specialty pharmaceutical company focused on the development and commercialization of branded therapeutics for diseases of the central nervous system, including neurological and psychiatric disorders. Our lead product, Zecuity (sumatriptan iontophoretic transdermal system), was approved by the FDA on January 17, 2013 for the acute treatment of migraine with or without aura in adults. Zecuity is a single-use, battery-powered patch that actively delivers sumatriptan, the most prescribed migraine medication, through the skin. Zecuity is the first patch approved by the FDA for the acute treatment of migraine. We designed Zecuity to overcome limitations of current migraine treatments that are related to route of administration and peak plasma concentrations, and in particular, to address the unmet needs of patients who experience migraine-relating nausea (MRN) as part of their attacks. We expect to make Zecuity available by prescription in the U.S. in the fourth quarter of 2013.

We are actively seeking partnerships to maximize the commercial potential for Zecuity. Our goal is to secure a commercial partner prior to the launch of Zecuity and to build our commercial infrastructure to complement that of our partner, which may include the hiring and deployment of our own specialty sales force. If we hire our own specialty sales force, we may seek to acquire complementary products to market and sell, or collaborate with pharmaceutical or biotechnology companies to market and sell their products. We may also seek to commercialize Zecuity outside the U.S., although we currently plan to do so only with a partner.

We also have two proprietary product candidates in preclinical development that address large market opportunities. NP201, for the continuous symptomatic treatment of Parkinson's disease, utilizes ropinirole, an FDA-approved dopamine agonist, and is designed to provide up to two months of continuous delivery. NP202, for the long-term treatment of schizophrenia and bipolar disorder, is designed to help address the long-standing problem of patient noncompliance by providing three months of continuous delivery of risperidone, an FDA-approved atypical antipsychotic. We are actively seeking partnerships to maximize the commercial potential for NP201 and NP202 in the U.S. and territories throughout the world and currently intend to limit spending on these programs until a development partner is obtained.

**Liquidity and Capital Resources**

We were incorporated in the State of Delaware in January 2005 and are a development-stage company. Since our inception, we have invested a significant portion of our efforts and financial resources in the development of Zecuity. Zecuity is the only product for which we have received marketing approval from the FDA, and to date we have not marketed, distributed or sold any products. As a result, we have generated no product revenue and have never been profitable. Our net loss for the years ended December 31, 2012, 2011 and 2010 was \$24.5 million, \$23.2 million and \$24.4 million, respectively. As of December 31, 2012, we had an accumulated deficit of \$140.8 million.

We have funded our operations to date primarily with the proceeds of the sale of common stock, convertible preferred stock, warrants, convertible notes and borrowings under credit facilities. From inception through December 31, 2012, we have received net proceeds of \$128.0 million from the sale of common stock, convertible preferred stock, warrants and convertible notes. In October 2012, we received net proceeds of \$26.3 million from the sale of 14 million units of our securities (the October 2012 Financing). The per unit purchase price was \$2.00, and each unit consisted of one one-thousandth (1/1,000) of a share of our newly-designated Series A Preferred Stock, par value \$0.001

## Edgar Filing: NUPATHE INC. - Form 10-K

### Table of Contents

per share, and a five-year warrant to purchase one share of our common stock, par value \$0.001 per share, at an exercise price of \$2.00 per share. All shares of Series A Preferred Stock have converted into common stock.

In connection with the October 2012 Financing, we undertook certain cost containment measures in order to focus our expenditures on gaining FDA approval of Zecuity, securing commercial partners and select pre-launch activities. The cost containment measures included, among others:

the elimination of 15 full-time-equivalent positions in our workforce;

the reduction in expenditures relating to commercialization activities for Zecuity and our earlier stage product candidates;  
and

the delay of the filing of an Investigational New Drug application for NP202 until a development partner is obtained.

In November 2012, we entered into a Loan and Security Agreement with Hercules Technology Growth Capital, Inc. (Hercules) pursuant to which we obtained an \$8.5 million term loan (Term Loan). We used \$7.75 million of the Term Loan proceeds to repay in full the term loans outstanding under our Term Loan Facility with MidCap Funding III, LLC and Silicon Valley Bank and the Term Loan Facility was terminated. As of December 31, 2012, the principal balance of the Term Loan was \$8.5 million and we are in compliance with all of the debt covenants.

We expect to continue to incur substantial additional operating losses for at least the next several years as we commercialize Zecuity and continue to develop our product candidates. Our future capital needs will depend on many factors, including:

the extent to which we are successful in obtaining a commercial partner for Zecuity and the timing, scope, terms and structure of such partnership;

the cost, scope and timing of activities undertaken for commercialization of Zecuity;

the extent to which we are successful in establishing collaboration, co-promotion, distribution or other similar arrangements for our product candidates;

the scope, progress, results and costs of development for our product candidates; and

the extent to which we acquire or invest in new products, businesses and technologies.

Our principal sources of liquidity are cash and cash equivalents of \$22.6 million as of December 31, 2012. As of December 31, 2012, we had working capital of \$19.8 million. During 2012, we used \$20.6 million of cash for operating activities and \$0.5 million for investing activities, which were partially funded from \$20.6 million of net cash provided by financing activities (primarily from the \$26.3 million of net proceeds from the October 2012 Financing).

We believe that our existing cash and cash equivalents will be sufficient to fund our operations and debt service obligations into the fourth quarter of 2013. However, changing circumstances may cause us to consume capital faster than we currently anticipate, and we may need to spend more money than currently expected because of such circumstances. The additional capital that we will require to launch Zecuity and fund our operations and debt service obligations beyond the fourth quarter of 2013 will depend largely upon the timing, scope, terms and structure of any commercial partnership that we are able to enter into for Zecuity because we intend to build our commercial infrastructure to complement that of our partner. However, there can be no assurance that we will be able to secure a commercial partner on acceptable terms or otherwise.

To meet our capital needs, we intend to raise additional capital through corporate collaborations, partnerships or other strategic transactions, debt or equity financings or other funding opportunities. There can be no assurance that we will be able to complete any such transaction on acceptable terms





Table of Contents

or otherwise. Furthermore, the covenants and the pledge of our assets as collateral under the 2012 Term Loan limit our ability to obtain additional debt financing. Until such time as we are able to secure the necessary capital, we intend to limit and delay certain expenditures required for commercialization of Zecuity.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, will result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, which are not favorable to us or our stockholders. If we raise additional funds through corporate collaboration, partnership or other strategic transactions, it may be necessary to relinquish valuable rights to Zecuity, our product candidates, our technologies or future revenue streams or to grant licenses or sell assets on terms that may not be favorable to us.

If we are unable to raise the necessary capital on terms acceptable to us, as and when needed, we will be required to delay the launch of Zecuity and to curtail and reduce our operations and costs and modify our business strategy, and we may be unable to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the year ended December 31, 2012 related to our ability to continue as a going concern.

We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence.

*Aspire Capital Purchase Agreement*

In August 2011, we entered into a common stock purchase agreement (Purchase Agreement) with Aspire Capital Fund, LLC (Aspire Capital), which provides that Aspire Capital is committed to purchase up to an aggregate of \$30.0 million of our common stock over the term of the Purchase Agreement. Upon execution of the Purchase Agreement, we issued 84,866 shares of common stock to Aspire Capital as a commitment fee in consideration for entering into the Purchase Agreement (the Commitment Shares) and we sold 70,721 shares of common stock to Aspire Capital at a per share purchase price of \$7.07 resulting in gross proceeds to us of \$0.5 million (the Initial Purchase Shares).

We have registered under the Securities Act of 1933 Aspire Capital's sale of the Commitment Shares, the Initial Purchase Shares, and 2,746,147 additional shares that we may elect to sell to Aspire Capital under the Purchase Agreement. As a result, on any trading day on which the closing sale price of common stock is not less than \$4.00 per share, we may direct Aspire Capital to purchase shares of Company common stock at a known per share purchase price based on prevailing market prices, using a formula as set forth in the Purchase Agreement (a Regular Purchase). The maximum number of shares that we may direct Aspire to purchase on any trading day pursuant to a Regular Purchase is 100,000 shares or such lesser number of shares that results in an aggregate purchase price of not greater than \$0.5 million.

In addition, on any trading day on which we direct Aspire Capital to make a Regular Purchase for the maximum number of shares set forth above, we may also direct Aspire Capital to purchase a number of shares of common stock equal to up to 30% of the aggregate shares of our common stock traded on the NASDAQ Global Market on the next trading day (a VWAP Purchase), subject to a maximum number of shares as we may determine and a minimum trading price, which is equal to the greater of (a) 90% of the closing price of our common stock on the business day immediately

Table of Contents

preceding the VWAP Purchase Date or (b) such higher price as we may set in the VWAP Purchase Notice. The per share purchase price of common stock sold to Aspire Capital pursuant to a VWAP Purchase is equal to 95% of the volume weighted average price for such purchase date.

There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any stock sales to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

Other than the Commitment Shares and Initial Purchase Shares as referenced above, we have not made any sales to Aspire Capital during the years ended December 31, 2012 and December 31, 2011. The extent to which we may utilize the Purchase Agreement as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, the volume of trading in our common stock and the extent to which we are able to secure funds from other sources. The Purchase Agreement expires in August 2013.

**Key Components of Our Statement of Operations**

***Research and Development Expenses***

Our research and development expenses consist of expenses incurred in developing, testing and seeking marketing approval of our product candidates, including:

Expenses associated with regulatory submissions, preclinical development, clinical trials and manufacturing;

Personnel related expenses, such as salaries, benefits, travel and other related expenses, including stock-based compensation;

Payments made to third party investigators who perform research and development on our behalf;

Payments to third party contract research organizations, laboratories and independent contractors;

Expenses incurred to obtain technology licenses if the technology licensed has not reached technological feasibility and has no alternative future use; and

Facility, maintenance and other related expenses.

We expense all research and development costs as incurred. Preclinical development expenses and clinical trial expenses for our product candidates are a significant component of our current research and development expenses. We track and record information regarding external research and development expenses for each study or trial that we conduct. From time to time, we use third party contract research organizations, laboratories and independent contractors in preclinical studies. We recognize the expenses associated with third parties performing these services for us in our preclinical studies based on the percentage of each study completed at the end of each reporting period. We coordinate clinical trials through a number of contracted investigational sites and recognize the associated expense based on a number of factors, including actual and estimated subject enrollment and visits, direct pass-through costs and other clinical site fees.

From our inception in January 2005 through December 31, 2012, we incurred research and development expenses of \$76.9 million, of which \$53.1 million was for the development of Zecuity (inclusive of \$5.5 million of acquired in-process research and development expense in connection with

Table of Contents

the patent application utilized by Zecuity), \$3.4 million was for the development of NP201 and \$0.9 million was for to the development of NP202. The remaining research and development expenses are for amounts incurred that we do not allocate to specific programs, such as personnel related expenses, including salaries and benefits, as well as general fixed costs for our facility and related expenses.

We will continue to incur research and development expenses in 2013 related to Zecuity. As a condition to FDA approval of Zecuity, we agreed to conduct the following post-marketing clinical and non-clinical studies:

| <b>Study Description</b>  | <b>Expected Start Date</b> | <b>Required Completion Date</b> |
|---|----------------------------|---------------------------------|
| Phase I: Open label, single-dose safety, PK and tolerability study of Zecuity in pediatric migraine patients (12 - 17 years)                    | August 2013                | July 2014                       |
| Phase III: Efficacy and tolerability of Zecuity in the treatment of acute migraine in adolescents: randomized, double-blind, placebo controlled | September 2014             | December 2015                   |
| Phase III: 12 month safety study in the treatment of acute migraine in adolescents: Open label  | September 2014             | December 2016                   |
| Non-clinical: 7 day dermal painting study (mice) using various penetration enhancers  | May 2013                   | November 2013                   |
| Non-clinical: A dermal carcinogenicity study of sumatriptan succinate in mice   | May 2014                   | December 2016                   |

As we are actively seeking development partnerships for NP201 and NP202 in the U.S. and territories throughout the world, we do not currently anticipate incurring significant research and development expenses in 2013 for the development of NP201 or NP202.

The amount of research and development expenses that we will incur in 2013 will depend largely upon the timing, scope, terms and structure of any commercial partnership that we are able to enter into for Zecuity because we intend to build our medical affairs and regulatory and quality affairs infrastructure to complement that of our partner. However, there can be no assurance that we will be able to secure a commercial partner on acceptable terms or otherwise. In the event we do not obtain a commercial partner and subject to obtaining additional capital, we expect research and development expenses to be greater in 2013 than 2012.

***Selling, General and Administrative Expenses***

Our selling, general and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for personnel serving in our executive, finance, accounting, legal, marketing, market research and human resource functions. Our selling, general and administrative expenses also include facility and related costs not included in research and development expenses, professional fees for legal, including patent-related expenses, expenses related to market research and commercialization preparation activities, consulting, tax and accounting services, insurance, depreciation and general corporate expenses.

We expect to incur significant selling, general and administrative expenses in 2013 as we prepare for, and commercialize, Zecuity in the U.S. Our selling, general and administrative expenses in 2013 will depend largely upon the timing, scope, terms and structure of any commercial partnership that we are able to enter into for Zecuity because we intend to build our commercial infrastructure to complement that of our partner. However, there can be no assurance that we will be able to secure a commercial partner on acceptable terms or otherwise. In the event we do not obtain a commercial

Table of Contents

partner and subject to obtaining additional capital, we expect selling, general and administrative expenses to be substantially greater in 2013 than 2012.

***Interest Income and Interest Expense***

Our interest income consists of interest earned on our cash and cash equivalents. Our interest expense consists primarily of cash and non-cash interest costs related to our outstanding debt. Additionally, in connection with some of our debt financings, we issued warrants, the fair value of which we recorded as deferred financing costs or debt discount. We amortize these deferred financing costs and debt discounts over the lives of the loans as interest expense in our statement of operations. Any warrants that we issued that were liability classified, in accordance with accounting principles generally accepted in the U.S (GAAP), were marked-to-market on a quarterly basis and any change in fair value was recorded as interest expense in our statement of operations.

***Change in fair value of warrants***

In October 2012, we issued warrants that include a provision for "price protection" anti-dilution, and, as a result, were liability classified at the grant date. The warrants will be revalued at each balance sheet date using a Monte-Carlo simulation analysis to determine the fair value. These warrants were marked to market at December 31, 2012 and the change in fair value is recorded in Change in fair value of warrants on the accompanying statement of operations.

***Net Operating Losses and Tax Loss Carryforwards***

Our net loss was \$24.5 million and \$23.2 million for the years ended December 31, 2012 and 2011, respectively. We have incurred cumulative net losses of \$121.1 million from inception through December 31, 2012. As of December 31, 2012, we had approximately \$108.4 million of federal net operating loss carryforwards and state research and development credits available to offset future taxable income. These federal and state net operating loss carryforwards will begin to expire in 2025. Due to the uncertainty of our ability to realize the benefit of any net operating loss carryforwards and credits, the deferred tax asset related to these carryforwards has been fully offset by a valuation allowance at December 31, 2012.

Our IPO, together with private placements and other equity financing transactions that have occurred since our inception, may trigger, or may have already triggered, an "ownership change" pursuant to Section 382 of the Internal Revenue Code. If an ownership change is triggered, it will limit our ability to use some of our net operating loss carryforwards. In addition, since we will need to raise substantial additional funding to finance our operations, we may undergo further ownership changes in the future, which could further limit our ability to use net operating loss carryforwards. As a result, if we generate taxable income, our ability to use some of our net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations.

**Critical Accounting Policies and Use of Estimates**

This "Management's Discussion and Analysis of Our Financial Condition and Results of Operations" discusses our financial statements, which have been prepared in accordance with GAAP and are included in this Form 10-K. The preparation of these financial statements in accordance with GAAP requires us to make estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to clinical trial expenses and stock-based compensation. We base our estimates on historical experience and on various other factors that we believe to be appropriate under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

Table of Contents

While our significant accounting policies are more fully discussed in note 3 to our financial statements, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements. We have reviewed these critical accounting policies and estimates with the audit committee of our board of directors.

***Research and Development Expenses***

Although we manage the conduct of our own clinical trials, we rely on third parties to conduct our preclinical and clinical studies and to provide services, including data management, statistical analysis and electronic compilation for our clinical trials, as well as for the manufacture of our clinical trial supplies. At the end of each reporting period, we compare the payments made to each service provider to the estimated progress towards completion of the related project. Factors that we consider in preparing these estimates include the number of subjects enrolled in studies, milestones achieved and other criteria related to the efforts of our vendors. These estimates are subject to change as additional information becomes available. Depending on the timing of payments to vendors and estimated services provided, we record net prepaid or accrued expenses related to these costs. We calculate expenses incurred for the manufacture of our clinical supplies using our estimate of costs and capitalize these expenses on our balance sheet to the extent we hold clinical supply materials on hand to be distributed for use in our clinical trials. We expense these costs as the supplies are consumed in the trials.

***Stock-Based Compensation***

We use the Black-Scholes option-pricing model to value our stock option awards. The Black-Scholes option-pricing model requires the input of subjective assumptions, including the expected life of stock options, stock price volatility and the risk-free interest rate. The risk-free interest rate is based on U.S. Treasury instruments with a remaining term equal to the expected term of the option. As a newly public company, we do not have sufficient history to estimate the expected life of our options or the volatility of our common stock price. We use comparable public companies as a basis for our expected volatility to calculate the fair value of our option grants. We intend to continue to consistently apply this process using comparable companies until a sufficient amount of historical information regarding the volatility of our own share price becomes available. We use the "simplified method," as allowed under the Securities and Exchange Commission's (SEC) accounting guidance, to determine the expected life, which is the midpoint between an option's vesting date and contractual term. The assumptions used in calculating the fair value of stock options represent our best estimate and involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use different assumptions, stock-based compensation could be materially different in the future. Prior to our IPO, the fair value of our common stock underlying grants of common stock options and restricted stock was determined by our board of directors or compensation committee.

**Impact of Recent Accounting Pronouncements**

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income (ASU 2011-05). The issuance of ASU 2011-05 is intended to improve the comparability, consistency and transparency of financial reporting and to increase the prominence of items reported in other comprehensive income. The guidance in ASU 2011-05 supersedes the presentation options in ASC Topic 220 and facilitates convergence of U.S. GAAP and IFRS by eliminating the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity and requiring that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 was effective for interim periods and years beginning after December 15,

Table of Contents

2011. The adoption of ASU 2011-05 did not have an impact on the Company's financial statements as the Company has no items of other comprehensive income.

**Results of Operations*****Comparison of Years Ended December 31, 2012 and 2011****Revenue*

The Company had no revenues during the years ended December 31, 2012 and December 31, 2011.

*Research and development expenses*

Research and development expenses for the years ended December 31, 2012 and 2011 were comprised of the following:

|                                  | Year Ended<br>December 31, |           | Increase<br>(Decrease) |       |
|----------------------------------|----------------------------|-----------|------------------------|-------|
|                                  | 2012                       | 2011      | \$                     | %     |
|                                  | (In thousands)             |           |                        |       |
| Clinical development             | \$ 1,271                   | \$ 2,852  | \$ (1,581)             | (55)% |
| Manufacturing (CMC)              | 4,353                      | 5,929     | (1,576)                | (27)  |
| Regulatory and quality assurance | 289                        | (1,266)   | 1,555                  | 123   |
| Medical affairs                  | 141                        | 653       | (512)                  | (78)  |
| Compensation and related         | 3,696                      | 3,753     | (57)                   | (2)   |
| Facilities and related           | 399                        | 486       | (87)                   | (18)  |
|                                  | \$ 10,149                  | \$ 12,407 | \$ (2,258)             | (18)% |

Research and development expenses decreased by \$2.3 million, or 18%, to \$10.1 million in 2012 from \$12.4 million in 2011. The regulatory and quality assurance expense in 2011 includes a \$1.5 million reduction related to a waiver of the NDA filing fee that we had paid to the FDA in the fourth quarter of 2010. At the time of payment, we expensed the full \$1.5 million for the filing fee. In March 2011, we received notice from the FDA that we qualified for a one-time waiver and we would be receiving a refund of the \$1.5 million filing fee, which we received in June 2011. As a result, in March 2011, we reversed the previously expensed amount of \$1.5 million which is classified as regulatory expense in the table above. Exclusive of this one-time expense and subsequent reversal, research and development expenses would have been \$10.1 million and \$13.9 million for the years ended December 31, 2012 and 2011, respectively, a decrease of \$3.8 million in 2012.

*Clinical development*

Nearly half of the overall decrease in research and development expenses is attributable to clinical development. During the year ended December 31, 2012, clinical development expenses decreased by \$1.6 million. This decrease is primarily the result of higher levels of development work in 2011 as NuPathe focused on the Zecuity NDA resubmission including:

\$0.7 million incurred during the 2011 period for the conclusion of a Zecuity open-label study, as well as \$0.4 million for the execution of a bioequivalence study during 2011; and

\$0.4 million incurred during the 2011 period for pre-clinical development work related to NP201 and NP202 which did not recur during the 2012 period.

Table of Contents*Manufacturing (CMC)*

During the year ended December 31, 2012, manufacturing expenses decreased by \$1.6 million. This decrease is primarily comprised of:

The 2011 period included \$1.4 million for the purchase of materials and components for the manufacture of Zecuity supplies, compared to \$0.6 million incurred during the 2012 period. The higher amounts incurred in 2011 were driven by the anticipated approval of our NDA;

The 2011 period included an incremental \$0.5 million of expense with our primary Zecuity manufacturer related to manufacturing scale up and production of clinical supplies; and

As a result of focused efforts on Zecuity during the 2012 period, we did not incur any CMC-related expenses for NP201 or NP202, whereas in the year ended December 31, 2011 we incurred a total of \$0.04 million for CMC on these two projects.

*Regulatory and quality assurance*

Exclusive of the \$1.5 million refund in 2011 discussed above, regulatory and quality assurance expenses increased by \$0.05 million in 2012. This increase results from expenses incurred for the July 2012 resubmission of the Zecuity NDA.

*Medical affairs*

Expenses for medical affairs decreased by \$0.5 million in 2012 as we focused our resources on the resubmission of the Zecuity NDA.

*Compensation and related*

Compensation and related expenses are personnel related expenses, including salaries and benefits, which we do not allocate to specific programs. Expenses for the year ended December 31, 2012 were \$0.06 million less than the same period in 2011. Slightly higher salaries and bonus expense in 2012 were offset by \$0.2 million for higher recruiting expense in 2011.

Research and development expenses by program for the years ended December 31, 2012 and 2011 are presented below:

|                     | Year Ended<br>December 31, |           | Increase<br>(Decrease) |       |
|---------------------|----------------------------|-----------|------------------------|-------|
|                     | 2012                       | 2011      | \$                     | %     |
|                     | (In thousands)             |           |                        |       |
| Zecuity             | \$ 5,914                   | \$ 7,144  | \$ (1,230)             | (17)% |
| NP201               | 4                          | 551       | (547)                  | (99)  |
| NP202               | 136                        | 474       | (338)                  | (71)  |
| General development | 4,095                      | 4,238     | (143)                  | (3)   |
|                     | \$ 10,149                  | \$ 12,407 | \$ (2,258)             | (18)% |

Exclusive of the \$1.5 million refund received in 2011 for the NDA filing fee discussed above, Zecuity expenses in 2012 were \$5.9 million compared to \$8.6 million in 2011. The \$2.7 million decrease in Zecuity spending in 2012 results primarily from decreases in clinical development and CMC expenses, as discussed more fully above. Decreased spending on NP201 in 2012 was primarily the result of our decision to focus our resources on the continued development of Zecuity, and therefore we delayed significant manufacturing and clinical development for NP201 during 2012. Modest expenditures on the nonclinical development of NP202 continued throughout 2012. Personnel related



Table of Contents

expenses, including salaries and benefits, are included in the table above as general development expenses as we do not allocate these expenses to specific programs.

*Selling, general and administrative expenses*

Selling, general and administrative expenses increased by \$1.5 million, or 16%, to \$10.9 million in 2012 from \$9.4 million in 2011. This increase is primarily the result of \$1 million of non-cash stock compensation expense related to the vesting of equity-based awards which were granted to the Company's new chief executive officer and \$1.3 million of aggregate expense in connection with the resignation of the Company's former chief executive officer in July 2012 for accrued separation payments, consulting fees and non-cash stock compensation expense related to the modification of such former officer's previously awarded equity-based awards.

Additional selling, general and administrative expenses that were higher during the year ended December 31, 2012 compared to the year ended December 31, 2011 include legal expenses, which increased \$0.2 million related to intellectual property and patent expenses, and insurance expense, which increased by \$0.25 million due to the full year impact of higher directors and officers insurance premiums. Partially offsetting these 2012 increases is \$1.6 million of higher expenses in 2011 related to the growth of our commercial operations as we were preparing for the anticipated launch of Zecuity. This included the full year impact of personnel costs as well as market research and consulting fees. These commercial operations expenses were reduced during 2012 as we focused our resources on the resubmission of our NDA for Zecuity.

*Interest expense*

Interest expense increased by \$0.09 million, or 7%, to \$1.6 million in 2012 from \$1.5 million in 2011. The 2012 increase is due to \$0.09 million paid in connection with an August 2012 modification to our Term Loan Facility, as well \$0.02 million of non-cash capitalized interest recorded in 2012 on construction of in-process equipment. These 2012 increases were partially offset by lower overall interest expense on our outstanding debt during 2012.

*Income tax benefit*

We recognized an income tax benefit of \$0.1 million in 2012 and \$0.05 million in 2011 related to the sale of Pennsylvania research and development tax credits to third party buyers.

*Loss on debt extinguishment*

In November 2012, we obtained an \$8.5 million term loan from a new lender (2012 Term Loan). A portion of the proceeds from the 2012 Term Loan were used to pay off our existing term loans under our Term Loan Facility with different lenders. In connection with the pay-off of our existing term loans and the termination of our Term Loan Facility, we wrote off the balance of unamortized deferred debt issuance costs related to that debt. The pay-off of the term loans also accelerated the payment of a contractual final interest payment due under the terms of our Term Loan Facility. The amount by which our reacquisition price of the debt exceeded the carrying amount of the existing debt was \$0.8 million and was recorded as a loss on debt extinguishment.

*Change in fair value of warrants*

In October 2012, in connection with our financing as well as in connection with a loan modification with our then lenders, the Company issued warrants to purchase a total of 14,188,426 shares of common stock. The exercise price of the warrants was subject to full ratchet anti-dilution price protection until the conversion of all shares of Series A Preferred Stock in the first quarter of 2013. These warrants were measured at fair value and liability-classified on the date of issuance. As the

Table of Contents

warrants are liability-classified, they are re-measured on the Company's reporting dates with changes in the carrying value reflected in current results of operations. This change in fair value of warrants from the date of issuance to December 31, 2012 was \$1.3 million and has been included in our statement of operations.

**Comparison of Years Ended December 31, 2011 and 2010***Revenue*

During the year ended December 31, 2010, the Company was awarded \$650,000 of Qualifying Therapeutic Discovery Project (QTDP) grants under section 48D of the U.S. Internal Revenue Code in connection with costs incurred during 2009 and 2010 for the Company's Zecuity, NP201 and NP202 development programs. Under the award guidelines, QTDP's had to show a reasonable potential to result in new therapies to treat areas of unmet medical need or prevent, detect or treat chronic or acute diseases and conditions, reduce the long-term growth of health care costs in the United States, or significantly advance the goal of curing cancer within 30 years. The Company had no revenues during the year ended December 31, 2011.

*Research and development expenses*

Research and development expenses for the years ended December 31, 2011 and 2010 were comprised of the following:

|                                  | Year Ended<br>December 31, |           | Increase<br>(Decrease) |       |
|----------------------------------|----------------------------|-----------|------------------------|-------|
|                                  | 2011                       | 2010      | \$                     | %     |
|                                  | (In thousands)             |           |                        |       |
| Clinical development             | \$ 2,852                   | \$ 5,813  | \$ (2,961)             | (51)% |
| Manufacturing (CMC)              | 5,929                      | 4,965     | 964                    | 19    |
| Regulatory and quality assurance | (1,266)                    | 2,571     | (3,837)                | (149) |
| Medical affairs                  | 653                        |           | 653                    | n/a   |
| Compensation and related         | 3,753                      | 3,019     | 734                    | 24    |
| Facilities and related           | 486                        | 696       | (210)                  | (31)  |
|                                  | \$ 12,407                  | \$ 17,064 | \$ (4,657)             | (27)  |

Research and development expenses decreased by \$4.7 million, or 27%, to \$12.4 million in 2011 from \$17.1 million in 2010. A significant reason for the 2011 decrease was a \$1.5 million reduction related to a waiver of the NDA filing fee that we had paid to the FDA in the fourth quarter of 2010. At the time of payment, we expensed the full \$1.5 million for the filing fee. In March 2011, we received notice from the FDA that we qualified for a one-time waiver and we would be receiving a refund of the \$1.5 million filing fee, which we received in June 2011. As a result, in March 2011, we reversed the previously expensed amount of \$1.5 million which is classified as regulatory expense in the table above. Exclusive of this one-time expense and subsequent reversal, research and development expenses would have been \$13.9 million and \$15.6 million for the years ended December 31, 2011 and 2010, respectively, a decrease of \$1.7 million in 2011.

*Clinical development*

Clinical development expenses were \$3.0 million less during 2011 as a result of a significant spending during 2010 for a 12-month, repeat use trial for Zecuity initiated in the third quarter of 2009, as well as two pharmacokinetic trials and a tolerability trial initiated in early 2010, most of which had concluded by the beginning of 2011. These higher clinical development expenses in 2010 were partially

## Edgar Filing: NUPATHE INC. - Form 10-K

### Table of Contents

offset by the initiation, during the second half of 2011, of a Phase I bioequivalence trial for Zecuity in response to the FDA's CRL.

#### *Manufacturing (CMC)*

Manufacturing expense increased to \$5.9 million during 2011 from \$5.0 million during 2010. This increase was due primarily to manufacturing scale up expenses for Zecuity as well as expenses incurred in the fourth quarter of 2011 in order to address some of the chemistry and manufacturing questions included within the FDA's CRL. Partially offsetting the higher Zecuity manufacturing expenses in 2011 was a reduction of \$0.5 million related to the manufacturing development of NP201. The NP201 manufacturing development expenses were reduced in 2011 as we focused our resources on the continued development of Zecuity.

#### *Regulatory and quality assurance*

Exclusive of the NDA filing fee and subsequent refund discussed above, regulatory expenses would have been \$234,000 and \$1.1 million during 2011 and 2010, respectively, a decrease of \$0.8 million in 2011. This decrease was due primarily to the fact that 2010 included extensive consulting costs related to the filing of an electronic NDA for Zecuity in 2011.

#### *Medical affairs*

The \$0.7 million of 2011 expense for medical affairs resulted from the expansion of our medical affairs function during 2011, which was not initiated until very late in 2010.

#### *Compensation and related*

The \$0.7 million increase during 2011 for compensation and related expenses was driven by incremental research and development headcount, annual salary increases for research and development personnel, and increased non-cash stock compensation expense.

Research and development expenses by program for the years ended December 31, 2011 and 2010 are presented below:

|                     | <b>Year Ended<br/>December 31,</b> |                  | <b>Increase<br/>(Decrease)</b> |             |
|---------------------|------------------------------------|------------------|--------------------------------|-------------|
|                     | <b>2011</b>                        | <b>2010</b>      | <b>\$</b>                      | <b>%</b>    |
|                     | <b>(In thousands)</b>              |                  |                                |             |
| Zecuity             | \$ 7,144                           | \$ 12,225        | \$ (5,081)                     | (42)%       |
| NP201               | 551                                | 1,096            | (545)                          | (50)        |
| NP202               | 474                                | 274              | 200                            | 73          |
| General development | 4,238                              | 3,469            | 769                            | 22          |
|                     | <b>\$ 12,407</b>                   | <b>\$ 17,064</b> | <b>\$ (4,657)</b>              | <b>(27)</b> |

As discussed above, the decrease in spending on Zecuity in 2011 includes the \$1.5 million NDA filing fee credit that we received in the first quarter of 2011, which was reflected as \$1.5 million of expense during the 2010 period, therefore resulting in a \$3.0 million difference when comparing 2011 to 2010. Further contributing to the lower 2011 expense for Zecuity was the lower clinical development expenses in 2011 as a result of a significant spending during 2010 for a 12-month, repeat use trial as well as two pharmacokinetic trials and a tolerability trial initiated in early 2010, most of which had concluded by the beginning of 2011. Partially offsetting these decreases to Zecuity clinical expense was the increased Zecuity manufacturing development expenses incurred, as well as the initiation of medical affairs expenses, as discussed above. Decreased spending on NP201 in 2011 was primarily the result of our decision to focus our resources on the continued development of Zecuity, and therefore we delayed

Table of Contents

significant manufacturing development for NP201 during 2011. Modest expenditures on the nonclinical development of NP202 continued throughout 2011. Personnel related expenses, including salaries and benefits, are included in the table above as general development expenses as we do not allocate these expenses to specific programs.

*Selling, general and administrative expenses*

Selling, general and administrative expenses increased by \$4.6 million, or 96%, to \$9.4 million in 2011 from \$4.8 million in 2010. This increase resulted partially from greater expenses related to the full-year impact of being a public company, such as higher personnel costs due to additional employees, salary increases, higher stock-based compensation expense and higher increased financial reporting expense and board of director's fees. Also contributing to the higher 2011 expenses was an additional \$2.2 million of expenses related to the growth of our commercial operations as we continued to prepare for the anticipated launch of Zecuity, including higher personnel costs and market research and consulting fees.

*Interest expense*

Interest expense decreased by \$2.2 million, or 59%, to \$1.5 million in 2011 from \$3.7 million in 2010. The 2011 expense included amounts incurred under our Term Loan Facility (Term A and Term B Loans) as well as non-cash interest expense for the amortization of the deferred financing costs and amortization of the fair value of the warrants issued under these loans. The 2010 expense included \$2.6 million of non-cash interest expense incurred during 2010 that was related to the amortization of the beneficial conversion feature (BCF) of secured subordinated promissory notes that we issued and sold to investors in April 2010 (April 2010 Convertible Notes), plus an additional \$0.3 million of non-cash interest accrued on these notes prior to their conversion, and an additional \$0.3 million of non-cash interest expense for the increase in fair value of our warrant liability that occurred during 2010 before the warrants were reclassified to stockholders' equity upon the completion of our IPO. Also included in the 2010 interest expense was \$0.2 million of non-cash amortization of deferred debt issuance costs and \$0.4 million of cash-paid interest on our outstanding debt.

*Income tax benefit*

We recognized an income tax benefit of \$0.05 million in 2011 and \$0.5 million in 2010 related to the sale of Pennsylvania research and development tax credits to third party buyers.

**Cash Flows**

Net cash used in operating activities in 2012 was \$20.6 million, largely the result of focused spending on the resubmission of the Zecuity NDA. During the year ended December 31, 2012, we used \$0.5 million of cash in investing activities. Cash provided by financing activities was \$20.6 million, primarily from the \$26.3 million of net proceeds from the October 2012 Financing and the \$8.5 million 2012 Term Loan, partially offset by the early pay off of our Term Loan Facility.

Net cash used in operating activities in 2011 was \$20.9 million, primarily the result of spending on our continued clinical development, manufacture and scale-up efforts for Zecuity, as well as costs incurred for the preparation of our response to the FDA's complete response letter, which was received in August 2011. During the year ended December 31, 2011, we used \$3.5 million of cash in investing activities, almost entirely for payments related to the purchase of commercial manufacturing equipment for NP101. Cash provided by financing activities was \$8.6 million, primarily from the \$10.0 million of proceeds received from Term B Loans under our Term Loan Facility, and \$0.4 million in net proceeds from the sale of common stock to Aspire Capital. These cash inflows from financings were offset by \$1.7 million of contractual debt repayments during 2011.

Table of Contents**Contractual Obligations**

The following table summarizes our contractual obligations as of December 31, 2012:

| Contractual Obligations(1)  | Total     | Payments Due by Period |                  |                  |                        |  |
|-----------------------------|-----------|------------------------|------------------|------------------|------------------------|--|
|                             |           | 2013                   | 2014 and<br>2015 | 2016 and<br>2017 | 2018 and<br>Thereafter |  |
|                             |           |                        |                  |                  |                        |  |
|                             |           |                        | (In thousands)   |                  |                        |  |
| Debt obligations(2)         | \$ 8,688  | \$ 439                 | \$ 6,668         | \$ 1,581         | \$                     |  |
| Interest payments on debt   | 2,219     | 850                    | 1,031            | 338              |                        |  |
| License maintenance fees(3) | 350       | 50                     | 100              | 100              | 100                    |  |
| Operating lease obligations | 169       | 156                    | 13               |                  |                        |  |
| Development expenditures(4) | 1,750     | 250                    | 500              | 500              | 500                    |  |
|                             | \$ 13,176 | \$ 1,745               | \$ 8,312         | 2,519            | \$ 600                 |  |

- (1) This table does not include any contingent milestone or royalty payments that may become payable to third parties under license agreements because the timing and likelihood of such payments are not known.
- (2) Represents \$8,500 owed under the 2012 Term Loan, as well as \$188 owed under vendor debt agreements. The 2012 Term Loan contains customary events of default including, among others, upon the occurrence of a payment default, a covenant default, a material adverse change or insolvency. Upon the occurrence of an event of default, the interest rate will be increased by 3% over the rate that would otherwise be applicable. In addition, the occurrence of an event of default could result in the acceleration of the Company's obligations under the 2012 Term Loan as well as grant the lender the right to exercise remedies with respect to the collateral.
- (3) Under an agreement with the University of Pennsylvania (Penn), we are required to pay annual license maintenance fees of up to \$50,000 until the first commercial sale of the first licensed product covered by the agreement. The agreement currently covers NP201 and NP202. Because we cannot currently estimate when the first sale of a licensed product will occur, the table reflects payments only through 2018.
- (4) Under the agreement with Penn discussed in footnote 3 to this table, we are required to expend an aggregate of at least \$250,000 annually toward the development and commercialization of NP201 and NP202, until the first commercial sale of the first licensed product under the agreement. Because we cannot currently estimate when the first sale of a licensed product will occur, the table reflects payments only through 2018.

In addition to the contractual commitments reflected in the table above, we have agreed to pay Penn aggregate milestone payments of up to \$950,000, per licensed product, upon the achievement of specified development and regulatory milestones related to each licensed product that contains ropinirole and other specified active ingredients, including the active ingredients in NP201 and NP202, and royalties in the low single digits on worldwide net sales of such licensed products. We and Penn have agreed to negotiate the milestone payments and royalties payable for each licensed product that contains an active ingredient other than those currently specified in the agreement. We are unable to determine the timing of the achievement of these milestones or whether and when we will commercialize and generate any sales for a licensed product.

We have also entered into a license agreement with Evonik Industries (Evonik) (as successor to SurModics Pharmaceuticals) under which we have agreed to pay Evonik milestone payments of up to an aggregate amount of \$4.75 million upon the achievement of specified development, regulatory and sales level milestones related to the first clinical indication approved by a regulatory authority for NP201. We must also pay an additional single milestone payment upon regulatory approval of each

Table of Contents

additional clinical indication for NP201 and royalties in the low single digits on worldwide net sales of commercial product. We are unable to determine the timing of the achievement of these milestones or whether and when we will commercialize and generate any sales for a licensed product.

**Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not have as of the filing of this 10-K with the SEC, any off-balance sheet arrangements as defined in Item 3(a)(4) of the SEC's Regulation S-K.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our exposure to market risk is confined to our cash and cash equivalents. As of December 31, 2012, we had cash and cash equivalents of \$22.6 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash and cash equivalents, we do not believe that reasonably possible near-term fluctuations in market rates would have any significant impact on the realized value of our investments, but may increase the interest expense associated with our debt.

We have no operations outside the U.S., however, we have an agreement with LTS, a manufacturer in Germany that provides services to us related to the production and assembly of Zecuity. Our payment obligations under this agreement are denominated in Euros. Under this agreement, we paid \$1.6 million in 2010, \$2.3 million in 2011 and \$1.8 million in 2012 to LTS. Additionally, in the first quarter of 2013, we entered into additional agreements with LTS related to additional investment in commercial manufacturing capacity. These agreements are denominated in Euros and approximate \$0.8 million of expenses expected to be incurred throughout 2013, based on exchange rates in effect at March 1, 2013. Because of our agreements with LTS, we are subject to fluctuations in the exchange rate between the U.S. dollar and the Euro. We do not engage in any hedging activities against changes in the exchange rate between the U.S. dollar and the euro because we believe reasonably possible near-term fluctuations of such exchange rate would not materially affect our results of operations, financial position or cash flows. We are currently in the process of transferring these manufacturing activities to one of LTS's U.S. subsidiaries and anticipate that our commercial manufacturing activities will be located in the U.S., thereby substantially reducing our exposure to fluctuations in the relative values of the U.S. dollar and the Euro.

Table of Contents

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**INDEX TO FINANCIAL STATEMENTS**

**NUPATHE INC.  
(A Development-Stage Company)**

|  | <b>Page</b> |
|--|-------------|
| <u>Report of Independent Registered Public Accounting Firm</u>                                 | <u>71</u>   |
| <u>Balance Sheets</u>  | <u>72</u>   |
| <u>Statements of Operations</u>  | <u>73</u>   |
| <u>Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)</u> | <u>74</u>   |
| <u>Statements of Cash Flows</u>  | <u>76</u>   |
| <u>Notes to Financial Statements</u>   | <u>77</u>   |

Table of Contents

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders  
NuPathe Inc.:

We have audited the accompanying balance sheets of NuPathe Inc. (a development-stage company) (the Company) as of December 31, 2012 and 2011, and the related statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2012 and the period from January 7, 2005 (inception) through December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of NuPathe Inc. as of December 31, 2012 and 2011, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2012 and for the period from January 7, 2005 (inception) through December 31, 2012, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in note 2 to the financial statements, the Company has incurred recurring losses and negative cash flows from operations since its inception that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Philadelphia, Pennsylvania  
March 27, 2013



Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Balance Sheets**

(in thousands, except share and per share data)

|  | December 31, |           |
|--|--------------|-----------|
|  | 2012         | 2011      |
| <b>ASSETS</b>  |              |           |
| Current assets:  |              |           |
| Cash and cash equivalents  | \$ 22,570    | \$ 23,059 |
| Prepaid expenses and other   | 450          | 333       |
| Total current assets   | 23,020       | 23,392    |
| Property and equipment, net  | 581          | 213       |
| Other assets   | 243          | 481       |
| Other assets-equipment funding (note 9(c))   | 6,763        | 6,763     |
| Total assets   | \$ 30,607    | \$ 30,849 |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>  |              |           |
| Current liabilities:   |              |           |
| Current portion of long-term debt  | \$ 378       | \$ 8,412  |
| Accounts payable   | 800          | 1,967     |
| Accrued expenses   | 1,995        | 2,018     |
| Total current liabilities  | 3,173        | 12,397    |
| Other long-term liabilities  | 83           |           |
| Long-term debt   | 8,102        | 5,481     |
| Warrant liability  | 16,236       |           |
| Total liabilities  | 27,594       | 17,878    |
| Commitments (note 9)   |              |           |
| Stockholders' equity:  |              |           |
| Preferred stock, \$0.001 par value; authorized 10,000,000 shares; issued and outstanding 8,804 and 0 at December 31, 2012 and December 31, 2011, respectively (liquidation value of \$17,608 at December 31, 2012) | 7,255        |           |
| Common stock, \$0.001 par value; authorized 90,000,000 shares; issued and outstanding 20,023,949 and 14,748,582 shares at December 31, 2012 and December 31, 2011, respectively                                    | 20           | 15        |
| Additional paid-in capital   | 136,506      | 115,940   |
| Deficit accumulated during the development stage   | (140,768)    | (102,984) |
| Total stockholders' equity   | 3,013        | 12,971    |
| Total liabilities and stockholders' equity   | \$ 30,607    | \$ 30,849 |

See accompanying notes to financial statements.

Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Statements of Operations**

(in thousands, except share and per share data)

|  | Year Ended December 31, |             |             | Period from   |
|--|-------------------------|-------------|-------------|---|
|  | 2012                    | 2011        | 2010        | January 7, 2005<br>(inception) through<br>December 31, 2012 |
| Grant revenue  | \$                      | \$          | \$ 650      | \$ 650  |
| Operating expenses:  |                         |             |             |   |
| Research and development                                     | 10,149                  | 12,407      | 17,064      | 71,407  |
| Acquired in-process research and development                 |                         |             |             | 5,500   |
| Selling, general and administrative                          | 10,884                  | 9,416       | 4,772       | 34,899  |
| Total operating expenses                                     | 21,033                  | 21,823      | 21,836      | 111,806   |
| Loss from operations   | (21,033)                | (21,823)    | (21,186)    | (111,156)   |
| Interest income  | 23                      | 72          | 47          | 669   |
| Interest expense   | (1,579)                 | (1,483)     | (3,718)     | (9,402)   |
| Change in fair value of warrants                             | (1,287)                 |             |             | (1,287)   |
| Loss on debt extinguishment                                  | (799)                   |             |             | (799)   |
| Loss before tax benefit                                      | (24,675)                | (23,234)    | (24,857)    | (121,975)   |
| Income tax benefit   | 141                     | 47          | 500         | 839   |
| Net loss   | (24,534)                | (23,187)    | (24,357)    | \$ (121,136)  |
| Deemed dividend-beneficial conversion feature                | (13,250)                |             |             |   |
| Accretion of redeemable convertible preferred stock          |                         |             | (2,533)     |   |
| Net loss applicable to common stockholders                   | \$ (37,784)             | \$ (23,187) | \$ (26,890) |   |
| Basic and diluted net loss per common share                  | \$ (2.48)               | \$ (1.58)   | \$ (4.39)   |   |
| Weighted average basic and diluted common shares outstanding | 15,210,047              | 14,630,125  | 6,126,123   |   |

See accompanying notes to financial statements.

Table of Contents

**NUPATHE INC.**  
(A Development-Stage Company)

**Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
**Period from January 7, 2005 (inception) through December 31, 2012**

(in thousands, except share and per share data)

|   | Stockholders' Equity (Deficit)               |              |                                   |              |              |              |                                  |  |          |
|---|--|--------------|-----------------------------------|--------------|--------------|--------------|----------------------------------|--|----------|
|   | Redeemable<br>Convertible<br>Preferred Stock |              | Convertible<br>Preferred<br>Stock |              | Common Stock |              | Additional<br>Paid-in<br>Capital | Deficit<br>Accumulated<br>During the<br>Development<br>Stage | Total    |
|   | Shares                                       | Amount<br>\$ | Shares                            | Amount<br>\$ | Shares       | Amount<br>\$ | \$                               | \$   | \$       |
| Balance, January 7, 2005 (inception)  |  |              |                                   |              |              |              |                                  |  |          |
| Issuance of common stock to initial stockholders at \$0.64 per share                                      |  |              |                                   |              | 338,116      |              | 216                              |  | 216      |
| Net loss  |  |              |                                   |              |              |              |                                  | (1,067)  | (1,067)  |
| Balance, December 31, 2005  |  |              |                                   |              | 338,116      |              | 216                              | (1,067)  | (851)    |
| Stock-based compensation  |  |              |                                   |              | 114,158      |              | 44                               |  | 44       |
| Conversion of convertible notes and accrued interest into Series A redeemable convertible preferred stock | 3,481,645                                    | 2,590        |                                   |              |              |              | 648                              |  | 648      |
| Sale of Series A redeemable convertible preferred stock at \$0.93 per share, net of expenses of \$267     | 8,064,516                                    | 7,233        |                                   |              |              |              |                                  |  |          |
| Accretion of Series A redeemable convertible preferred stock to redemption value                          |  | 341          |                                   |              |              |              | (341)                            |  | (341)    |
| Net loss  |  |              |                                   |              |              |              |                                  | (5,215)  | (5,215)  |
| Balance, December 31, 2006  | 11,546,161                                   | 10,164       |                                   |              | 452,274      |              | 567                              | (6,282)  | (5,715)  |
| Stock-based compensation  |  |              |                                   |              |              |              | 59                               |  | 59       |
| Sale of Series A redeemable convertible preferred stock at \$0.93 per share, net of expenses of \$20      | 5,376,345                                    | 4,980        |                                   |              |              |              |                                  |  |          |
| Accretion of Series A redeemable convertible preferred stock to redemption value                          |  | 1,126        |                                   |              |              |              | (626)                            | (500)  | (1,126)  |
| Net loss  |  |              |                                   |              |              |              |                                  | (9,675)  | (9,675)  |
| Balance, December 31, 2007  | 16,922,506                                   | 16,270       |                                   |              | 452,274      |              |                                  | (16,457)   | (16,457) |
| Stock-based compensation  |  |              |                                   |              |              |              | 158                              |  | 158      |
| Exercise of stock options   |  |              |                                   |              | 155          |              |                                  |  |          |
| Sale of Series A redeemable convertible preferred stock at \$0.93 per share                               | 2,688,171                                    | 2,500        |                                   |              |              |              |                                  |  |          |
| Sale of Series B redeemable convertible preferred stock at \$0.93 per share, net of expenses of \$304     | 22,594,385                                   | 20,708       |                                   |              |              |              |                                  |  |          |
| Accretion of Series A and Series B redeemable convertible preferred stock to redemption value             |  | 2,330        |                                   |              |              |              | (158)                            | (2,172)  | (2,330)  |
| Net loss  |  |              |                                   |              |              |              |                                  | (17,511)   | (17,511) |
| Balance, December 31, 2008  | 42,205,062                                   | 41,808       |                                   |              | 452,429      |              |                                  | (36,140)   | (36,140) |
| Stock-based compensation  |  |              |                                   |              |              |              | 319                              |  | 319      |
| Forfeiture of restricted stock  |  |              |                                   |              | (61,753)     |              |                                  |  |          |
| Sale of Series B redeemable convertible preferred stock at \$0.93 per share, net of expenses of \$16      | 8,786,952                                    | 8,155        |                                   |              |              |              |                                  |  |          |
| Conversion of convertible notes and accrued interest into Series B redeemable convertible preferred stock | 2,104,326                                    | 1,957        |                                   |              |              |              |                                  |  |          |
| Beneficial conversion feature related to the convertible note and warrant agreement                       |  |              |                                   |              |              |              | 556                              |  | 556      |
| Accretion of Series A and Series B redeemable convertible preferred stock to redemption value             |  | 3,617        |                                   |              |              |              | (875)                            | (2,741)  | (3,616)  |
| Net loss  |  |              |                                   |              |              |              |                                  | (15,591)   | (15,591) |

Edgar Filing: NUPATHE INC. - Form 10-K

|                            |            |        |         |          |          |
|----------------------------|------------|--------|---------|----------|----------|
| Balance, December 31, 2009 | 53,096,340 | 55,537 | 390,676 | (54,472) | (54,472) |
|----------------------------|------------|--------|---------|----------|----------|

See accompanying notes to financial statements.

Table of Contents

**NUPATHE INC.**  
(A Development-Stage Company)

**Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
**Period from January 7, 2005 (inception) through December 31, 2012 (Continued)**

(in thousands, except share and per share data)

|   | Stockholders' Equity (Deficit)               |          |                                |          |              |        |                                  |  |           |          |
|---|--|----------|--------------------------------|----------|--------------|--------|----------------------------------|--|-----------|----------|
|   | Redeemable<br>Convertible<br>Preferred Stock |          | Convertible<br>Preferred Stock |          | Common Stock |        | Additional<br>Paid-in<br>Capital | Deficit<br>Accumulated<br>During the<br>Development<br>Stage | Total     |          |
|   | Shares                                       | Amount   | Shares                         | Amount   | Shares       | Amount |                                  |  |           |          |
| Stock-based compensation  |  |          |                                |          |              |        | 543                              |  | 543       |          |
| Exercise of stock options   |  |          |                                |          | 4,878        |        | 8                                |  | 8         |          |
| Accretion of Series A and Series B redeemable convertible preferred stock to redemption value |  | 2,534    |                                |          |              |        | (1,568)                          | (968)  | (2,536)   |          |
| Conversion of preferred stock including accrued dividends, into common stock                  | (53,096,340)                                 | (58,071) |                                |          | 7,861,785    |        | 8                                | 58,064   | 58,072    |          |
| Sale of common stock net of expenses of \$7,028   |  |          |                                |          | 5,000,000    |        | 5                                | 42,967   | 42,972    |          |
| Conversion of convertible notes and accrued interest into common stock                        |  |          |                                |          | 1,292,122    |        |                                  | 2  | 10,336    |          |
| Beneficial conversion feature related to convertible notes and warrant agreements             |  |          |                                |          |              |        |                                  | 2,584  | 2,584     |          |
| Reclassification of warrants to purchase common stock   |  |          |                                |          |              |        |                                  | 1,113  | 1,113     |          |
| Net loss  |  |          |                                |          |              |        |                                  | (24,357)   | (24,357)  |          |
| Balance, December 31, 2010  |  |          |                                |          | 14,549,461   |        | 15                               | 114,047  | (79,797)  | 34,265   |
| Stock-based compensation  |  |          |                                |          |              |        |                                  | 1,216  |           | 1,216    |
| Issuance of restricted stock  |  |          |                                |          | 16,000       |        |                                  |  |           |          |
| Exercise of stock options   |  |          |                                |          | 27,534       |        |                                  | 51   |           | 51       |
| Sale of common stock, net of expenses of \$146  |  |          |                                |          | 155,587      |        |                                  | 354  |           | 354      |
| Fair value of warrants issued in connection with loan facility                                |  |          |                                |          |              |        |                                  | 272  |           | 272      |
| Net loss  |  |          |                                |          |              |        |                                  |  | (23,187)  | (23,187) |
| Balance, December 31, 2011  |  | \$       |                                |          | 14,748,582   |        | 15                               | 115,940  | (102,984) | 12,971   |
| Stock-based compensation  |  |          |                                |          |              |        |                                  | 2,623  |           | 2,623    |
| Cancellation of restricted stock  |  |          |                                |          | (11,000)     |        |                                  |  |           |          |
| Exercise of stock options   |  |          |                                |          | 40,367       |        |                                  | 57   |           | 57       |
| Sale of preferred stock units, net of expenses of \$1,713                                     |  |          | 14,000                         | 11,537   |              |        |                                  |  |           | 11,537   |
| Common shares issued pursuant to conversion of preferred                                      |  |          | (5,196)                        | (4,282)  | 5,196,000    |        |                                  | 5  | 4,277     |          |
| Common shares issued pursuant to loan agreement   |  |          |                                |          | 50,000       |        |                                  | 146  |           | 146      |
| Deemed dividend on preferred shares   |  |          |                                |          |              |        |                                  | 13,250   | (13,250)  |          |
| Fair value of warrants issued in connection with loan facility                                |  |          |                                |          |              |        |                                  | 213  |           | 213      |
| Net loss  |  |          |                                |          |              |        |                                  |  | (24,534)  | (24,534) |
| Balance, December 31, 2012  |  | \$       | 8,804                          | \$ 7,255 | 20,023,949   | \$ 20  | \$ 136,506                       | \$ (140,768)   | \$        | 3,013    |

See accompanying notes to financial statements.



Table of Contents

**NUPATHE INC.**  
(A Development-Stage Company)

**Statements of Cash Flows**

(in thousands, except share and per share data)

|   | Year Ended December 31, |             |             | Period from   |
|---|-------------------------|-------------|-------------|---|
|   | 2012                    | 2011        | 2010        | January 7, 2005<br>(inception) through<br>December 31, 2012 |
| <b>Cash flows from operating activities:</b>  |                         |             |             |   |
| Net loss  | \$ (24,534)             | \$ (23,187) | \$ (24,357) | \$ (121,136)  |
| Adjustments to reconcile net loss to net cash used in operating activities:                 |                         |             |             |   |
| Depreciation expense  | 103                     | 78          | 47          | 358   |
| Loss on asset disposal  | 5                       |             |             | 29  |
| Increase in fair value of warrants  | 1,287                   |             |             | 1,287   |
| Loss on debt extinguishment   | 799                     |             |             | 799   |
| Cash paid for interest on debt extinguishment   | (350)                   |             |             | (350)   |
| Acquired in-process research and development  |                         |             |             | 5,500   |
| Stock-based compensation  | 2,623                   | 1,216       | 543         | 4,971   |
| Noncash interest expense  | 243                     | 291         | 3,336       | 5,758   |
| Changes in operating assets and liabilities:  |                         |             |             |   |
| Prepaid expenses and other assets   | 317                     | 1,071       | 300         | 964   |
| Accounts payable  | (1,167)                 | 769         | (266)       | 800   |
| Accrued expenses  | 60                      | (1,155)     | 1,993       | 2,057   |
| Net cash used in operating activities   | (20,614)                | (20,917)    | (18,404)    | (98,963)  |
| <b>Cash flows from investing activities:</b>  |                         |             |             |   |
| Purchase of in-process research and development   |                         |             |             | (5,500)   |
| Payments under equipment funding agreement  |                         | (3,353)     | (3,410)     | (6,763)   |
| Purchases of property and equipment   | (477)                   | (193)       | (75)        | (968)   |
| Net cash used in investing activities   | (477)                   | (3,546)     | (3,485)     | (13,231)  |
| <b>Cash flows from financing activities:</b>  |                         |             |             |   |
| Proceeds from issuance of debt  | 8,500                   | 10,000      | 5,000       | 26,000  |
| Proceeds from convertible notes   |                         |             | 10,063      | 14,467  |
| Payment of debt issuance costs  | (103)                   | (76)        | (174)       | (428)   |
| Repayment of debt   | (14,139)                | (1,725)     | (988)       | (18,788)  |
| Proceeds from sale of preferred stock, net  | 26,287                  |             |             | 69,863  |
| Proceeds from sale of common stock, net   | 57                      | 405         | 42,979      | 43,650  |
| Net cash provided by financing activities   | 20,602                  | 8,604       | 56,880      | 134,764   |
| Net increase (decrease) in cash and cash equivalents  | (489)                   | (15,859)    | 34,991      | 22,570  |
| Cash and cash equivalents, beginning of period  | 23,059                  | 38,918      | 3,927       |   |
| Cash and cash equivalents, end of period  | \$ 22,570               | \$ 23,059   | \$ 38,918   | \$ 22,570   |
| <b>Supplemental cash flow disclosures:</b>  |                         |             |             |   |
| Noncash investing and financing activities:   |                         |             |             |   |
| Conversion of note principal and accrued interest to redeemable convertible preferred stock | \$                      | \$          | \$          | \$ 4,547  |
| Conversion of note principal and accrued interest to common stock                           |                         |             | 10,337      | 10,337  |
| Conversion of preferred stock plus accrued dividends to common stock                        |                         |             | 58,072      | 58,072  |

Edgar Filing: NUPATHE INC. - Form 10-K

|   |        |       |       |        |
|---|--------|-------|-------|--------|
| Reclassification of warrant liability   |        |       | 1,113 | 1,113  |
| Fair value of warrants issued in connection with loan facilities                        | 213    | 272   |       | 485    |
| Fair value of warrants issued in connection with equity financing and loan modification | 14,949 |       |       | 14,949 |
| Financing arrangement with third party vendors  |        | 401   | 386   | 991    |
| Accretion of redeemable convertible preferred stock                                     |        |       | 2,534 | 9,948  |
| Deemed dividend-beneficial conversion feature   | 13,250 |       |       | 13,250 |
| Cash paid for interest  | 1,267  | 1,108 | 381   | 3,277  |

See accompanying notes to financial statements.



Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements**

**Amounts are in thousands, except share and per share data**

**(1) Background**

NuPathe Inc. (the Company) is a specialty pharmaceutical company focused on the development and commercialization of branded therapeutics for diseases of the central nervous system. Our lead product, Zecuity (sumatriptan iontophoretic transdermal system), was approved by the FDA on January 17, 2013 for the acute treatment of migraine, with or without aura, in adults. The Company was incorporated in Delaware on January 7, 2005 (inception) and has its principal office in Conshohocken, Pennsylvania. The Company operates as a single business segment and is a development-stage company.

**(2) Development-Stage Risks and Liquidity**

The Company has incurred recurring losses and negative cash flows from operations since its inception and has accumulated a deficit during the development stage of \$140,768 as of December 31, 2012. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of Zecuity and its products in development.

Management estimates that the Company's cash and cash equivalents of \$22,570 as of December 31, 2012 will be sufficient to fund operations and debt service obligations into the fourth quarter of 2013. The additional capital that the Company will require to launch Zecuity and fund its operations and debt service obligations beyond that point will depend largely upon the timing, scope, terms and structure of a commercial partnership for Zecuity. Until such time as the Company is able to secure additional capital, the Company intends to limit and delay certain expenditures required for the commercialization of Zecuity. There is no assurance that the Company will be able to secure a commercial partner on acceptable terms, and additionally no assurance that additional required capital will be available when needed or on acceptable terms. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The Company is subject to those risks associated with any development-stage specialty pharmaceutical company that has substantial expenditures for research and development. There can be no assurance that the Company's research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially successful. In addition, the Company operates in an environment of rapid technological change, and is largely dependent on the services of its employees, consultants, suppliers and contract manufacturers.

**(3) Summary of Significant Accounting Policies**

*(a) Use of Estimates*

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from such estimates.

Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(3) Summary of Significant Accounting Policies (Continued)**

*(b) Fair Value of Financial Instruments*

Management believes that the carrying amounts of the Company's financial instruments (including cash equivalents), prepaid expenses and other current assets, accounts payable and accrued expenses, approximate fair value due to the short-term nature of those instruments. The carrying amount of the Company's debt obligations approximate fair value based on interest rates available on similar borrowings.

The Company follows Financial Accounting Standards Board (FASB) accounting guidance on fair value measurements for financial assets and liabilities measured on a recurring basis. The guidance requires fair value measurements be classified and disclosed in one of the following three categories:

*Level 1:* Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

*Level 2:* Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liabilities; or

*Level 3:* Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The following fair value hierarchy table presents information about each major category of the Company's financial assets and liability measured at fair value on a recurring basis as of December 31, 2012 and 2011:

|                             | <b>Fair Value Measurement at Reporting Date Using</b>                                     |  |  |              |
|-----------------------------|---|--|--|--------------|
|                             | <b>Quoted Prices<br/>in Active<br/>Markets for<br/>Identical<br/>Assets<br/>(Level 1)</b> | <b>Significant<br/>Other<br/>Observable<br/>Inputs<br/>(Level 2)</b> | <b>Significant<br/>Unobservable<br/>Inputs<br/>(Level 3)</b> | <b>Total</b> |
| <b>At December 31, 2012</b> |   |  |  |              |
| <b>Assets:</b>              |   |  |  |              |
| Cash equivalents            | \$ 21,964   | \$   | \$   | \$ 21,964    |
| <b>Liabilities:</b>         |   |  |  |              |
| Warrant liability           | \$  | \$   | \$ 16,236  | \$ 16,236    |
| <b>At December 31, 2011</b> |   |  |  |              |
| <b>Assets:</b>              |   |  |  |              |
| Cash equivalents            | \$ 22,144   | \$   | \$   | \$ 22,144    |

Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(3) Summary of Significant Accounting Policies (Continued)**

The reconciliation of warrant liability measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows:

|   |    |        |
|---|----|--------|
| Balance at January 1, 2012                | \$ |        |
| Issuance of warrants                      |    | 14,949 |
| Change in fair value of warrant liability |    | 1,287  |
| Balance at December 31, 2012              | \$ | 16,236 |

The fair value of the warrant liability is based on Level 3 inputs. For this liability, The Company developed its own assumptions that do not have observable inputs or available market data to support the fair value. See Note 7b for further discussion of the warrant liability.

**(c) Cash Equivalents**

The Company considers all highly liquid debt instruments that have maturities of three months or less when acquired to be cash equivalents. As of December 31, 2012 and 2011, cash equivalents of \$21,964 and \$22,144, respectively, consisted of money market mutual funds invested in commercial paper and short-term corporate and government obligations. The Company's cash accounts are subject to account control agreements with the lender under the 2012 Term Loan that give the lender the right to assume control of the accounts in the event of a loan default (note 6).

**(d) Property and Equipment**

Property and equipment are recorded at cost and are depreciated on a straight-line basis over their estimated useful lives. The Company uses a life of three years for laboratory equipment and computer equipment, including software, and five years for office equipment and furniture. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the asset. Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, then an impairment charge is recognized for the amount by which the carrying value of the asset exceeds the fair value of the asset. As of December 31, 2012 and 2011, management believes that no revision of the remaining useful lives or write-down of long-lived assets is required.

**(e) Government Grants**

Grants received are recognized as revenue when the related work is performed and the qualifying research and development costs are incurred. In October 2010, the Company was awarded \$650 in research grants by the U.S. government under the Qualifying Therapeutic Discovery Project program which was recognized as grant revenue for the year ended December 31, 2010.

Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(3) Summary of Significant Accounting Policies (Continued)**

**(f) *Research and Development and In-Process Research and Development***

Research and development costs are charged to expense as incurred. Upfront and milestone payments made to third parties who perform research and development services on the Company's behalf will be expensed as services are rendered. Costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future use.

**(g) *Income Taxes***

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

**(h) *Stock-Based Compensation***

The Company measures stock-based awards to employees and board members at grant date fair value and records compensation expense, net of expected forfeitures, if any, on a straight-line basis over the vesting period of the award. For stock-based awards that have performance based vesting criteria, compensation cost is recognized when it is deemed probable that the vesting criteria will be met.

Determining the appropriate fair value of stock-based awards requires the use of subjective assumptions, including, for stock options, the expected life of the option and expected stock price volatility, and, prior to the Company's initial public offering (IPO), the fair value of the Company's common stock. The Company uses the Black-Scholes option-pricing model to value its stock option awards. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and management uses different assumptions, stock-based compensation expense could be materially different for future awards.

The expected life of stock options was estimated using the "simplified method," as the Company has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. Using the simplified method, the midpoint between the vesting period and the contractual term of the option is selected as the expected life of the option. Sufficient history to estimate the expected life of stock options or the volatility of our common stock price is not available. The Company uses a basket of comparable public companies as a basis for the expected volatility assumption. The Company intends to continue to consistently apply this process using comparable companies until a sufficient amount of historical information regarding the volatility of the Company's share price becomes available. Nonemployee awards are revalued until an award vests and compensation expense is recorded over the performance

Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(3) Summary of Significant Accounting Policies (Continued)**

period of each separate vesting tranche of the award, or using the accelerated attribution method. The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from the Company's current estimates, such amounts will be recorded as an adjustment in the period in which estimates are revised. As of December 31, 2012, there are no unvested nonemployee awards outstanding.

*(i) Net Loss Per Common Share*

Basic and diluted net loss per common share is determined by dividing net loss applicable to common stockholders by the weighted average common shares outstanding during the period. For all periods presented, the outstanding and previously outstanding shares of convertible preferred stock, common stock options, unvested restricted stock and warrants have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted loss per share are the same.

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of December 31, 2012, 2011 and 2010, as they would be anti-dilutive:

|   | December 31, |           |           |
|---|--------------|-----------|-----------|
|   | 2012         | 2011      | 2010      |
| Shares of convertible preferred stock (common stock equivalent) | 8,804,000    |           |           |
| Shares underlying outstanding options to purchase common stock  | 2,788,599    | 1,784,285 | 1,415,106 |
| Shares of unvested restricted stock                             |              | 16,000    |           |
| Shares underlying outstanding warrants to purchase common stock | 14,403,716   | 200,268   | 140,520   |

*(j) Segment Information*

The Company is managed and operated as one business. The entire business is managed by a single management team that reports to the chief executive officer. The Company does not operate separate lines of business or separate business entities with respect to any of its product candidates. Accordingly, the Company does not prepare discrete financial information with respect to separate product areas and does not have separately reportable segments.

*(k) Recently Issued Accounting Pronouncements*

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income (ASU 2011-05). The issuance of ASU 2011-05 is intended to improve the comparability, consistency and transparency of financial reporting and to increase the prominence of items reported in other comprehensive income. The guidance in ASU 2011-05 supersedes the presentation options in ASC Topic 220 and facilitates convergence of U.S. GAAP and IFRS by eliminating the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity and requiring that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive

Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(3) Summary of Significant Accounting Policies (Continued)**

statements. ASU 2011-05 was effective for interim periods and years beginning after December 15, 2011. The adoption of ASU 2011-05 did not have an impact on the Company's financial statements as the Company has no items of other comprehensive income.

**(4) Property and Equipment**

Property and equipment consisted of the following:

|  | <b>December 31,</b> |               |
|--|---------------------|---------------|
|  | <b>2012</b>         | <b>2011</b>   |
| Computer equipment, software, office equipment and furniture | \$ 268              | \$ 290        |
| Lab equipment  | 109                 | 105           |
| Leasehold improvements                                       | 43                  | 43            |
| Construction in progress                                     | 461                 |               |
|  | 881                 | 438           |
| Less accumulated depreciation and amortization               | (300)               | (225)         |
|  | <b>\$ 581</b>       | <b>\$ 213</b> |

Depreciation and amortization expense was \$103, \$78 and \$47 for the years ended December 31, 2012, 2011 and 2010, respectively.

**(5) Accrued Expenses**

Accrued expenses consisted of the following:

|   | <b>December 31,</b> |                 |
|---|---------------------|-----------------|
|   | <b>2012</b>         | <b>2011</b>     |
| Accrued compensation and benefits         | \$ 1,196            | \$ 897          |
| Accrued professional fees                 | 244                 | 257             |
| Accrued research and development expenses | 460                 | 518             |
| Accrued interest and other                | 95                  | 346             |
|   | <b>\$ 1,995</b>     | <b>\$ 2,018</b> |

**(6) Debt****(a) Convertible Notes**

In April 2010, the Company issued convertible promissory notes for cash proceeds of \$10,063 to existing investors, including three officers of the Company (the April 2010 Convertible Notes). The April 2010 Convertible Notes bore interest of 8% per year and were due on December 31, 2010, if not converted prior to that date. The April 2010 Convertible Notes and related accrued interest were mandatorily convertible into common stock upon the completion of a qualifying IPO, at a conversion price equal to 80% of the offering price per share in such IPO. Upon the completion of the Company's



Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(6) Debt (Continued)**

IPO in August 2010, the April 2010 Convertible Notes and related accrued interest converted into 1,292,122 shares of common stock. The Company initially recorded the April 2010 Convertible Notes net of a \$2,584 beneficial conversion feature, which has been fully recognized as interest expense during 2010 as the result of the conversion of the April 2010 Convertible Notes.

**(b) Term Loans and Vendor Debt**

*2012 Term Loan*

In November 2012, the Company entered into a Loan and Security Agreement with a new lender and received loan proceeds of \$8,500 (the 2012 Term Loan). The 2012 Term Loan proceeds were primarily used to repay the Term Loan Facility discussed below and the balance is available for general corporate purposes.

The 2012 Term Loan bears interest at an annual rate equal to the Wall Street Journal prime rate minus 3.25%, subject to a minimum rate of 9.85%. At December 31, 2012, the 2012 Term Loan bore interest at 9.85%. The Company is required to make interest-only payments for the first twelve months of the 2012 Term Loan's 42-month term; principal payments will commence in December 2013 and the loan matures in May 2016. As of December 31, 2012 the balance of the 2012 Term Loan, net of unamortized debt discount of \$208 as discussed below, is \$8,292 with \$190 of the amount being classified as current.

In connection with the 2012 Term Loan, NuPathe paid an origination fee to the lender consisting of a cash payment of \$42,500 and 50,000 shares of common stock. The fair value of the common stock of \$146 was recorded as debt issuance costs. The Company also issued the lender a warrant to purchase 106,631 shares of common stock at an exercise price of \$2.79. The warrant has a five year exercise period. The fair value of the warrant issued to the lender was \$213, which was recorded as a debt discount at the time of issuance and will be amortized to interest expense over the life of the loan. At the time of final payment of the 2012 Term Loan, the Company will be required to pay a final payment fee of \$298 (representing 3.5% of the original principal amount of the Term Loan).

The Company's obligations under the 2012 Term Loan are secured by a first priority lien on all of the Company's assets, excluding intellectual property, which is subject to a negative pledge. The Company's cash and investment accounts are subject to account control agreements with the lender that give the lender the right to assume control of the account in the event of a default under the Loan Agreement. The Loan Agreement contains operating covenants including, among others, covenants restricting the Company's ability to incur additional indebtedness, pay dividends or other distributions, effect a sale of any part of its business or merge with or acquire another company. The 2012 Term Loan also includes customary events of default including, among others, upon the occurrence of a payment default, a covenant default, a material adverse change or insolvency. Upon the occurrence of an event of default, the interest rate will be increased by 3% over the rate that would otherwise be applicable. In addition, the occurrence of an event of default could result in the acceleration of the Company's obligations under the 2012 Term Loan as well as grant the lender the right to exercise remedies with respect to the collateral. As of December 31, 2012, the Company has met all covenants and conditions under the 2012 Term Loan.



Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(6) Debt (Continued)**

In August 2012 and September 2012, the Company entered into two short-term loan agreements with third party vendors to finance insurance premiums. The aggregate amount financed under the agreements was \$434. As of December 31, 2012 the balance of the remaining short-term loans was \$188, which is required to be repaid by April 2013.

*Term Loan Facility*

In May 2010, the Company executed a loan and security agreement with lenders to fund working capital requirements (the Term Loan Facility). Borrowings under the Term Loan Facility of \$7,077 were repaid in full in November 2012. A loss on debt extinguishment of \$799 was recorded in connection with the repayment and was comprised of \$449 of unamortized issuance costs and \$350 of interest that was not previously accrued.

Upon execution of the Term Loan Facility in May 2010, the Company received \$5,000 of loan proceeds (Term A Loan). The Company was required to make interest-only payments for the first twelve months of the Term A Loan's 39-month term; principal payments commenced in June 2011. As discussed below, in September 2012, the Term Loan Facility was amended to provide for reduced principal payments through June 2013, followed by straight line amortization through June 2014. In November 2012, the Term A Loan balance of \$1,884 was repaid in full. The Term A Loan originally bore interest at an annual rate of LIBOR plus 8.75%, subject to a LIBOR floor of 3.00%. In June 2011, the interest rate was reduced to an annual rate of LIBOR plus 8.50%, subject to a LIBOR floor of 3.00%.

As a result of the completion of the Company's IPO in August 2010, an additional \$6,000 of funding became available to the Company under the Term Loan Facility (Term B Loan). In June 2011, the Company and the lenders amended the Term Loan Facility to:

increase the amount of Term B Loan available to the Company from \$6,000 to \$10,000;

require the Company to maintain at least \$3,000 of unrestricted cash; and

reduce the LIBOR rate margin for term loans under the facility from 8.75% to 8.50%.

Concurrently with the amendment, the Company received \$10,000 of Term B Loan (representing the total amount of Term B Loan available to the Company under the amended facility). The Company was required to make interest-only payments for the first six months of the Term B Loan's 26-month term; principal payments commenced in January 2012. As discussed below, in September 2012, the Term Loan Facility was amended to provide for reduced principal payments through June 2013, followed by straight line amortization through June 2014. In November 2012, the Term B Loan balance of \$5,193 was repaid in full. The Term B Loan bore interest at an annual rate of LIBOR plus 8.50%, subject to a LIBOR floor of 3.00%.

Table of Contents

**NUPATHE INC.**  
(A Development-Stage Company)

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(6) Debt (Continued)**

On August 13, 2012 and September 25, 2012, the Company entered into amendments to the Term Loan Facility, which, among other things:

reduced the minimum unrestricted cash balance that the Company was required to maintain from \$3,000 to \$1,000;

reduced the monthly principal payments under the Term Loan Facility from \$685 to \$230 upon completion of the October 2012 Financing through June 30, 2013, after which the principal balance would amortize straight-line through June 2014; and

temporarily eliminated the prepayment fee under the Term Loan Facility if certain conditions were met through January 16, 2013.

As consideration for these amendments, the Company paid an amendment fee of \$82 to the lenders upon the closing of the October 2012 Financing and was required to pay an additional \$300 (for a total of \$600) in final interest payment at the maturity of the facility. The Company also issued warrants to purchase 188,426 shares of common stock at an exercise price of \$2.00 per share to the lenders in connection with the October 2012 Financing, and canceled warrants to purchase 91,609 shares of common stock at \$7.45 per share that were previously issued to the lenders in connection with the Term A and Term B loans. The initial fair value of the new warrants of \$216 was recorded as debt issuance costs and was amortized to interest expense in the fourth quarter of 2012 as the loan was repaid. The unamortized value of the warrants that were canceled is a component of the loss on debt extinguishment for the year ended December 31, 2012.

As of December 31, 2012, our future payments under our debt agreements are as follows:

| Debt maturities:          | Total     | Payments Due by Period |          |          |          | 2017 and<br>Thereafter |
|---------------------------|-----------|------------------------|----------|----------|----------|------------------------|
|                           |           | 2013                   | 2014     | 2015     | 2016     |                        |
| (In thousands)            |           |                        |          |          |          |                        |
| Principal obligations     | \$ 8,688  | \$ 439                 | \$ 3,168 | \$ 3,500 | \$ 1,581 | \$                     |
| Interest payments on debt | 2,219     | 850                    | 681      | 350      | 338      | \$                     |
|                           | \$ 10,907 | \$ 1,289               | \$ 3,849 | \$ 3,850 | \$ 1,919 | \$                     |

**(7) Capital Structure and Equity Financings***(a) Equity Financing**October 2012 Financing*

In September 2012, the Company entered into a Securities Purchase Agreement (the Purchase Agreement) with certain qualified institutional purchasers and individual investors, pursuant to which the Company sold units of the Company's securities (the Units) to investors for an aggregate purchase price of \$28,000 (the October 2012 Financing). Net proceeds from the October 2012 Financing were \$26,287 with \$1,713 of transaction fees recorded as a reduction of the allocation to preferred stock. The per Unit purchase price for the Units was \$2.00, and each Unit consisted of one one-thousandth



Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(7) Capital Structure and Equity Financings (Continued)**

(1/1,000) of a share of the Company's newly designated Series A Preferred Stock, par value \$0.001 per share (the Series A Preferred Stock), and a warrant (the Warrants) to purchase one share of the Company's common stock, par value \$0.001 per share, at an exercise price of \$2.00 per share. Under the Purchase Agreement, the Company issued 14,000,000 units, which is equivalent to 14,000 shares of Series A Preferred and warrants to purchase 14,000,000 shares of common stock.

The holders of the Series A Preferred Stock are entitled to receive cumulative dividends at a rate per annum of 8% of \$2.00 per 1/1,000 of a share of Series A Preferred Stock (which rate shall increase to 12% if the Company has not obtained approval by the United States Food and Drug Administration (the FDA) of the Company's Zecuity product on or before June 30, 2013). Upon the liquidation, sale or merger of the Company, each holder of Series A Preferred Stock is entitled to receive for each 1/1,000 of a share owned by such holder an amount equal to the greater of (i) \$2.00, plus all accrued but unpaid dividends and interest, and (ii) the amount such holder would have received if such 1/1,000 of a share had been converted to common stock immediately prior to such event. As of December 31, 2012, no dividends were accrued as a declaration date had not yet occurred.

Each 1/1,000 of a share of Series A Preferred Stock is convertible, at the holder's option, into such number of shares of common stock equal to (i) \$2.00 divided by the conversion price then in effect (which conversion price is initially equal to \$2.00), plus (ii) an amount equal to all accrued but unpaid dividends on such fractional share divided by the closing price of common stock on the trading day immediately preceding the date of conversion, unless the Company has elected to pay the dividend amount in cash upon conversion. The conversion price of the Series A Preferred Stock is subject to "full ratchet" antidilution protection such that, in the event the Company issues shares of common stock or securities convertible into shares of common stock at an effective per share price less than the conversion price then in effect, the conversion price shall be reduced to the effective price per share for such additional shares of common stock.

The shares of Series A Preferred Stock will automatically convert into common stock upon (i) the consent of the holders of a majority of the shares of the Series A Preferred Stock, (ii) the conversion of the majority of shares of the Series A Preferred Stock, or (iii) the second to occur of (A) FDA approval of the Company's Zecuity product candidate and (B) consummation of a financing, licensing, partnership or other corporate collaboration resulting in gross proceeds to the Company of at least \$22 million.

The Warrants entitle the holder thereof to purchase one share of common stock at a price of \$2.00 per share. The exercise price of the Warrants is subject to "full ratchet" antidilution protection such that, in the event the Company issues shares of common stock or securities convertible into shares of common stock at an effective per share price less than the exercise price then in effect, the exercise price shall be reduced to the effective price per share for such additional shares of common stock. The "full ratchet" antidilution feature of the Warrants will terminate concurrently with the automatic conversion of the Series A Preferred Stock. The Warrants may be exercised at any time on or after April 23, 2013 through and including October 23, 2017, the expiration date of the Warrants, and may be exercised by paying the exercise price of \$2.00 per share, or pursuant to a "cashless exercise."

Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(7) Capital Structure and Equity Financings (Continued)**

Because of the antidilution protection, the warrants are liability classified on the accompanying balance sheet. The fair value of the warrants issued in connection with the financing was determined to be \$14,750 and was recorded as a liability at the date of issuance. The Company first allocated the proceeds from the October 2012 financing to the warrant liability with the remaining proceeds allocated to the Series A Preferred Stock. After allocating the proceeds, it was determined that the Series A Preferred Stock has a beneficial conversion feature (BCF). A BCF of \$13,250 was recorded in the fourth quarter of 2012 and has been reflected as a deemed dividend in the accompanying statement of operations. Pursuant to accounting guidance, the amount of the BCF was limited to the amount of the proceeds allocated to the Series A Preferred Stock.

From the date of issuance through December 31, 2012, there were 5,196 shares of the Series A Preferred Stock converted into 5,196,000 shares of common stock. In the first quarter of 2013, the remaining 8,804 shares of Series A Preferred Stock converted into 8,804,000 shares of common stock and the "full ratchet" antidilution feature of the Warrants terminated.

**(b) Warrants**

As of December 31, 2012, the following warrants to purchase common stock were outstanding:

|              | Number of<br>Shares | Exercise<br>Price | Expiration |
|--------------|---------------------|-------------------|------------|
| Common stock | 14,188,426          | \$ 2.00           | 2017       |
| Common stock | 106,631             | \$ 2.79           | 2017       |
| Common stock | 108,659             | \$ 7.45           | 2016       |

14,403,716

The warrants to purchase 14,188,246 shares of common stock that are exercisable at \$2.00 per share issued to investors in our October 2012 Financing, as described above, and to the lenders under our Term Loan Facility in connection with loan modifications, as described in Note 6b, were subject to "full ratchet" antidilution protection. These warrants were measured at their estimated fair value of \$14,949 and were liability-classified on the date of issuance. Because the warrants are liability-classified, they are re-measured on the Company's reporting dates with changes in the carrying value reflected in current results of operations. The change in fair value of warrants from the date of issuance to December 31, 2012 was \$1,287 and has been included in the Company's statement of operations. The fair value of the warrants at December 31, 2012 is \$16,236 and is shown as a warrant liability on the accompanying balance sheet. The fair value of the warrants is determined using a Monte Carlo analysis. The fair value is subjective and is affected by changes in inputs to the valuation model including the price per share of the Company's common stock, assumptions regarding FDA approval, future stock price activity, the timing of exercise of the warrants, volatility of the Company's common stock and peer company common stock and risk-free rates based on U.S. Treasury yields. Changes in these assumptions can materially affect the fair value estimate.

Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(7) Capital Structure and Equity Financings (Continued)**

*(c) Aspire Capital*

In August 2011, the Company entered into a common stock purchase agreement (Purchase Agreement) with Aspire Capital Fund, LLC (Aspire Capital), which provides that Aspire is committed to purchase up to an aggregate of \$30,000 of the Company's common stock over the term of the Purchase Agreement. Upon execution of the Purchase Agreement, the Company issued 84,866 shares of common stock to Aspire as a commitment fee in consideration for entering into the Purchase Agreement (the Commitment Shares) and the Company sold 70,721 shares of common stock to Aspire at a per share purchase price of \$7.07 resulting in gross proceeds to the Company of \$500 (the Initial Purchase Shares).

The Company has registered under the Securities Act of 1933 Aspire Capital's sale of the Commitment Shares, the Initial Purchase Shares and 2,746,147 additional shares that the Company may elect to sell to Aspire Capital under the Purchase Agreement. On any trading day on which the closing sale price of common stock is not less than \$4.00 per share, the Company may direct Aspire Capital to purchase shares of the Company's common stock at a known per share purchase price based on prevailing market prices, using a formula as set forth in the Purchase Agreement (a Regular Purchase). The maximum number of shares that the Company may direct Aspire Capital to purchase on any trading day pursuant to a Regular Purchase is 100,000 shares or such lesser number of shares that results in an aggregate purchase price of not greater than \$500.

In addition, on any trading day on which the Company directs Aspire Capital to make a Regular Purchase for the maximum number of shares set forth above, the Company may also direct Aspire Capital to purchase a number of shares of common stock equal to up to 30% of the aggregate shares of the Company's common stock traded on the NASDAQ Global Market on the next trading day (a VWAP Purchase), subject to a maximum number of shares the Company may determine and a minimum trading price, which is equal to the greater of (a) 90% of the closing price of the Company's common stock on the business day immediately preceding the VWAP Purchase Date or (b) such higher price as set by the Company in the VWAP Purchase Notice. The per share purchase price of common stock sold to Aspire pursuant to a VWAP Purchase is equal to 95% of the volume weighted average price for such purchase date.

There are no trading volume requirements or restrictions under the Purchase Agreement, and the Company will control the timing and amount of any sales stock to Aspire Capital. Aspire Capital has no right to require any sales by the Company, but is obligated to make purchases from the Company as the Company directs in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by the Company at any time, at our discretion, without any penalty or cost to the Company.

As of December 31, 2012, the Company has not made any sales to Aspire Capital other than the 70,721 shares of common stock sold to Aspire Capital upon execution of the Purchase Agreement and the 84,866 shares of common stock issued to Aspire Capital as a commitment fee in consideration for entering into the Purchase Agreement. This Purchase Agreement expires in August 2013.

Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(7) Capital Structure and Equity Financings (Continued)***(d) Initial Public Offering*

In August 2010, the Company completed its initial public offering of common stock selling 5,000,000 shares at an offering price of \$10.00 per share, resulting in gross proceeds of \$50,000. Net proceeds after underwriting fees and offering expenses were approximately \$43,000.

*(e) Redeemable Convertible Preferred Stock*

All pre-IPO outstanding shares of the Company's redeemable convertible preferred stock, plus accrued dividends thereon, were converted into 7,861,785 shares of common stock upon the completion of the IPO in August 2010.

**(8) Stock-Based Compensation**

As of December 31, 2012, the Company is authorized to grant up to 2,975,385 shares of common stock under the NuPathe Inc. 2010 Omnibus Incentive Compensation Plan (the 2010 Plan). Such grants may be made to eligible employees, directors, consultants and advisors to the Company in the form of restricted stock, stock options, stock appreciation rights, stock units, performance units and other stock-based awards. Awards under the 2010 Plan are made by the compensation committee of the Company's board of directors. As of December 31, 2012, there were 2,050,409 incentive and non-qualified stock options and 583,325 restricted stock units outstanding under the 2010 Plan, as well as 738,190 non-qualified stock options that were granted outside of the 2010 Plan. As of December 31, 2012, there were 211,318 shares of common stock available for future grants under the 2010 Plan. Pursuant to the terms of the 2010 Plan, additional shares of common stock will become available for issuance under the plan each year on the first trading day in January. The number of additional shares that will become available for issuance is equal to 5% of the total number of shares of common stock outstanding on the last trading day in December of the immediately preceding calendar year or 1,500,000, whichever is less.

Stock-based compensation expense for the years ended December 31, 2012, 2011 and 2010 includes compensation expense for employee (which also includes director) and nonemployee stock option grants and restricted stock grants. The compensation expense for the years ended December 31, 2012, 2011 and 2010 is as follows:

|                   | Year Ended December 31, |          |        |
|-------------------|-------------------------|----------|--------|
|                   | 2012                    | 2011     | 2010   |
| Stock options:    |                         |          |        |
| Employee          | \$ 2,209                | \$ 1,197 | \$ 507 |
| Nonemployee       |                         |          | 27     |
|                   | 2,209                   | 1,197    | 534    |
| Restricted stock: |                         |          |        |
| Employee          | 414                     | 19       | 9      |
|                   | \$ 2,623                | \$ 1,216 | \$ 543 |

Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(8) Stock-Based Compensation (Continued)**

Stock-based compensation expense was included in the accompanying statements of operations for the years ended December 31, 2012, 2011 and 2010, as follows:

|                                     | Year Ended December 31, |          |        |
|-------------------------------------|-------------------------|----------|--------|
|                                     | 2012                    | 2011     | 2010   |
| Research and development            | \$ 271                  | \$ 210   | \$ 143 |
| Selling, general and administrative | 2,352                   | 1,006    | 400    |
|                                     | \$ 2,623                | \$ 1,216 | \$ 543 |

***Stock Options***

The weighted average fair value of the options granted during 2012, 2011 and 2010 was estimated at \$2.38, \$3.26 and \$6.36, respectively, on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

|                         | Year Ended December 31, |         |         |
|-------------------------|-------------------------|---------|---------|
|                         | 2012                    | 2011    | 2010    |
| Expected dividend yield | %                       | %       | %       |
| Expected volatility     | 84.72%                  | 82.1%   | 84.1%   |
| Risk-free interest rate | 0.9%                    | 1.5%    | 1.9%    |
| Expected life           | 6 years                 | 6 years | 6 years |
|                         |                         |         | 90      |

---



Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

Amounts are in thousands, except share and per share data

**(8) Stock-Based Compensation (Continued)**

The following table summarizes the aggregate stock option activity:

|  | Number of<br>Shares | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term in Years | Aggregate<br>Intrinsic<br>Value |
|--|---------------------|--|--|---------------------------------|
| Outstanding at January 1, 2010                   | 950,693             | \$ 1.81                                  |  |                                 |
| Granted  | 483,372             | 8.87                                     |  |                                 |
| Exercised  | (4,878)             | 1.55                                     |  |                                 |
| Cancelled/forfeited                              | (14,081)            | 1.76                                     |  |                                 |
| Outstanding at December 31, 2010                 | 1,415,106           | 4.22                                     |  |                                 |
| Granted  | 432,590             | 4.69                                     |  |                                 |
| Exercised  | (27,534)            | 1.85                                     |  |                                 |
| Cancelled/forfeited                              | (35,877)            | 7.27                                     |  |                                 |
| Outstanding at December 31, 2011                 | 1,784,285           | 4.31                                     |  |                                 |
| Granted  | 1,531,790           | 3.45                                     |  |                                 |
| Exercised  | (42,482)            | 1.52                                     |  | \$ 72                           |
| Cancelled/forfeited                              | (484,994)           | 6.07                                     |  |                                 |
| Outstanding at December 31, 2012                 | 2,788,599           | 3.58                                     | 7.97   | \$ 1,677                        |
| Vested and expected to vest at December 31, 2012 | 2,678,261           | 3.60                                     | 7.92   | \$ 1,642                        |
| Exercisable at December 31, 2012                 | 1,450,461           | \$ 3.23                                  | 6.83   | \$ 1,478                        |

Of the 2,788,599 stock options outstanding at December 31, 2012, 110,338 had performance-based vesting criteria. These 110,338 stock options were awarded to executive officers in 2012 and had an aggregate grant date fair value of \$237. These awards include vesting criteria that are contingent upon the achievement of certain corporate milestones, as defined in the grant agreements. For stock-based awards that have performance-based vesting criteria, compensation cost is recognized when it is deemed probable that the vesting criteria will be met. As of December 31, 2012, the Company has not deemed the achievement of the vesting criteria to be probable, and therefore there has been no compensation expense recorded for these performance-based awards to date.

Of the 1,531,790 stock options that were granted during 2012, 122,012 were granted to certain directors pursuant to an election by such directors to receive all or a portion of their cash director fees in stock options.

The aggregate intrinsic values set forth in the table above represent the total amount by which the value of the shares of common stock subject to such options exceeds the exercise price of such options, based on the Company's closing stock price of \$3.38 on December 31, 2012.

Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(8) Stock-Based Compensation (Continued)**

As of December 31, 2012, there was \$2,694 of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 3.1 years. As of December 31, 2012 there were a total of 1,548,053 in-the-money options outstanding.

In connection with the resignation of the Company's former chief executive officer in July 2012, the Company recorded \$380 of non-cash expense related to the modification of equity-based awards previously issued to such officer.

The following table summarizes information about stock options outstanding under the 2010 Plan as of December 31, 2012:

| Exercise Price   | Options outstanding |   | Options exercisable |   |
|------------------|---------------------|---|---------------------|---|
|                  | Number of Options   | Weighted average remaining contractual term (years) | Number of Options   | Weighted average remaining contractual term (years) |
| \$0.80 - \$2.11  | 955,490             | 5.85  | 930,007             | 5.77  |
| \$2.12 - \$3.42  | 648,866             | 9.21  | 71,303              | 9.10  |
| \$3.43 - \$4.74  | 803,399             | 9.56  | 212,847             | 9.54  |
| \$4.75 - \$6.06  | 80,000              | 7.82  | 39,063              | 7.80  |
| \$6.07 - \$7.37  | 10,683              | 8.50  | 10,339              | 8.49  |
| \$7.38 - \$8.69  | 121,104             | 8.10  | 86,816              | 8.17  |
| \$8.70 - \$10.00 | 169,057             | 7.61  | 100,086             | 7.61  |
|                  | 2,788,599           | 7.97  | 1,450,461           | 6.83  |

Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(8) Stock-Based Compensation (Continued)***Restricted Stock*

The following table summarizes the aggregate restricted stock activity for the years ended December 31, 2012, 2011 and 2010:

|                                       | Number of<br>Shares | Weighted<br>Average<br>Grant Date<br>Fair Value |
|---------------------------------------|---------------------|---|
| Nonvested shares at January 1, 2010   | 8,887               | \$ 0.96   |
| Granted                               |                     |   |
| Vested                                | (8,887)             | 0.96  |
| Forfeited                             |                     |   |
| Nonvested shares at December 31, 2010 |                     |   |
| Granted                               | 16,000              | \$ 7.73   |
| Vested                                |                     |   |
| Forfeited                             |                     |   |
| Nonvested shares at December 31, 2011 |                     |   |
| Granted                               | 583,325             | \$ 3.38   |
| Vested                                | (121,665)           | 3.56  |
| Forfeited                             | (11,000)            | 7.73  |
| Nonvested shares at December 31, 2012 |                     |   |
|                                       | 466,660             | \$ 3.38   |

As of December 31, 2012, there was \$1,577 of unrecognized compensation expense related to unvested restricted stock which is expected to be recognized over the next 3.6 years.

*2013 Option Exchange*

In January 2013, the Company completed an exchange of certain previously issued stock options for shares of restricted stock and restricted stock units (the Exchange). In the Exchange, certain employees of the Company exchanged two eligible stock options for one share of restricted stock or one restricted stock unit (RSU). The Exchange was completed in accordance with, and as permitted by, the terms of the 2010 Plan. In connection with the Exchange, options to purchase 1,236,837 shares were cancelled and 618,415 shares of restricted stock and restricted stock units were issued. Shares of restricted stock and RSUs issued in the Exchange will vest 50% on January 7, 2014, with the remaining shares vesting in four equal quarterly installments thereafter. All shares of restricted stock and RSUs issued in the Exchange will be subject to forfeiture if the employee's service to the Company terminates before those shares vest, except as otherwise provided in a written employment agreement entered into between the employee and the Company which, in certain cases, may provide for accelerated vesting of equity securities, including restricted stock or RSUs. Shares of Company common stock will be issued with respect to vested RSUs on the earliest of: (i) March 31 of the calendar year immediately following the year in which the RSU vests; (ii) a change of control of the Company; or (iii) the employees separation from service from the Company.

Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(9) Commitments***(a) Leases*

The Company leases office space and office equipment under operating leases, which expire at various times through December 2015. Rent expense under these leases was \$316, \$314, and \$299 for the years ended December 31, 2012, 2011 and 2010, respectively. Rent expense under these leases since inception was \$1,849.

Future minimum lease payments as of December 31, 2012 are as follows:

|      |        |
|------|--------|
| 2013 | 156    |
| 2014 | 7      |
| 2015 | 6      |
|      | \$ 169 |

*(b) License Agreements**University of Pennsylvania*

The Company entered into a patent license agreement with the University of Pennsylvania (Penn), which became effective in July 2006 and was amended in May 2007. Under the patent license agreement, Penn granted to the Company exclusive, worldwide rights under specified patent applications, and patents issuing therefrom, to make, use and sell products using Long Acting Delivery (LAD) technology. Under the agreement, the Company has the right to sublicense, subject to specified conditions, including the payment of sublicense fees. The patent license agreement requires that the Company use commercially reasonable efforts to develop and commercialize licensed products and requires the Company to commit a minimum of \$250 per year towards such activities until the first commercial sale of the first licensed product. The license agreement requires the Company to make annual license maintenance payments of up to \$50 to Penn until the first commercial sale of the first licensed product. The license agreement covers the Company's product candidates NP201 and NP202. In addition, the Company has agreed to pay Penn aggregate milestone payments of up to \$950 upon the achievement of specified development and regulatory milestones related to each licensed product as specified and royalty payments equal to a specified percentage of future commercial sales of licensed products subject to the license through the expiration of the licensed patents.

*Evonik Industries AG, Inc.*

In September 2009, the Company entered into a license agreement with Evonik Industries AG, Inc. (Evonik), as successor to SurModics Pharmaceuticals, Inc, pursuant to which the Company received an exclusive worldwide license, with the right to sublicense, under Evonik's intellectual property, including its interest in joint inventions developed under a feasibility agreement, to make, have made, use, sell, import and export products covered by the license agreement. The Company granted Evonik an exclusive, perpetual, worldwide, royalty-free license under the Company's interest in joint inventions for uses that do not relate to products covered by the agreement or include any of the Company's existing technology or confidential information. The Company also granted Evonik a right

Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(9) Commitments (Continued)**

of first negotiation to manufacture clinical supplies of covered products. If the Company and Evonik enter into such clinical manufacturing agreement, Evonik has a right of first negotiation to manufacture commercial supplies of covered products. The Company is obligated to pay aggregate milestones of up to \$4,750 upon the achievement of specified development, regulatory and sales level milestones related to the first clinical indication approved by regulatory authority for covered products. The license agreement currently covers the Company's product candidate NP201. The Company must also pay an additional milestone payment upon regulatory approval of each additional clinical indication for covered products and specified royalties on sales of commercial product.

**(c) Equipment Funding Agreement**

In June 2010, the Company entered into an equipment funding agreement with LTS Lohmann Therapie-Systeme AG (LTS), under which the Company agreed to fund the purchase by LTS of manufacturing equipment for the Company's primary product candidate, Zecuity. The Company made 14 monthly installments to LTS that commenced in June 2010, according to an agreed upon payment schedule. As of December 31, 2012, €4,970, or \$6,763 based on exchange rates in effect at the time the payments were made, has been recorded as a noncurrent asset in the accompanying balance sheet. All amounts owed under this funding agreement have been paid in full as of December 31, 2012. Amounts capitalized under the LTS funding agreement will be amortized to cost of goods sold upon the commencement of commercial sales of Zecuity. If the Company were to ever cease development of Zecuity, amounts capitalized under this agreement would be immediately expensed. LTS owns the purchased equipment and is responsible for its routine and scheduled maintenance and repair and is required to use the purchased equipment solely to manufacture Zecuity.

Additionally, in the first quarter of 2013, we amended the funding agreement with LTS to fund additional investment in commercial manufacturing capacity. Our additional funding obligations resulting from such amendment are denominated in Euros and approximate \$0.8 million of expenses expected to be incurred in 2013, based on exchange rates in effect at March 1, 2013.

**(d) Employment Agreements**

Certain officers and employees of the Company have employment agreements providing for severance and continuation of benefits in the event the Company terminates their employment without cause or they resign for good reason.

Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(10) 401(k) Profit Sharing Plan**

The Company maintains a 401(k) Profit Sharing Plan (the 401(k) Plan) available to all employees meeting certain eligibility criteria. The 401(k) Plan permits participants to contribute up to 90% of their salary, not to exceed the limits established by the Internal Revenue Code. All contributions made by participants into the participants' accounts vest immediately. Since 2008, the Company has provided a biweekly matching contribution to participant's accounts as provided for under the 401(k) Plan. This contribution is determined by a formula that is based on the employee's contributions, not to exceed 3% of their eligible wages, as defined by the 401(k) Plan. The Company sponsored match was \$155, \$136, and \$95 for the years ended December 31, 2012, 2011 and 2010, respectively.

**(11) Income Taxes**

The Company sold \$141, \$47 and \$500 of Pennsylvania research and development tax credits to a third party buyer during the years ended December 31, 2012, 2011 and 2010, respectively. Accordingly, the Company recorded an income tax benefit of \$141, \$47 and \$500 for the years ended December 31, 2012, 2011 and 2010, respectively.

The components of benefit for income taxes attributable to continuing operations were as follows:

|          | Year Ended<br>December 31, |      |      |
|----------|----------------------------|------|------|
|          | 2012                       | 2011 | 2010 |
| Federal: |                            |      |      |
| Current  |                            |      |      |
| Deferred |                            |      |      |
| Total    |                            |      |      |
| State:   |                            |      |      |
| Current  | 141                        | 47   | 500  |
| Deferred |                            |      |      |
| Total    | 141                        | 47   | 500  |

A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows:

|  | Year Ended<br>December 31, |        |        |
|--|----------------------------|--------|--------|
|  | 2012                       | 2011   | 2010   |
| Percent of pre-tax income:             |                            |        |        |
| U.S. federal statutory income tax rate | 34.0%                      | 34.0%  | 34.0%  |
| State taxes, net of federal benefit    | 5.9                        | 6.4    | 5.8    |
| Other                                  | (2.3)                      | 1.5    | (1.4)  |
| Change in valuation allowance          | (37.0)                     | (41.7) | (36.3) |
| Effective income tax rate              | 0.6%                       | 0.2%   | 2.1%   |

Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(11) Income Taxes (Continued)**

The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets were as follows:

|   | <b>December 31,</b> |             |
|---|---------------------|-------------|
|   | <b>2012</b>         | <b>2011</b> |
| Net operating loss carryforwards        | \$ 43,026           | \$ 34,843   |
| Research and development credit         | 2,368               | 2,126       |
| Depreciation and amortization           | 1,677               | 1,785       |
| Capitalized start-up costs              | 56                  | 85          |
| Other temporary differences             | 1,458               | 609         |
| <br>                                    |                     |             |
| Gross deferred tax asset                | 48,585              | 39,448      |
| Deferred tax assets valuation allowance | (48,585)            | (39,448)    |
|   | \$                  | \$          |

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible. Due to the Company's history of losses, the deferred tax assets are fully offset by a valuation allowance at December 31, 2012 and 2011. The valuation allowance in 2012 increased by \$9,137 over 2011 and the valuation allowance in 2011 increased by \$9,690 over 2010, related primarily to additional net operating losses incurred by the Company and additional capitalized research and development expenses.

As of December 31, 2012 and 2011, \$139 and \$209, respectively, of the Company's expenses had been capitalized for tax purposes as start-up costs. For tax purposes, capitalized research and development costs will be amortized over fifteen years beginning when the Company commences operations, as defined under the Internal Revenue Code.

The following table summarizes carryforwards of net operating losses and tax credits as of December 31, 2012:

|                                  | <b>Amount</b> | <b>Expiration</b> |
|----------------------------------|---------------|-------------------|
| Federal net operating losses     | \$ 105,992    | 2026 - 2032       |
| State net operating losses       | 105,992       | 2026 - 2032       |
| Research and development credits | 2,368         | 2025 - 2032       |

The Tax Reform Act of 1986 (the Act) provides for a limitation of the annual use of net operating loss and research and development tax credit carryforwards following certain ownership changes (as defined by the Act) that could limit the Company's ability to utilize these carryforwards. The Company has not completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since its formation, due to the significant costs and complexities associated with such a study. The Company may have experienced various ownership changes, as

Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

**Amounts are in thousands, except share and per share data**

**(11) Income Taxes (Continued)**

defined by the Act, as a result of past financings. Accordingly, the Company's ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes; therefore, the Company may not be able to take full advantage of these carryforwards for federal or state income tax purposes.

On January 1, 2009, the Company adopted the provisions of FASB ASC 740-10, Accounting for Uncertainty in Income Taxes, which provides a financial statement recognition threshold and measurement attribute for a tax position taken or expected to be taken in a tax return. Under FASB ASC 740-10, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based solely on the technical merits of the position. The tax benefits recognized in the financial statements from such a position should be measured based on the largest benefit that has a greater than 50% likelihood to be sustained upon ultimate settlement. FASB ASC 740-10 also provides guidance on derecognition of income tax assets and liabilities, classification of current and deferred income tax assets and liabilities, accounting for interest and penalties associated with tax positions and income tax disclosures.

The Company did not have unrecognized tax benefits as of December 31, 2012 and does not expect this to change significantly over the next twelve months. In connection with the adoption of FASB ASC 740-10, the Company will recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. As of December 31, 2012, the Company has not accrued interest or penalties related to uncertain tax positions. The Company's tax returns for the years ended December 31, 2009 through December 31, 2012 are still subject to examination by major tax jurisdictions.



Table of Contents

**NUPATHE INC.**  
**(A Development-Stage Company)**

**Notes to Financial Statements (Continued)**

Amounts are in thousands, except share and per share data

**(12) Quarterly Financial Information (unaudited)**

This table summarizes the unaudited quarterly results of operations for the quarters in 2012 and 2011:

|  | 2012 Results  |                |               |                |    | Total      |
|--|---------------|----------------|---------------|----------------|----|------------|
|  | First quarter | Second quarter | Third quarter | Fourth quarter |    |            |
| Operating expenses   | \$ 5,841      | \$ 5,779       | \$ 5,745      | \$ 3,668       | \$ | 21,033     |
| Increase in fair value of warrants                           |               |                |               | (1,287)        |    | (1,287)    |
| Loss on debt extinguishment                                  |               |                |               | (799)          |    | (799)      |
| Interest expense, net  | (443)         | (389)          | (444)         | (280)          |    | (1,556)    |
| Loss before tax benefit.                                     | (6,284)       | (6,168)        | (6,189)       | (6,034)        |    | (24,675)   |
| Income tax benefit   |               |                |               | 141            |    | 141        |
| Net loss   | \$ (6,284)    | \$ (6,168)     | \$ (6,189)    | \$ (5,893)     | \$ | (24,534)   |
| Deemed dividend  |               |                |               | (13,250)       |    | (13,250)   |
| Net loss applicable to shareholders                          | \$ (6,284)    | \$ (6,168)     | \$ (6,189)    | \$ (19,143)    | \$ | (37,784)   |
| Basic and diluted net loss per common share                  | \$ (0.43)     | \$ (0.42)      | \$ (0.42)     | \$ (1.15)      | \$ | (\$2.48)   |
| Weighted average basic and diluted common shares outstanding | 14,732,582    | 14,736,809     | 14,752,214    | 16,608,248     |    | 15,210,047 |

|  | 2011 Results  |                |               |                |    | Total      |
|--|---------------|----------------|---------------|----------------|----|------------|
|  | First quarter | Second quarter | Third quarter | Fourth quarter |    |            |
| Operating expenses   | \$ 3,544      | \$ 6,233       | \$ 6,937      | \$ 5,109       | \$ | 21,823     |
| Interest expense, net  | (179)         | (232)          | (505)         | (495)          |    | (1,411)    |
| Loss before tax benefit                                      | (3,723)       | (6,465)        | (7,442)       | (5,604)        |    | (23,234)   |
| Income tax benefit   |               |                |               | 47             |    | 47         |
| Net loss   | \$ (3,723)    | \$ (6,465)     | \$ (7,442)    | \$ (5,557)     | \$ | (23,187)   |
| Basic and diluted net loss per common share                  | \$ (0.26)     | \$ (0.44)      | \$ (0.51)     | \$ (0.38)      | \$ | (\$1.58)   |
| Weighted average basic and diluted common shares outstanding | 14,553,748    | 14,561,519     | 14,670,247    | 14,732,582     |    | 14,630,125 |

Table of Contents

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

Not applicable.

**ITEM 9A. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Form 10-K, the effectiveness of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level in ensuring that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the Exchange Act), is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

**Management's Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining an adequate system of internal control over financial reporting. Our system of internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the U.S.

Our internal control over financial reporting includes those policies and procedures that:

pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;

provide reasonable assurance that our transactions are recorded as necessary to permit preparation of our financial statements in accordance with accounting principles generally accepted in the U.S., and that our receipts and expenditures are being made only in accordance with authorizations of our management and our directors; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. Further, because of changes in conditions, effectiveness of internal controls over financial reporting may vary over time. Our system contains self-monitoring mechanisms, and actions are taken to correct deficiencies as they are identified.

Our management conducted an evaluation of the effectiveness of the system of internal control over financial reporting based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our system of internal control over financial reporting was effective as of December 31, 2012.

Table of Contents

This Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to the rules of the SEC that permit us to provide only management's report in this Form 10-K.

**Changes to Internal Controls Over Financial Reporting**

There has been no change in internal controls over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

On March 27, 2013, the Company entered into a Third Amendment to its Office Space Lease with Washington Street Associates II, L.P. dated January 10, 2008, as amended on November 1, 2010 and January 31, 2013 (the "Office Lease"), pursuant to which NuPathe leases its principal executive offices. The Third Amendment extends the term of the Office Lease to June 30, 2013 at a monthly rate of \$26,001 for the remaining term of the lease. All other provisions of the Office Lease are unchanged by the Third Amendment and remain in full force and effect.

On March 27, 2013, the Company and Terri B. Sebree, the Company's President, entered into Amendment No. 1 (the "Amendment") to Ms. Sebree's Amended and Restated Employment Agreement. The Amendment extends the time period during which Ms. Sebree may elect to resign and receive the payments and other benefits specified in her Amended and Restated Employment Agreement, to December 31, 2013. The Amendment also specifies certain terms of the consulting agreement which Ms. Sebree will be required to enter into in order to receive such payments and other benefits. All other provisions of the Amended and Restated Employment Agreement are unchanged by the Amendment.

The foregoing is a summary description of certain terms of the Amendment to Ms. Sebree's Amended and Restated Employment Agreement and the Third Amendment to the Company's Office Lease and, by its nature, is incomplete. It is qualified in its entirety by the text of the Amendment and the text of the Third Amendment filed as Exhibits 10.26 and 10.35, respectively, to this Form 10-K and incorporated herein by reference. All readers are encouraged to read the entire text of such amendments.

Table of Contents

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

We have adopted a code of business conduct and ethics that applies to all of our directors, officers and employees. Our code of business conduct and ethics contains provisions that satisfy the standards for a "code of ethics" set forth in Item 406 of Regulation S-K of the rules and regulations of the SEC. Our code of business conduct and ethics also contains a special code of ethics that is applicable to our chief executive officer and our senior financial officers. Our code of business conduct and ethics is available through the "Investor Relations Corporate Governance" page of our website, the address of which is [www.nupathe.com](http://www.nupathe.com).

To the extent that we amend any provision of our code of conduct or grant a waiver from any provision of our code of conduct that is applicable to any of our directors or our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions, we intend to satisfy our disclosure obligations under applicable SEC rules by posting such information on our website under the heading "Investor Relations Corporate Governance."

The references to our website are intended to be inactive textual references only, and the content of our website is not incorporated by reference herein.

The additional information required by this item will be included under the headings "Proposal No. 1 Election of Directors," "Executive Officers and Key Employee," "Corporate Governance," and "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive proxy statement for our 2013 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2012 (our 2013 Proxy Statement), and is incorporated herein by reference.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this item will be included in our 2013 Proxy Statement under the heading "Executive Compensation," and is incorporated herein by reference.

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

The information required by this item will be included in our 2013 Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information," and is incorporated herein by reference.

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

The information required by this item will be included in our 2013 Proxy Statement under the heading "Director Independence and Relationships and Related Party Transactions," and is incorporated herein by reference.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this item will be included in our 2013 Proxy Statement under the heading "Proposal No. 2 Ratification of the Selection of the Independent Registered Public Accounting Firm," and is incorporated herein by reference.

Table of Contents

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

*Financial Statements:* The following financial statements are included in Part II, Item 8 of this Form 10-K:

|  |           |
|--|-----------|
| <u>Report of Independent Registered Public Accounting Firm</u>                                 | <u>71</u> |
| <u>Balance Sheets</u>  | <u>72</u> |
| <u>Statements of Operations</u>  | <u>73</u> |
| <u>Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)</u> | <u>74</u> |
| <u>Statements of Cash Flows</u>  | <u>76</u> |
| <u>Notes to Financial Statements</u>   | <u>77</u> |

*Financial Statement Schedules:* All schedules to our financial statements are omitted because they are not applicable or not required, or because the required information is included in the financial statements or notes thereto.

*Exhibits:* A list of exhibits filed as part of this Form 10-K is set forth in the Exhibit Index beginning on page 95 of this Form 10-K and is incorporated by reference herein. Where so indicated in the Exhibit Index, exhibits which were previously filed are incorporated by reference.

Table of Contents**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

**NUPATHE INC.**

Date: March 27, 2013

By:

/s/ ARMANDO ANIDO

---

Armando Anido  
*Chief Executive Officer*

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Armando Anido and Keith A. Goldan, jointly and severally, his or her attorney-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

| <b>Signature</b>                              | <b>Title</b>   | <b>Date</b>    |
|---|--|----------------|
| <u>/s/ ARMANDO ANIDO</u><br>Armando Anido     | Chief Executive Officer and Director (Principal Executive Officer)   | March 27, 2013 |
| <u>/s/ KEITH A. GOLDAN</u><br>Keith A. Goldan | Chief Financial Officer (Principal Financial and Accounting Officer) | March 27, 2013 |
| <u>/s/ WAYNE P. YETTER</u><br>Wayne P. Yetter | Chairman of the Board  | March 27, 2013 |
| <u>/s/ MICHAEL COLA</u><br>Michael Cola       | Director   | March 27, 2013 |
| <u>/s/ JAMES A. DATIN</u><br>James A. Datin   | Director   | March 27, 2013 |

Edgar Filing: NUPATHE INC. - Form 10-K

Table of Contents

| <b>Signature</b>  | <b>Title</b> | <b>Date</b>    |
|---|--------------|----------------|
| <hr/> <i>/s/ WILLIAM J. FEDERICI</i><br>William J. Federici   | Director     | March 27, 2013 |
| <hr/> <i>/s/ RICHARD S. KOLLENDER</i><br>Richard S. Kollender | Director     | March 27, 2013 |
| <hr/> <i>/s/ ROBERT P. ROCHE, JR.</i><br>Robert P. Roche, Jr. | Director     | March 27, 2013 |
| <hr/> <i>/s/ BRIAN J. SISKI</i><br>Brian J. Sisko             | Director     | March 27, 2013 |

Table of Contents**INDEX TO EXHIBITS**

| <b>Exhibit<br/>Number</b> | <b>Exhibit Description</b>  | <b>Form</b> | <b>Incorporated by Reference</b> |                | <b>Filing Date</b> | <b>Filed<br/>Herewith</b> |
|---------------------------|---|-------------|----------------------------------|----------------|--------------------|---------------------------|
|                           |   |             | <b>File No.</b>                  | <b>Exhibit</b> |                    |                           |
| 3.1                       | Restated Certificate of Incorporation of NuPathe Inc.   | 8-K         | 001-34836                        | 3.1            | August 12, 2010    |                           |
| 3.2                       | Bylaws of NuPathe Inc.  | 8-K         | 001-34836                        | 3.2            | August 12, 2010    |                           |
| 4.1                       | Certificate of Powers, Designations, Preferences, Rights and Qualifications, Limitations or Restrictions of Series A Preferred Stock        | 8-K         | 001-34836                        | 99.2           | September 26, 2012 |                           |
| 4.2                       | Amended and Restated Investor Rights Agreement, dated as of July 8, 2008, as amended on July 20, 2010 and August 4, 2010                    | S-1/A       | 333-166825                       | 4.1            | August 5, 2010     |                           |
| 4.3                       | Preferred Stock Warrant, dated as of March 29, 2007, as amended, issued to Oxford Finance Corp.   | S-1/A       | 333-166825                       | 4.2            | June 15, 2010      |                           |
| 4.4                       | Form of Warrant to Purchase Shares of Series B Preferred Stock, as amended  | S-1/A       | 333-166825                       | 4.3            | June 15, 2010      |                           |
| 4.5                       | Form of Warrant to Purchase Shares of Common Stock, dated October 23, 2012  | 8-K         | 001-34836                        | 99.3           | September 26, 2012 |                           |
| 4.6                       | Warrant, dated November 26, 2012, issued by NuPathe Inc. in favor of Hercules Technology Growth Finance, Inc.                               | 8-K         | 001-34836                        | 99.3           | November 27, 2012  |                           |
| 4.7                       | Registration Rights Agreement, dated as of August 2, 2011, between NuPathe Inc. and Aspire Capital Fund, LLC                                | 8-K         | 001-34836                        | 4.1            | August 2, 2011     |                           |
| 10.1*                     | Patent License Agreement, effective as of July 1, 2006, as amended, between NuPathe Inc. and The Trustees of the University of Pennsylvania | S-1/A       | 333-166825                       | 10.1           | June 15, 2010      |                           |
| 10.2*                     | Development and License Agreement, dated September 14, 2007, as amended, between NuPathe Inc. and LTS Lohmann Therapie-Systeme AG           | S-1/A       | 333-166825                       | 10.2           | July 27, 2010      |                           |
| 10.3                      | Asset Purchase and License Agreement, dated July 8, 2008, between NuPathe Inc. and Travanti Pharma Inc.                                     | S-1/A       | 333-166825                       | 10.3           | June 15, 2010      |                           |



Edgar Filing: NUPATHE INC. - Form 10-K

Table of Contents

| Exhibit Number | Exhibit Description   | Form  | Incorporated by Reference |         |                   | Filed Herewith |
|----------------|---|-------|---------------------------|---------|-------------------|----------------|
|                |   |       | File No.                  | Exhibit | Filing Date       |                |
| 10.4*          | Feasibility Evaluation Agreement, dated March 19, 2007, as amended, between NuPathe Inc. and Evonik Industries AG, Inc. (as successor to SurModics Pharmaceuticals, Inc.) | S-1/A | 333-166825                | 10.4    | July 27, 2010     |                |
| 10.5*          | License Agreement, dated September 23, 2009, between NuPathe Inc. and Evonik Industries AG, Inc. (as successor to SurModics Pharmaceuticals, Inc.)                        | S-1/A | 333-166825                | 10.5    | July 27, 2010     |                |
| 10.6*          | Equipment Funding Agreement, dated June 1, 2010, between NuPathe Inc. and LTS Lohmann Therapie-Systeme AG   | S-1/A | 333-166825                | 10.11   | July 27, 2010     |                |
| 10.7           | Amendment to Equipment Funding Agreement, January 18, 2013, between NuPathe Inc. and LTS Lohmann Therapie-Systeme AG  |       |                           |         |                   | X              |
| 10.8           | Equipment Purchase Agreement, dated April 23, 2012, by and between Automated Engineering, LLC and NuPathe Inc.  | 8-K   | 001-34836                 | 10.1    | April 26, 2012    |                |
| 10.9           | Office Space Lease, dated January 10, 2008, between NuPathe Inc. and Washington Street Associates II, L.P.  | S-1/A | 333-166825                | 10.10   | June 15, 2010     |                |
| 10.10          | First Amendment to Office Space Lease, dated November 1, 2010, between NuPathe Inc. and Washington Street Associates II, L.P.   | 10-K  | 001-34836                 | 10.12   | March 18, 2011    |                |
| 10.11          | Second Amendment to Office Space Lease, dated January 31, 2013, by and between Washington Street Associates II, L.P. and NuPathe Inc.                                     | 8-K   | 001-34836                 | 99.1    | February 5, 2013  |                |
| 10.12          | Loan and Security Agreement, dated November 26, 2012, by and between Hercules Technology Growth Finance, Inc. and NuPathe Inc.  | 8-K   | 001-34836                 | 99.1    | November 29, 2012 |                |

Edgar Filing: NUPATHE INC. - Form 10-K

Table of Contents

| <b>Exhibit Number</b> | <b>Exhibit Description</b>   | <b>Form</b>   | <b>Incorporated by Reference</b> |                | <b>Filing Date</b> | <b>Filed Herewith</b> |
|-----------------------|--|---------------|----------------------------------|----------------|--------------------|-----------------------|
|                       |  |               | <b>File No.</b>                  | <b>Exhibit</b> |                    |                       |
| 10.13                 | Secured Promissory Note, dated November 26, 2012, issued by NuPathe Inc. in favor of Hercules Technology Growth Finance, Inc.  | 8-K           | 001-34836                        | 99.2           | November 29, 2012  |                       |
| 10.14                 | Common Stock Purchase Agreement, dated August 2, 2011 between NuPathe Inc. and Aspire Capital Fund, LLC  | S-1           | 001-34836                        | 10.31          | August 2, 2011     |                       |
| 10.15                 | Securities Purchase Agreement, dated September 25, 2012, among NuPathe Inc. and the investors named therein  | 8-K           | 001-34836                        | 99.1           | September 26, 2012 |                       |
| 10.16#                | Amended and Restated 2005 Equity Compensation Plan, as amended, including forms of Incentive Stock Option Grant, Nonqualified Stock Option Grant and Restricted Stock Grant Agreement thereunder | S-1/A         | 333-166825                       | 10.12          | June 15, 2010      |                       |
| 10.17#                | NuPathe Inc. 2010 Omnibus Incentive Compensation Plan, as amended and restated effective April 11, 2011  | Schedule 14-A | 001-34836                        | Appendix A     | April 22, 2011     |                       |
| 10.18#                | Form of Incentive Stock Option Grant Agreement for awards under NuPathe Inc. 2010 Omnibus Incentive Compensation Plan  | 10-Q          | 001-34836                        | 10.2           | November 12, 2010  |                       |
| 10.19#                | Form of Nonqualified Stock Option Grant Agreement for awards under NuPathe Inc. 2010 Omnibus Incentive Compensation Plan   | 10-Q          | 001-34836                        | 10.3           | November 12, 2010  |                       |
| 10.20#                | Form of Nonqualified Stock Option Grant Agreement for awards to non-employee directors under NuPathe Inc. 2010 Omnibus Incentive Compensation Plan   | 10-Q          | 001-34836                        | 10.4           | November 12, 2010  |                       |
| 10.21#                | Form of Restricted Stock Grant Agreement for awards under NuPathe Inc. 2010 Omnibus Incentive Compensation Plan  | 10-Q          | 001-34836                        | 10.5           | November 12, 2010  |                       |
| 10.22#                | Form of Restricted Stock Unit Agreement for awards under NuPathe Inc. 2010 Omnibus Incentive Compensation Plan   |               |                                  |                |                    | X                     |
| 10.23#                | NuPathe Inc. 2010 Employee Stock Purchase Plan   | S-1/A         | 333-166825                       | 10.14          | July 21, 2010      |                       |

## Edgar Filing: NUPATHE INC. - Form 10-K

### Table of Contents

| Exhibit<br>Number | Exhibit Description  | Form  | Incorporated by Reference |         | Filing Date    | Filed<br>Herewith |
|-------------------|--|-------|---------------------------|---------|----------------|-------------------|
|                   |  |       | File No.                  | Exhibit |                |                   |
| 10.24#            | Employment Agreement, dated July 25, 2012, between Armando Anido and NuPathe Inc.  | 8-K   | 001-34836                 | 99.1    | July 30, 2012  |                   |
| 10.25#            | Amended and Restated Employment Agreement, dated July 25, 2012, between Terri B. Sebree and NuPathe Inc.                           | 8-K   | 001-34836                 | 99.2    | July 30, 2012  |                   |
| 10.26#            | First Amendment, dated March 27, 2013, to Amended and Restated Employment Agreement between Terri B. Sebree and NuPathe Inc.       |       |                           |         |                | X                 |
| 10.27#            | Amended and Restated Employment Agreement, dated July 25, 2012, between Keith A. Goldan and NuPathe Inc.                           | 8-K   | 001-34836                 | 99.4    | July 30, 2012  |                   |
| 10.28#            | Amended and Restated Employment Agreement, dated July 25, 2012, between Michael F. Marino and NuPathe Inc.                         | 8-K   | 001-34836                 | 99.5    | July 30, 2012  |                   |
| 10.29#            | Amended and Restated Employment Agreement, dated July 25, 2012, between Gerald W. McLaughlin and NuPathe Inc.                      | 8-K   | 001-34836                 | 99.6    | July 30, 2012  |                   |
| 10.30#            | Severance Agreement and Release of Claims, dated July 25, 2012, between Jane H. Hollingsworth and NuPathe Inc.                     | 8-K   | 001-34836                 | 99.7    | July 30, 2012  |                   |
| 10.31#            | Consulting Agreement, dated July 25, 2012, between Jane H. Hollingsworth and NuPathe Inc.  | 8-K   | 001-34836                 | 99.8    | July 30, 2012  |                   |
| 10.32#            | NuPathe Inc. Non-Employee Director Compensation Policy   | 10-K  | 001-34836                 | 10.26   | March 18, 2011 |                   |
| 10.33#            | Form of Director Indemnification Agreement   | S-1/A | 333-166825                | 10.20   | July 9, 2010   |                   |
| 10.34#            | List of current directors with a Director Indemnification Agreement in the form provided as Exhibit 10.33                          |       |                           |         |                | X                 |
| 10.35             | Third Amendment to Office Space Lease, dated March 27, 2013, by and between Washington Street Associates II, L.P. and NuPathe Inc. |       |                           |         |                | X                 |

## Edgar Filing: NUPATHE INC. - Form 10-K

### Table of Contents

| Exhibit Number | Exhibit Description  | Form | Incorporated by Reference |         |             | Filed Herewith |
|----------------|--|------|---------------------------|---------|-------------|----------------|
|                |  |      | File No.                  | Exhibit | Filing Date |                |
| 23.1           | Consent of KPMG LLP, independent registered public accounting firm   |      |                           |         |             | X              |
| 24.1           | Power of Attorney (included in the signature page to this Form 10-K)   |      |                           |         |             | X              |
| 31.1           | Certification of Chief Executive Officer pursuant to Rule 13a-14 (a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |      |                           |         |             | X              |
| 31.2           | Certification of Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002  |      |                           |         |             | X              |
| 32.1           | Certification by 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        |      |                           |         |             | X              |
| 101.INS        | XBRL Instance Document   |      |                           |         |             |                |
| 101.SCH        | XBRL Taxonomy Extension Schema Document  |      |                           |         |             |                |
| 101.CAL        | XBRL Taxonomy Extension Calculation Link Base Document   |      |                           |         |             |                |
| 101.LAB        | XBRL Taxonomy Extension Label Linkbase Document  |      |                           |         |             |                |
| 101.PRE        | XBRL Taxonomy Extension Presentation Linkbase Document   |      |                           |         |             |                |
| 101.DEF        | XBRL Taxonomy Extension Definition Linkbase Document   |      |                           |         |             |                |

\* Certain information in this exhibit has been omitted pursuant to an Order Granting Confidential Treatment issued by the Securities and Exchange Commission.

# Indicates management contract or compensatory plan or arrangement.

Furnished herewith.