Versartis, Inc.
Form 10-K
March 06, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2014

OR

¨TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-36361

Versartis, Inc.

(Exact name of Registrant as specified in its Charter)

| | |
|---|---|
| Delaware<br>( State or other jurisdiction of<br>incorporation or organization) | 26-4106690<br>(I.R.S. Employer<br>Identification No.) |
| 4200 Bohannon Drive, Suite 250 | 94025 |

Menlo Park, CA
(Address of principal executive offices) (Zip Code)
Registrant's telephone number, including area code: (650) 963-8580

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

| | |
|---|---|
| Common Stock, Par Value $0.0001 Per Share; | Common stock traded on the NASDAQ Global Select Market |

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

None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ¨ NO x

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ¨ NO x

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 x NO ¨

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). YES x NO ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) 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. x

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definition of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

| | | | |
|---|---|---|---|
| Large accelerated filer ¨ | | Accelerated filer | ¨ |
| Non-accelerated filer x (Do not check if a small reporting company) | | Small 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 x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The NASDAQ Global Select Market on June 30, 2014, the last business day of the registrant's most recently completed second fiscal quarter, was $182,105,415.

The number of shares of Registrant's Common Stock outstanding as of February 28, 2015 was 29,255,436.

Portions of the Registrant's Definitive Proxy Statement relating to the Annual Meeting of Shareholders, scheduled to be held on May 21, 2015, are incorporated by reference into Part III of this Report.

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PART I

Item 1. Business.

Unless the context otherwise requires, references in this Form 10-K to the "company," "Versartis," "we," "us" and "our" refer t
Versartis, Inc.

Overview

We are an endocrine-focused biopharmaceutical company initially developing our novel long-acting recombinant human growth hormone, VRS-317, for growth hormone deficiency, or GHD, an orphan disease. A key limitation to current recombinant human growth hormone, or rhGH, products is that they impose the burden of daily injections over multiple years, often resulting in poor compliance, which in turn can lead to suboptimal treatment outcomes in GHD patients. Despite this limitation, global annual sales from currently marketed rhGH products have grown to more than $3 billion in 2013. Based on market research, we believe that the market for daily rhGH products can continue to grow up to $4 billion by 2018. VRS-317 is intended to reduce the burden of daily treatment by requiring significantly fewer dosing events and injections, potentially improving compliance and, therefore, treatment outcomes. Accordingly, we believe VRS-317 may take significant market share. Our first indication for VRS-317 is pediatric GHD, which represents an approximately $1.5 billion existing market opportunity. We have completed the Phase 2a stage of our pediatric GHD clinical trial, demonstrating that weekly, semi-monthly and monthly dosing regimens over six months of treatment provide comparable safety and efficacy to daily rhGH administered at the highest approved dose on the labels of Genotropin® and Norditropin®, the two market leading daily rhGH products. We have submitted the Phase 3 clinical protocol to the FDA and have initiated the Phase 3 trial in the United States with submission in Europe and Canada in early 2015. We have also successfully submitted and cleared a Clinical Trial Notification, or CTN, with the Japanese regulatory agency, Pharmaceuticals Medicines and Devices Agency, or the PMDA, for a pediatric GHD Phase 2/3 registration trial in Japan and have begun initiating clinical sites in Japan. We are also developing monthly dosing of VRS-317 for adult GHD patients and plan to initiate a Phase 2/3 registration study in the second half of 2015. We may develop VRS-317 for idiopathic short stature, or ISS, and Turner Syndrome, which together accounted for approximately 20% of the global rhGH market in 2013. We have global rights to VRS-317 and, if VRS-317 is approved, given the highly concentrated prescriber base, we intend to commercialize it with our own specialty sales force in the United States and Canada, and potentially other geographies.

GHD is a chronic disease with multiple causes that affects two distinct patient groups, pediatric patients and adult patients, although rhGH treatment options for the two groups are the same. Children with GHD typically have pathologic degrees of short stature, a tendency toward obesity, delayed and deficient mineralization of the skeleton, impaired growth of skeletal muscle and development of a high risk lipid profile. GHD during adulthood manifests as alterations in body composition, such as decreased lean and increased fat mass with skeletal demineralization, and causes adverse changes in cardiovascular outcome markers. Patients with untreated GHD also face increased mortality.

The current standard of care for GHD is daily subcutaneous injections of rhGH. Patients treated with rhGH to offset their lack of adequate endogenous growth hormone receive thousands of injections over the course of many years. In therapy-compliant GHD children, rhGH therapy initially promotes "catch-up growth," enabling patients to approach or achieve heights on a standard growth curve, and thereafter permits them to maintain normal growth throughout the course of treatment. GHD children who are fully compliant with their daily treatments may attain an adult height

comparable to that of their family members and national norms. In therapy-compliant GHD adults, daily subcutaneous injections of rhGH have resulted in improvements in body composition parameters, bone density, cardiovascular outcomes and quality of life.

Despite the demonstrated benefits of rhGH therapy, published studies have shown that a majority of patients on a daily rhGH regimen, which requires up to 365 dosing events per year, are not fully compliant and fail to achieve expected treatment outcomes. Lack of compliance may be due to the burden of these frequent dosing events, each of which typically involves a series of twenty or more steps to prepare and inject rhGH. It often requires up to one hour per dosing event. Significant reductions in the degree of growth in pediatric GHD patients have been observed as a result of missing as few as two injections per week. As a result, pediatric endocrinologists have consistently sought a long-acting rhGH therapy to reduce the treatment burden on patients and their caregivers without compromising safety or efficacy. Importantly, other rhGH manufacturers have attempted to develop a long-acting product using microsphere, PEGylation, fusion and alternative delivery technologies. Each of these approaches has not been successful due to regulatory, safety, efficacy or manufacturing issues, or a combination thereof.

We believe VRS-317 will fulfill this significant need for a long-acting rhGH product. In our Phase 1a clinical trial, VRS-317 has demonstrated a half-life at least thirty times longer than daily rhGH and to date has shown a safety and tolerability profile comparable to that of marketed daily rhGH products. VRS-317, which is a new chemical entity, combines the same rhGH amino acid sequence utilized in currently approved rhGH products with a proprietary in-licensed half-life extension technology, XTEN, to enable less frequent administration. The XTEN technology is comprised of novel sequences of hydrophilic amino acids added at the genetic level as part of the manufacturing process. The resulting properties of VRS-317 enable us to produce it using common recombinant protein manufacturing techniques at a per-dose equivalent cost that we believe may be less than that of marketed rhGH products.

There are currently seven rhGH products marketed in the United States for the treatment of GHD. We are pursuing the same regulatory pathway for VRS-317 followed by most of these products for pediatric GHD patients: a dose-finding study and a Phase 3 registration trial with a primary endpoint of 12 month mean height velocity. Mean height velocity refers to the mean height change of the individuals in a treatment group over a specified time period. In June 2014, we completed the Phase 2a stage of our Phase 1b/2a pediatric GHD clinical trial, in which we evaluated weekly, semi-monthly and monthly dosing of VRS-317. In the completed Phase 1b stage of this clinical trial, we selected insulin-like growth factor-I, or IGF-I, which is a commonly used marker, as the primary pharmacodynamic marker to measure the effect of VRS-317 treatment. All subjects had relative IGF-I deficiency at baseline, and the increase from baseline in the 30 day average IGF-I standard deviation score, or IGF-I SDS, was proportional to dose, enabling the development of a pharmacokinetic/pharmacodynamic, or PK/PD, model. Based on this PK/PD model, in the Phase 2a stage of our clinical trial, a total monthly dose of 5.0 mg/kg of VRS-317 was administered to pediatric GHD patients either weekly, semi-monthly or monthly. Over the six months of treatment with VRS-317 in the Phase 2a stage of the study, VRS-317 was found to be safe and well tolerated in these pre-pubertal GHD children. In all three dose groups, VRS-317 maintained mean IGF-I increases over baseline and within the lower part of the therapeutic range (which we define as the portion of the therapeutic range with an IGF-I SDS from -1.0 to 0.0) without IGF-I overexposure, confirming the PK/PD model developed from the Phase 1b stage of the study. In addition, we demonstrated that six months of dosing of VRS-317, when given at weekly, semi-monthly and monthly intervals, achieves annualized six month height velocity (which was the study's primary endpoint) comparable to the annual height velocity for similar GHD children given a dose of daily rhGH that is the highest approved dose on the labels of Genotropin® and Norditropin®.

Upon completion of the Phase 2a stage of the trial, we offered patients the opportunity to participate in the Extension Study and to continue with VRS-317 treatment. Approximately 95% of the patients completing the Phase 2a stage elected to participate in the Extension Study. We increased the VRS-317 dose of the 20 patients who received the 1.15 mg/kg weekly dose to the 3.5 mg/kg semi-monthly dose for the Extension Study. As predicted by our PK/PD model, the IGF-I levels of these patients increased into the upper part of the therapeutic range without IGF-I overexposure. Daily rhGH therapy dosed at 40 µg/kg/day in similar moderate GHD patients caused a comparable IGF-I response in a published U.S. study. More importantly, the subset of patients who were treated with the 1.15 mg/kg weekly dose in the Phase 2a stage and then completed a full six months of treatment with the 3.5 mg/kg semi-monthly dose in the Extension Study achieved a nearly 2 cm/yr increase in mean annualized height velocity, from 7.5 cm/yr in the first six months to 9.3 cm/yr in the second six months. Typically, based on observations from existing approved daily rhGH therapies, a decrease in height velocity in the second six months of treatment would be expected with daily rhGH therapy. The results of the Extension Study to date have demonstrated a dose response in both IGF-I levels and height velocity supporting the selection of the 3.5 mg/kg semi-monthly dose as the Phase 3 dose. To date, the 3.5 mg/kg semi-monthly dose of VRS-317 has been found to be safe and well tolerated with only a few mild transient adverse events in a minority of patients.

We have met with the FDA and corresponded with the EMA to develop our Phase 3 registration study for pediatric GHD. We have submitted a protocol to the FDA for our randomized open label Phase 3 registration study in pediatric

GHD patients and initiated this study in early 2015. The study will take place in the United States, Western Europe and Canada using nearly identical inclusion and exclusion criteria as our Phase 1b/2a study and is expected to enroll comparable pre-pubertal, naïve to treatment pediatric GHD patients. We expect to enroll up to 136 patients in a 3:1 randomization comparing 3.5 mg/kg of VRS-317 semi-monthly to 34 µg/kg/day of rhGH, which is the highest approved dose on the labels of Genotropin® and Norditropin®. VRS-317 will be administered utilizing a 30 gauge needle, which is comparable to the needle sizes typically used for daily rhGH products. The primary endpoint for the study is non-inferiority between the two treatment groups based upon 12 month height velocity results. We anticipate having six month interim results in mid-2016 and final data in early 2017 to enable filing for marketing authorization in the United States, Europe and Canada assuming a successful trial.

We have also met with the PMDA in Japan regarding a registration trial of VRS-317 for pediatric GHD patients. From the PMDA's feedback, we have designed a pediatric Phase 2/3 registration study and have submitted the study protocol and Clinical Trial Notification to the PMDA. In addition, we will be conducting an Extension Study in Japan to obtain additional information on switching GHD children currently on daily rhGH therapy to VRS-317 therapy and on the long-term safety of VRS-317. We are currently initiating clinical sites in Japan and intend to begin of enrolling pre-pubertal naïve to treatment GHD children in early 2015.

In the first half of 2015, we intend to meet with the FDA and obtain advice from the EMA regarding our plans for a Phase 2/3 registration study in GHD adults evaluating monthly dosing of VRS-317. We anticipate that this study will be a randomized double blind placebo controlled study to assess the safety and efficacy of VRS-317 in GHD adults. This study will be conducted in the United States, Western Europe, Canada and Australasia, and we intend to begin enrollment in the second half of 2015. We believe that monthly VRS-317 dosing in GHD adults would offer a significant advantage in convenience and compliance over the weekly rhGH products in clinical development by other companies.

In addition to pediatric and adult GHD, we may study VRS-317 in ISS and Turner Syndrome, for which daily rhGH products are currently approved. ISS and Turner Syndrome comprise significant segments of the remaining portion of the rhGH market and are likely potential indications for future VRS-317 clinical development.

We have worldwide development and commercialization rights to VRS-317. If VRS-317 is approved, we believe it has the potential to capture a significant share of the existing rhGH market. We intend to market VRS-317 in the United States and Canada through a specialty sales force of approximately 50 people, targeting high prescribing pediatric endocrinologists. In Europe we may pursue a similar commercialization strategy or seek collaboration, distribution and/or marketing arrangements with third parties. In Japan, we may develop and commercialize VRS-317 ourselves, or may collaborate with third parties.

We are led by a team of experienced biotechnology industry executives and recognized experts in the treatment of GHD who bring significant capabilities in the development and commercialization of a novel long-acting rhGH therapy. Our management team is led by our co-founder and Chief Executive Officer, Jeffrey L. Cleland, Ph.D. Dr. Cleland led the development of the only FDA-approved long-acting rhGH product, Nutropin Depot®, while at Genentech, Inc., or Genentech. Our financial team is led by our Chief Financial Officer, Joshua T. Brumm, who has previously led finance teams for both emerging growth biotechnology and medical device companies, including Pharmacyclics, Inc. and ZELTIQ Aesthetics, Inc. Mr. Brumm has extensive commercial and operating experience in addition to having completed a number of financial and strategic transactions. Our clinical team is led by George Bright, M.D., Vice President of Clinical Development, Bert Bakker, M.D., Ph.D., Senior Vice President of Medical Affairs, and Eric Humphriss, M.B.A., Vice President of Clinical Operations. Dr. Bright, a pediatric endocrinologist, has been treating children with GHD for more than 35 years and was a leader in the development of a daily rhGH product, Norditropin®, and a product for the treatment of IGF-I, deficiency, Increlex®. Dr. Bakker, a pediatric endocrinologist, has been treating children with GHD for more than 30 years and managed the registry for Genentech's rhGH products, and he has also led the clinical development of a long acting rhGH candidate. Mr. Humphriss managed Genentech's pediatric GHD registry. Our manufacturing team is led by Patrick Murphy, who headed the team that manufactured the first rhGH product, Protropin®, while at Genentech. Our device team is led by Greg Yedinak, who has developed and led manufacturing of ZP Patch Technology® and was also involved in production of Protropin®, Nutropin®, and Nutropin AQ®, while at Genentech. Leading our commercialization efforts is Keith Lui, who led the launch of Imbruvica® and ZELBORAF® and worked on the marketing teams for Avastin® and Rituxan®.

Our strategy

Our goal is to become a leading biopharmaceutical company focused on developing and commercializing therapeutics. The key elements of our strategy are to:

- Complete the clinical development of and seek regulatory approval for semi-monthly dosing of VRS-317 for the treatment of GHD in children in the United States, Europe, Canada and Japan. We are currently focused on independently completing the clinical development of VRS-317 in pre-pubertal naïve to treatment children with GHD. In early 2015, we initiated a Phase 3 registration trial in the United States, Western Europe and Canada. The Phase 3 trial is designed to demonstrate non-inferiority of VRS-317 compared to the current standard of care, daily

rhGH at the highest approved dose on the labels of Genotropin® and Norditropin® (34 µg/kg/day), with 12 month mean height velocity as the primary efficacy endpoint. We expect to report interim six month mean height velocity results from this trial in mid-2016 followed by top line twelve month mean height velocity results in early 2017. In Japan, we are initiating a Phase 2/3 registration trial in early 2015. Extension Studies will be conducted for both the Phase 3 and Phase 2/3 trials to gather long-term safety data as well as data on switching patients from daily rhGH therapy to VRS-317 treatment.

- Complete the clinical development of and seek regulatory approval for monthly dosing of VRS-317 for the treatment of GHD in adults in the United States, Europe, Canada, Australia and other countries. In our Phase 1a clinical trial in adult GHD patients, we demonstrated the potential for monthly dosing. We believe that over half of the adults diagnosed with GHD either refuse therapy or stop therapy due to the burden of daily injections. Reducing the dosing frequency from daily to monthly may increase compliance and maintain more patients on long-term therapy. In the first half of 2015, we plan to meet with the FDA and seek scientific advice from the EMA regarding our planned Phase 2/3 registration trial in GHD adults. We will propose a randomized double blind placebo controlled study to evaluate changes in body composition, such as fat mass or truncal fat, with monthly dosing of VRS-317. Our study design will be comparable that used for approval of daily rhGH products for use in GHD adults. We anticipate initiating the Phase 2/3 registration trial in the second half of 2015 in the United States, Western Europe, Canada and Australasia.

- Commercialize VRS-317 independently in the United States and Canada with a specialty sales force, and identify a commercialization strategy in Europe and other countries to maximize our returns. We believe that a long-acting product candidate like VRS-317, if approved for pediatric GHD, could take significant market share from currently marketed products, all of which require daily injections. Of the over $3 billion and growing global rhGH market, we believe that sales of rhGH products for pediatric GHD currently represent approximately $1.5 billion. We believe the United States and European markets for rhGH for pediatric GHD are currently approximately $450 million and $550 million, respectively, and that the global market for rhGH for adult GHD is currently approximately $500 million. If VRS-317 receives marketing approval, we plan to commercialize it in the United States and Canada ourselves with a specialty sales force of approximately 50 people targeting high prescribing pediatric endocrinologists. In Europe and other countries, we may pursue a similar commercialization strategy or seek collaboration, distribution and/or marketing arrangements with third parties.
- Evaluate registration and commercialization, either independently or in collaboration with third parties, in Japan. The market for daily rhGH products in Japanese GHD children was approximately $500 million in 2013. The dose of rhGH used in Japan (25 µg/kg/day) is lower than that used in the United States (43 µg/kg/day) leading to lower efficacy in Japanese GHD children compared to U.S. GHD children. VRS-317, if approved in Japan at the same dose as in the United States, may offer Japanese GHD children an opportunity to achieve similar height velocity to GHD children in the United States. We intend to demonstrate in the Phase 2/3 registration trial in Japanese GHD children that the mean 12 month height velocity achieved with VRS-317 will be better than that observed historically for daily rhGH therapy. The potential for a combination of better treatment outcomes and improved compliance from VRS-317 in Japan may provide significant differentiation from the currently marketed rhGH products. Once we have clinical trial results from the global pediatric GHD Phase 3 trial and the pediatric GHD Phase 2/3 registration trial in Japan, we will evaluate the optimal registration and commercialization strategy in Japan, which may include seeking a collaboration, distribution and/or marketing arrangements with third parties.
- Explore the use of VRS-317 in ISS and Turner Syndrome. In addition to pursuing approval for VRS-317 in the approximately $1.5 billion pediatric GHD market, we may develop the product candidate for one or more additional indications in the overall $3 billion rhGH market. In particular, we may explore ISS and Turner Syndrome indications, for which the burden of daily rhGH therapy significantly impacts compliance. We may consider initiating one or more trials in these additional indications to potentially expand the market for VRS-317.
- Evaluate the opportunity to in-license or acquire complementary products, product candidates or technologies. We plan to expand our product pipeline through opportunistically in-licensing or acquiring the rights to complementary products, product candidates and technologies. We may seek additional licenses to develop the XTEN half-life extension technology for use with drugs that affect other endocrine disease targets. We expect that we will not generally engage in early stage research and drug discovery and will avoid the related costs and risks of these activities.

Growth hormone deficiency

GHD is a chronic disease with multiple causes that can affect two distinct patient groups, pediatric patients and adult patients. The disease leads to significant health problems in both pediatric and adult patients, and untreated patients face increased mortality. There are currently seven marketed rhGH products in the United States for the treatment of GHD. However, a key limitation of these products is the burden of daily injections, which can limit compliance and lead to suboptimal treatment outcomes. As such, we believe that there is a significant unmet need for an improved therapeutic option for both pediatric and adult GHD patients.

Pediatric GHD

GHD in children is characterized by reduced growth performance and a loss of height as compared to a patient's age-matched peers. We estimate that approximately 80% of childhood cases are idiopathic, or of unknown cause. GHD may also result from congenital defects in the anatomy of the hypothalamus and pituitary, often associated with mutations in genes responsible for the differentiation and development of the cells in the pituitary that produce human

growth hormone, or hGH, or the receptor for hGH releasing hormone. Other causes of GHD in children include traumatic brain injuries, neoplastic lesions of the central nervous system and/or the required surgical and/or radiation therapies, or side effects of some chemotherapy procedures.

In all cases, pediatric GHD is diagnosed based on several clinical parameters, including heights substantially below a normal growth curve range, a demonstration that hGH is deficient by two or more hGH stimulation tests or by frequent hGH sampling protocols, the ruling out of other potential causes of growth failure and, where required, genetic testing and/or magnetic resonance imaging, or MRI, of the brain, hypothalamus and pituitary.

Idiopathic GHD in children does not typically persist into adult life, while patients with organic causes of pediatric GHD often do experience adult GHD. Guidelines recommend that pediatric patients be treated until adult height is reached. In adulthood, pediatric GHD patients require additional screening to establish whether there is a need to undergo retreatment with rhGH. Research indicates that, depending upon the test group and screening methodology, up to 87.5% of adults with childhood onset GHD were no longer

diagnosed as suffering from GHD upon retesting. As such, the prevalence for children and adults is separately estimated from literature studies and the total prevalence taken as the sum of childhood onset and adult onset cases.

The available data from the United States and European Union consistently estimate the prevalence of GHD in children as just below 3 per 10,000. One of the most comprehensive studies of the prevalence of GHD is the Utah Growth Study conducted in the early 1990s. This study estimated a prevalence of GHD in Utah school children of 1 in 3,480, which is equal to 2.87 per 10,000.

Adult GHD

Most cases of adult-onset GHD, a well-recognized clinical disorder, are related to the occurrence and treatment of pituitary adenomas or as a result of traumatic brain injuries. The diagnosis of adult GHD requires a demonstration of insufficient levels of hGH by hGH stimulation testing or frequent hGH sampling techniques, but GHD may be diagnosed in some adults by the finding of three other pituitary hormone deficiencies in combination with a low IGF-I level.

The available data from the United States and European Union consistently estimate the prevalence of GHD in adults as approximately 1 per 10,000. The British Society of Endocrinology estimates the prevalence of adult-onset GHD as 1 in 10,000 in the United Kingdom, and we believe there is a similar prevalence in the United States.

Combining the GHD prevalence estimates in adults (1 in 10,000) and children (3 in 10,000) yields a combined GHD prevalence estimate of 4 in 10,000 in the United States and Europe.

Treatment goals and currently available therapies for GHD

In GHD children, early treatment goals are the establishment of “catch-up” growth to decrease differences in height between the patient and similarly aged peers and preventing the accrual of additional deficits from untreated GHD. Long-term treatment goals extend to the attainment of heights comparable to family members and national norms and require approximately seven years for these goals to be achieved. Growth prediction models, based on treatment outcomes in large registries of GHD children, may be used to individualize rhGH dosing. In adults, the desired treatment outcomes are improvements in body composition parameters, skeletal mineralization to prevent osteopenia, metabolic and inflammatory markers to reduce cardio- and cerebrovascular disease, and quality of life.

Daily subcutaneous administration of rhGH is used as a replacement therapy for daily production of hGH to obtain these treatment goals. Administration of rhGH stimulates the production of IGF-I, which is important for the regulation of normal physiology. Daily rhGH therapy does not mimic the typical endogenous pulsatile release of hGH in normal healthy individuals, but daily injections of rhGH have been demonstrated for over 30 years to be a safe and effective therapy for treatment of GHD. In addition, clinical studies of continuous infusion of rhGH with a pump demonstrate comparable mean height velocity, IGF-I levels and safety to those observed with daily rhGH injections for six months. No other treatment modalities are known to be effective, and there are no known preventative therapies for GHD.

All currently marketed rhGH products in the United States—Norditropin® (Novo Nordisk), Humatrope® (Eli Lilly), Nutropin-AQ® (Roche/Genentech), Genotropin® (Pfizer), Saizen® (Merck Serono), Tev-tropin® (Teva Pharmaceuticals) and Omnitrope (Sandoz GmbH)—are administered by daily subcutaneous injections, and no major pharmacological differences are known to exist between these products with respect to safety or efficacy. The daily rhGH dose for these marketed products for the treatment of pediatric GHD ranges from 24 to 43 μg rhGH/kg/day. Despite approvals as early as 2006, biosimilars represented less than 10% of the market in 2013, even with initial price discounts of 20% to 25% relative to branded products. One biosimilar manufacturer has since abandoned its

initial discounting strategy in favor of pricing and marketing strategies similar to those used by manufacturers of branded products. Manufacturers of the branded products continue to emphasize novel delivery methods and devices along with complementary services in order to differentiate themselves from each other as well as to minimize the impact of any future biosimilars. Existing rhGH products are available as a lyophilized powder with diluents, or rhGH for injection using vial and syringe, auto-injectors or pen devices.

Limitations of currently available therapies

In order to achieve the benefits associated with the currently marketed daily subcutaneous injections of rhGH, patients must maintain strict dosing compliance. Full dosing compliance requires patients to endure painful, daily injections and for parents or caregivers to undergo the many preparation steps required for rhGH administration on a daily basis. Studies from diverse geographic areas demonstrate that full compliance with daily rhGH dosing presents challenges for patients and caregivers and, as a result, doses are frequently missed. Because there is no immediately noticeable effect of treatment, as with insulin, for example, patients and caregivers may not perceive a detriment to skipping doses. Patients may also become noncompliant from dissatisfaction with near

term treatment outcomes. In a study of children with GHD, 46% of patients missed two injections per week and 26% missed three or more injections per week. As shown in the figure below, for patients missing two or more injections per week there was a statistically significant reduction in their change in height velocity standard deviation score, or HVSDS, compared to high-compliance patients. A greater HVSDS indicates more rapid growth.

In additional studies, 33% to 77% of children had levels of noncompliance that can be estimated to have reduced efficacy as measured by first year height velocity. Although a similar study in GHD adults has not been reported, we believe there would be a comparable outcome of diminished therapeutic benefit. Continued treatment without substantial therapeutic benefit is not generally considered an acceptable approach, especially in the treatment of children with repeated subcutaneous injections. Accordingly, methods to increase treatment compliance, such as a significant reduction in frequency of injections, may have the therapeutic benefit of maintaining the efficacy observed for daily rhGH therapy in highly compliant GHD children and adults and improve treatment outcomes for those with poor compliance with daily injections. For example, enhanced clinical responsiveness has been demonstrated for long-acting forms of gonadotropin releasing hormone in fertility studies. Similarly, the relevant medical literature indicates that frequency of administration significantly affects patients' adherence to chronic treatments for a number of disorders. We believe that adherence to treatment can be improved with decreased frequency of administration.

Our approach to increased compliance and better therapeutic outcomes is to reduce the frequency of subcutaneous injections. In children in particular, we and others who have studied long-acting rhGH anticipate that reducing injection frequency may lead to increased treatment compliance, and in turn, better outcomes.

Attempts to develop long-acting rhGH products

We believe that for a long-acting rhGH product to be successful, there should be minimal trade-offs compared to the current daily rhGH products when assessing safety, efficacy and manufacturing.

Previous attempts by others to develop a long-acting rhGH have not succeeded due to regulatory, safety, efficacy or manufacturing issues, or a combination of those factors. The only FDA-approved long-acting rhGH, Nutropin Depot, was developed by Genentech and approved in 1999. Nutropin Depot was dosed semi-monthly or monthly with a large gauge needle and caused significant pain on injection with nodule formation and lipoatrophy at the injection sites. Lipoatrophy is a localized loss of fat tissue that is stimulated by a sustained exposure of subcutaneous tissue to rhGH and can cause undesirable skin deformations. The efficacy of Nutropin Depot was less than the approved daily rhGH products because the duration of the rhGH release from the formulation was less than the dose interval. Nutropin Depot was ultimately removed from the market due to the significant resources required to continue manufacturing and commercializing the product. Additional attempts at sustained release formulations have not yet led to marketed products in the United States, Europe or Japan, due to regulatory, safety, efficacy and/or manufacturing issues. Three published attempts have been made at PEGylation of rhGH, which is a process to chemically attach polyethylene glycol to rhGH in order to extend its residence time in the bloodstream after administration. This residence time is commonly measured by half-life, which is the amount of time it takes for a quantity to decline to one-half its starting value. Pfizer first attempted PEGylation of rhGH to achieve a weekly dosed product. However, the PEGylated rhGH was not readily absorbed at the injection site and caused severe lipoatrophy in GHD children,

resulting in a discontinuation of development. Another attempt to PEGylate rhGH by Novo Nordisk also failed in GHD children because a weekly profile was not achieved. Merck Serono in collaboration with Ambrx evaluated an alternative method of PEGylation, but the rights to the product candidate were returned to Ambrx after completion of a clinical trial in adults. The past attempts at long-acting rhGH have all had significant trade-offs that diminished their commercial potential.

Attributes of VRS-317

VRS-317 was engineered using XTEN technology to extend the residence time in the bloodstream by reducing the clearance of rhGH from the body by the two primary mechanisms, kidney filtration and receptor mediated clearance. XTEN technology was developed by Amunix Operating, Inc., or Amunix, and involves the use of novel sequences of natural hydrophilic amino acids that can be genetically fused to a desired protein, such as rhGH in the case of VRS-317. These novel sequences have been shown to be non-immunogenic and to enable the tuning of therapeutic protein properties to obtain the desired pharmacological properties in vivo. In VRS-317, a long N-terminal XTEN sequence, $XTEN_1$, is added to rhGH as a fusion protein, increasing the hydrodynamic size of the rhGH and thereby reducing glomerular filtration. A C-terminal XTEN sequence, $XTEN_2$, is also added to potentially reduce receptor mediated clearance by decreasing receptor binding. VRS-317 (119 kDa) has a molecular weight 5.4 times greater than rhGH (22 kDa). The difference in molecular weight is the result of the additional XTEN polypeptide chains, and no changes have been made to the rhGH sequence. In published preclinical studies, VRS-317 has been demonstrated to have the same dose dependent biological effects on IGF-I secretion and bone growth as rhGH.

VRS-317 is expressed as a soluble protein in the periplasm of the E. coli bacteria that are commonly used in the manufacture of biological molecules, or biologics. After isolation from the cells, VRS-317 is purified by a series of column chromatography steps, buffer exchanged and then concentrated to achieve the final bulk drug substance. VRS-317 is a clear aqueous solution manufactured for subcutaneous injection.

We believe VRS-317 has the following advantages that support its rapid development:

- VRS-317 has a longer half-life than daily rhGH products and may offer a significantly more convenient dosing solution for GHD patients. VRS-317 has been shown in our clinical trials to have the advantage of a longer half-life and potentially require less frequent dosing than daily rhGH. In our Phase 1a clinical trial in adults with GHD, VRS-317 had a mean elimination half-life of 131 hours at the highest dose tested, representing at least a thirty-fold increase in half-life as compared to the two to four hour half-lives reported for subcutaneously administered rhGH. The prolonged half-life of VRS-317 provided sustained pharmacodynamic responses that lasted over the duration of each dosing interval tested in the Phase 2a stage of our pediatric GHD Phase 1b/2a clinical trial: weekly, semi-monthly and monthly. In the Phase 2a stage, VRS-317 dosed weekly, semi-monthly or monthly was demonstrated to have comparable safety and efficacy to daily rhGH at highest approved dose on the labels of Genotropin® and Norditropin®. We were able to successfully develop and confirm a PK/PD model from the Phase 1b/2a trial. This model enabled us to increase the VRS-317 1.15 mg/kg weekly dose to 3.5 mg/kg semi-monthly in the Extension Study, resulting in a substantial increase in mean annualized height velocity and an increase in the IGF-I levels to the upper part of the therapeutic range without IGF-I overexposure. These dose response results combined with our PK/PD model demonstrate the ability to select a dose and regimen with the potential to achieve the desired efficacy in future clinical trials.
- VRS-317 has demonstrated an attractive safety and tolerability profile in GHD children. In our clinical program to date, VRS-317 has been found to be well tolerated with no serious or unexpected adverse events. In particular, lipoatrophy, a localized loss of fat tissue that can be stimulated by a sustained exposure of adipocytes to rhGH in the

subcutaneous injection site, has not been seen after repeated doses in the Phase 2a stage of our Phase 1b/2a clinical trial or in the ongoing Extension Study. Additionally, there have been no reports in our clinical trials of VRS-317 of common problems that were observed in prior studies of long-acting formulations, such as nodule formation at the injection site. In the Extension Study, VRS-317 was found to be safe and well tolerated in patients completing six months of VRS-317 treatment (12 months of total treatment), the number of adverse events declined in the second six months of therapy and there were no new adverse events or increases in adverse events for patients switching to the 3.5 mg/kg semi-monthly dose. In addition, there were very few

IGF-I SDS excursions above 2.0 and no excursions above 3.0. In our Phase 3 clinical trial, VRS-317 will be administered using a 30 gauge needle, which is comparable to the needle sizes typically used for daily rhGH products. At the pediatric Phase 3 dose of 3.5 mg/kg semi-monthly, a majority of the patients will receive a single injection. The attractive safety and tolerability profile of VRS-317 in GHD children is especially important in the context of rhGH as a chronic therapy.

- VRS-317 has the potential to provide comparable efficacy to the highest approved dose on the labels of Genotropin® and Norditropin®. In the completed Phase 2a stage of our Phase 1b/2a clinical trial, we demonstrated that weekly, semi-monthly and monthly VRS-317 dosing maintained mean IGF-I increases over baseline and within the lower part of the therapeutic range without IGF-I overexposure, confirming the PK/PD model developed from the Phase 1b stage of the study. We also demonstrated that six months of dosing of VRS-317, when given at weekly, semi-monthly and monthly intervals, achieves a mean annualized six month height velocity (which was the study's primary endpoint) comparable to the annual height velocity for similar GHD children given a dose of daily rhGH that is the highest approved dose on the labels of Genotropin® and Norditropin®. In the Extension Study to date, 57 pediatric GHD patients from the Phase 2a stage of our Phase 1b/2a study have completed 12 months of continuous VRS-317 dosing. During the Extension Study two dose groups of pediatric GHD patients were maintained on the 2.5 mg/kg semi-monthly or 5.0 mg/kg monthly dose from the Phase 2a stage until they had received 12 months of continuous treatment. Mean twelve month height velocity in these patients was not significantly different from the mean annualized height velocity at earlier time points. Typically, based on observations from existing approved daily rhGH therapies, a decrease in mean height velocity in the second six months of treatment would be expected over time with daily rhGH therapy. To move the IGF-I levels into the upper part of the therapeutic range, we used our PK/PD model and increased the VRS-317 dose of the twenty 1.15 mg/kg weekly dose patients in the Extension Study to 3.5 mg/kg semi-monthly. The IGF-I levels of these patients increased into the upper part of the therapeutic range without IGF-I overexposure, as predicted by our PK/PD model. Daily rhGH therapy dosed at 40 µg/kg/day in similar moderate GHD patients caused a comparable IGF-I response in a published U.S. study. More importantly, the subset of patients who were treated with the 1.15 mg/kg weekly dose in the Phase 2a stage and then completed a full six months of treatment with the 3.5 mg/kg semi-monthly dose in the Extension Study achieved a nearly a 2 cm/yr increase in mean annualized height velocity, from 7.5 cm/yr in the first six months to 9.3 cm/yr in the second six months. As noted above, a decrease in height velocity in the second six months of treatment would typically be expected with daily rhGH therapy. The results of the Extension Study to date have demonstrated a dose response in both IGF-I levels and height velocity supporting the selection of 3.5 mg/kg VRS-317 semi-monthly as the pediatric Phase 3 dose.
- VRS-317 has the potential to achieve greater height velocities compared to daily rhGH approved for use in Japanese GHD children. In Japan, children with GHD treated with daily rhGH receive the lowest dose of any developed country (the only approved dose in Japan is 25 µg/kg/day). As a result, GHD children treated with rhGH in Japan have a lower rate of first-year growth than GHD children treated with rhGH at 43 µg/kg/day in the United States. Despite the lower approved dose in Japan, the Japanese government pays a higher price per unit of rhGH and a similar price per patient as compared to pricing in the United States. We intend to select a dose of VRS-317 for use in Japan that would provide first-year growth comparable to GHD children in the United States. As such, VRS-317 may offer the opportunity to provide Japanese GHD children with height velocities comparable to GHD children in the United States, which would be superior efficacy to the current Japanese daily rhGH dose.
- VRS-317 has the potential to be dosed as a single monthly injection in GHD adults. The successful demonstration of monthly dosing in the pediatric Phase 1b/2a trial combined with the results of our completed Phase 1a trial in GHD adults support the development of a monthly VRS-317 dosing regimen in GHD adults. Currently, GHD adults receive daily rhGH injections and titrate their dose of rhGH in order to achieve IGF-I responses in the normal range. From our current knowledge of the PK/PD profile of VRS-317 in GHD adults, we are able to develop dosing algorithms to improve our ability to titrate GHD adults to the appropriate monthly VRS-317 dose to achieve IGF-I levels in the normal range leading to beneficial changes in body composition. Because GHD adults require significantly lower doses of rhGH or VRS-317 than GHD children, we are able to dose GHD adults with the current VRS-317 formulation once per month with a single injection using a 30 gauge needle.

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VRS-317 has a manufacturing process that is less complex than the traditional rhGH manufacturing processes and may ultimately offer a cost-of-goods advantage versus current rhGH products. VRS-317 is expressed in E. coli as a soluble protein. The XTEN amino acid sequences fused to rhGH to form VRS-317 confer improved pharmaceutical properties compared to rhGH alone, including greater solubility, a lower isoelectric point and a higher net negative charge. These improved properties enable a straightforward purification process without the need for complex steps that can reduce manufacturing yields, such as protein folding. The steps used in the process for manufacturing VRS-317 drug substance all involve a common biotechnology manufacturing process. VRS-317's improved properties simplify the purification process compared to traditional rhGH products, and we believe that when produced on a commercial scale, it may offer a cost-of-goods advantage over current rhGH products.

- VRS-317 has the potential for monthly dosing in GHD children. We have initiated a life cycle strategy to develop a once monthly formulation of VRS-317 for GHD children. The results of our completed Phase 1b/2a clinical trial along with 12 month height velocity and safety data reported from our ongoing Extension Study support the potential for monthly dosing of VRS-317 in GHD children. The dose selected for our pediatric Phase 3 trial and tested in the Extension Study is 3.5 mg/kg semi-monthly, equivalent to 7 mg/kg once per month. We have studies underway seeking to develop a formulation of VRS-317 that would enable us to deliver a minimum of 7 mg/kg once per month as a single injection to the majority of pediatric GHD patients. If successful, we would meet with the FDA and seek advice from the EMA regarding the ability to bridge to this new formulation and the design of a Phase 3 registration study to support monthly VRS-317 dosing in GHD children.

Clinical development for VRS-317

The clinical development of VRS-317 was initiated in December 2010 with an Investigational New Drug, or IND, application submitted by Versartis in the United States and a parallel submission of a Clinical Trial Application in the United Kingdom. Additional submissions were provided to the Swedish and Serbian regulatory authorities. The first in-human study, our Phase 1a clinical trial, was conducted in GHD adults in the United States, the United Kingdom, Sweden and Serbia. The Phase 1a clinical trial enrolled patients on a stable dose of daily rhGH therapy who were withdrawn from therapy until their IGF-I levels were below a pre-specified level and then randomized into either placebo or VRS-317 treatment. This double blind placebo controlled Phase 1a clinical trial enabled the objective assessment of the safety of VRS-317 treatment compared to placebo. The Phase 1a clinical trial was completed in early 2012.

Upon the successful completion of the Phase 1a clinical trial, we initiated a Phase 1b/2a clinical trial in GHD children in the United States by filing an amendment to our existing IND. The Phase 1b stage of the clinical trial included 48 naïve to treatment pre-pubertal GHD children receiving a single dose of VRS-317 in an ascending dose design. The starting dose used in the study was the highest dose tested in adults (0.80 mg/kg VRS-317) and escalation was stopped at a dose of 6.0 mg/kg VRS-317 after the desired IGF-I response was achieved. No stopping criteria were met at any of the dose levels tested. Patients completing the Phase 1b stage of the study were allowed to enroll in the Phase 2a stage. The Phase 2a stage was fully enrolled with 64 patients, and patients previously treated in the Phase 1b stage were balanced for characteristics (age and previous VRS-317 exposure) with the potential to affect the primary endpoint (mean height velocity) across each of the three dosing arms.

Completed Phase 1a clinical trial in GHD adults

In adult GHD patients, VRS-317 concentrations and IGF-I responses were proportional to dose in the completed Phase 1a single ascending dose study. In adults with GHD, VRS-317 has a mean elimination half-life of 131 hours at the highest dose tested. The extended half-life of VRS-317 represents at least a thirty-fold increase in half-life as compared to the two to four hour half-lives reported for subcutaneously administered rhGH. VRS-317 concentrations at the end of the month in this study were proportional to total dose, further supporting the potential for up to monthly dosing.

After a single subcutaneous dose of 0.80 mg/kg of VRS-317, GHD adults achieved a normalization of their IGF-I levels (IGF-I standard deviation score (SDS) between -1.5 and +1.5) for an average of three weeks. IGF-I SDS is a measure of the difference in IGF-I concentration between a single GHD patient and the mean for normal adults of the same sex and comparable age. These results suggested that a lower total rhGH dose in the form of VRS-317 may provide comparable safety and efficacy over the course of treatment.

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All subjects completed the study. The highest dose assessed in the Phase 1a study of GHD adults (0.80 mg/kg VRS-317) was reported to be well tolerated, with no significant safety issues observed. A minority of patients reported drug-related adverse events, or AEs. The reported AEs were generally mild, transient and of the type generally expected when rhGH is administered to an adult with GHD. There were no serious or unexpected AEs. There were no laboratory safety signals observed. In addition, VRS-317 at 0.80 mg/kg in GHD adults increased mean IGF-I into the customary therapeutic range (IGF-I SDS > - 1.5) for approximately three weeks. GHD adults are typically titrated with daily rhGH to achieve an IGF-I SDS in the normal range. In addition, the dose of rhGH required to achieve normalization of IGF-I is dependent upon the patient's age and sex. Unlike the above single ascending dose study, the Phase 2/3 registration trial of VRS-317 in GHD adults will include stratification for age and sex. PK/PD modeling was performed using the Phase 1a results, and this model enables the development of dosing algorithms for patients based upon their age and sex. The Phase 2/3 trial is designed to demonstrate a safe and effective once monthly dose of VRS-317 as a single injection with a 30 gauge needle in GHD adults.

Completed Phase 1b stage of the Phase 1b/2a clinical trial in GHD children

GHD children require a much higher dose of daily administered rhGH (24 - 43 µg/kg/day) than GHD adults (2 - 12 µg/kg). The dosing recommendation for rhGH in GHD children is dependent upon the local regulatory agency granting the drug approval. It was therefore likely that a higher dose of VRS-317 would be required in GHD children compared to GHD adults.

A Phase1b/2a study was conducted in pre-pubertal GHD children in the United States to assess the safety, pharmacokinetics, and IGF-I responses to VRS-317 in the Phase 1b stage. We enrolled pre-pubertal naïve to treatment patients who were representative of a typical moderate GHD patient population treated with growth hormone therapy in the United States and parts of Western Europe where GHD is diagnosed and routinely treated. The mean age was seven to eight years old, with a mean height standard deviation score of minus 2.5, a mean bone age delay of one to one and a half years and a mean growth hormone stimulation test result of 5 ng/mL. Age, height standard deviation score and growth hormone stimulation test result have the greatest impact on response to rhGH therapy. When starting rhGH therapy, younger children grow faster than older children and more severe GHD patients, e.g. those with lower height standard deviation scores and/or lower growth hormone stimulation test results, grow faster than moderate GHD patients. Comparisons across pediatric GHD studies can only be done if these key attributes are similar.

In the Phase 1b stage, 48 pre-pubertal, naïve to treatment children received a single subcutaneous dose of VRS-317. GHD was diagnosed by medical history, several clinical parameters and paired growth hormone stimulation tests. In ascending order, subjects received VRS-317 doses of 0.80, 1.20, 1.80, 2.70, 4.00 or 6.00 mg/kg. Blood samples for PK/PD determinations were obtained at six time points over 30 days. Safety monitoring was carried out for 60 days post-dose. Stopping rules were specified by protocol. The membership and activities of the Safety Review Committee, or SRC, were specified in the SRC Charter, which was developed prior to study onset. SRC meetings were successfully concluded prior to each dose escalation; no stopping criteria were met at any time point.

In GHD children, single dose VRS-317 over the specified dose range was reported to be well tolerated, with no significant safety issues observed. All subjects completed the study. A minority of subjects reported drug-related AEs. Reported AEs were mild, transient and of the type generally observed when starting rhGH in children. No serious or unexpected AEs were reported. There were no laboratory safety signals observed. Subcutaneous nodule formation and lipoatrophy were not reported.

After subcutaneous administration to GHD children, VRS-317 is rapidly absorbed achieving a maximum concentration ($C_{max}$) in three to four days after dosing, similar to that noted in GHD adults. The total exposure and $C_{max}$ were dose proportional and not dependent upon gender in this patient population. Because sparse blood sampling is used in small children, the number of time points did not allow for an accurate determination of the terminal elimination half-life. However, as noted in GHD adults, significant concentrations of VRS-317 remained 30 days after injection.

IGF-I was selected as the primary pharmacodynamic marker to measure the effect of VRS-317 treatment. The therapeutic range for IGF-I in children varies greatly with age, with mean values more than doubling during childhood. IGF-I SDS is determined based on comparison to children of the same age. All subjects had relative IGF-I deficiency at baseline (IGF-I SDS < -1.0) and the increase from baseline in the 30 day average IGF-I SDS was proportional to dose. Only two subjects had an IGF-I level above the therapeutic range (IGF-I SDS > 2.0) and no subjects had an IGF-I SDS ³ 3.0. The two subjects with IGF-I SDS > 2.0 had IGF-I SDS values in the therapeutic range by the next sampling time point. No reported safety issues arose in connection with these transient elevations. Sustained IGF-I SDS changes did not come at the expense of initial elevated exposure to IGF-I. These PK/PD data from the Phase 1b stage were used to develop a model correlating the VRS-317 exposure to the average increase in IGF-I. The PK/PD model allowed for the selection of doses and regimens for the Phase 2a stage with the objective of increasing the average IGF-I levels into the therapeutic range.

Completed Phase 2a stage of the Phase 1b/2a clinical trial

The Phase 2a stage of the Phase 1b/2a study has been completed and enrolled 64 naïve to treatment pre-pubertal GHD children into three dosing arms based upon the PK/PD model from the Phase 1b stage: 5 mg/kg VRS-317 once per month, 2.5 mg/kg VRS-317 semi-monthly, and 1.15 mg/kg VRS-317 weekly. Per protocol, upon completion of three months of treatment in 75% of the subjects in the Phase 2a stage of the trial, the SRC met and reviewed the safety of repeat dosing of VRS-317 in GHD children in this study. The SRC agreed that it was safe to continue the study and no stopping criteria were met. The primary endpoint of the Phase 2a stage was mean six month height velocity.

Over the six months of treatment with VRS-317 in the Phase 2a stage of the study, VRS-317 was found to be safe and well tolerated in these pre-pubertal GHD children. There were no related serious adverse events or unexpected adverse events. Other related adverse events were primarily mild and transient and of the type expected when rhGH is initiated in children naïve to rhGH treatment. With more than 1,300 injections administered in the Phase 2a stage, discomfort at injection sites was reported in the minority of patients and was mild and transient. Nodule formation or lipoatrophy was not observed at injection sites.

In all three dose groups,VRS-317 maintained mean IGF-I increases over baseline and within the lower part of the therapeutic range without IGF-I overexposure when given at weekly, semi-monthly and monthly intervals, confirming the PK/PD model developed from the Phase 1b stage of the study. Only five subjects had transient IGF-I SDS values greater than 2.0, all in the 5.0 mg/kg monthly dose groups and there were no IGF-I SDS values above 3.0.

In addition, we demonstrated that six months of dosing of VRS-317, when given at weekly, semi-monthly and monthly intervals, achieved mean annualized six month height velocities (which was the study's primary endpoint) comparable to the mean annual height velocity for similar GHD children given a dose of daily rhGH that is the highest approved dose on the labels of Genotropin® and Norditropin®. More specifically, the mean annualized height velocity results were compared to age-matched, historical controls of mean 12 month height velocity from the KIGS database as published by Ranke and Lindberg. Using this analysis for the 64 patients enrolled in the Phase 2a stage, the weekly arm had a mean annualized height velocity of 7.6 cm/yr compared to 8.4 cm/yr in a historical control, the semi-monthly arm had a mean annualized height velocity of 8.7 cm/yr compared to 8.3 cm/yr in historical controls and the monthly arm had a mean annualized height velocity of 7.9 cm/yr compared to 8.3 cm/yr in historical controls. There was not a statistically significant difference in height velocity between any of the three dosing frequencies tested.

Correlation of three, six and twelve month mean height velocity

For daily rhGH treatment, height velocity changes as a function of time spent on therapy. In a published study of Omnitrope® and Genotropin®, patients were dosed with rhGH over a seven year period. Patients on Genotropin® were switched to Omnitrope® after nine months of treatment (Geno/Omnitrope Group B). As shown in the chart below, initially, GHD children experience rapid catch-up growth in the first one to three years of treatment and then the rate of growth slows down approaching normal growth rates observed in children that do not have GHD.

The correlations between cumulative intervals of mean height velocity measurements have been noted in a variety of studies of daily rhGH therapy and one long-acting rhGH therapy, Nutropin Depot. For example, the mean height velocity in a treatment group over three months is well correlated to the mean height velocity in the same group over six months. Daily rhGH therapy studies have been conducted in pediatric GHD patients, measuring the mean height velocity at three, six and twelve months. These studies indicate an average decrease in the mean height velocity of 0.3 cm/yr from three months to six months and an additional decrease of 0.6 cm/yr from six months to twelve months.

The mean height velocity obtained in a controlled clinical trial is highly dependent on the demographics of the pediatric GHD patients enrolled in the clinical trial. The most significant factor determining a mean height velocity in naïve to treatment pre-pubertal GHD patients is the patient's age at start of treatment. Other factors that may influence the extent of response to daily rhGH therapy include the degree of height deficit for age and the hGH level achieved in the hGH stimulation test, both of which assess the severity of GHD. In historical published studies conducted in countries where rhGH therapy is unavailable or unaffordable, pre-pubertal GHD patients were more severely GHD than age matched peers in the United States, and therefore, greater mean height velocities were observed in these patients compared to their age-matched counterparts in the United States.

In published registries of daily rhGH therapy from patients in the United States and European countries where daily rhGH therapy is used, the mean height velocity is a reliable surrogate for expected outcomes in a controlled clinical trial using a comparable daily rhGH dose as used in these registries. As a result, an age-matched historical control analysis using published registry data on first year mean height velocities for daily rhGH therapy in pre-pubertal GHD children is a well-established procedure for assessment of new rhGH therapies. In fact, the FDA allowed the Nutropin Depot Phase 3 trial to be conducted using age-matched historical controls. Genentech conducted a number of controlled clinical studies of daily rhGH in the 1980s and 1990s. These studies demonstrated a clear dose-response relationship between the daily rhGH dose and the first year height velocity in pre-pubertal naïve to treatment moderate GHD patients in the United States. Using this dose response relationship, we note that VRS-317 dosed at 2.5 mg/kg semi-monthly provides comparable first year growth rate to the highest approved dose on the labels of Genotropin® and Norditropin®, 34 µg/kg/day.

Ongoing Extension Study in pediatric GHD patients

Upon completion of the Phase 2a stage of the trial, we offered patients the opportunity to participate in the Extension Study and to continue with VRS-317 treatment. Approximately 95% of the patients completing the Phase 2a stage elected to participate in the Extension Study. We increased the VRS-317 dose of the 20 patients who received the 1.15 mg/kg weekly dose to the 3.5 mg/kg semi-monthly dose for the Extension Study based on our PK/PD model. In the Phase 2a stage and continuing in the Extension Study, pediatric GHD patients who received the 2.5 mg/kg semi-monthly dose of VRS-317 experienced an IGF-I response in the lower part of the therapeutic range similar to that typically achieved from the 34 µg/kg/day dose of rhGH. In the first six months of the Extension Study, pediatric GHD patients who were moved to the 3.5 mg/kg semi-monthly dose of VRS-317 achieved IGF-I levels in the upper part of the therapeutic range without IGF-I overexposure, as predicted by our PK/PD model. As shown in the chart below, the patients who were moved to the 3.5 mg/kg semi-monthly dose for the Extension Study had a mean IGF-I SDS that was almost a full standard deviation higher than that of the patients who received the 2.5 mg/kg semi-monthly dose throughout the Phase 2a stage and the Extension Study. Daily rhGH therapy dosed at 40 µg/kg/day, in similar moderate GHD patients caused a comparable IGF-I response into the upper part of the therapeutic range in a published U.S. study.

More importantly, as shown in the chart below, the five Extension Study patients who were treated with the 1.15 mg/kg weekly dose in the Phase 2a stage and then completed a full six months of treatment with the 3.5 mg/kg semi-monthly dose achieved a nearly 2 cm/yr increase in mean annualized height velocity, from 7.5 cm/yr in the first six months to 9.3 cm/yr in the second six months. Typically, a decrease in height velocity in the second six months of treatment would be expected for daily rhGH therapy. The results of the Extension Study to date have demonstrated a dose response in both IGF-I levels and height velocity supporting the selection of the 3.5 mg/kg VRS-317 semi-monthly as the Phase 3 dose. To date, the 3.5 mg/kg semi-monthly dose of VRS-317 has been found to be safe and well tolerated with only a few mild transient adverse events in a minority of the patients.

In addition to the group of patients whose doses were increased in the Extension Study, two dose groups of pediatric GHD patients, 2.5 mg/kg semi-monthly and 5.0 mg/kg monthly, from the Phase 2a stage were maintained on the same VRS-317 dose and regimen until they had received 12 months of continuous treatment. As shown in the chart below, mean 12 month height velocity in these patients was not significantly different from the mean annualized height velocity at earlier time points. Typically, based on observations from existing approved daily rhGH therapies, a decrease in mean height velocity in the second six months of treatment would be expected with daily rhGH therapy. For comparison, an analysis of two studies (n = 211 patients) conducted in moderate GHD pediatric patients at an rhGH dose of 34 μg/kg/day reported mean 3, 6, and 12 month annualized height velocities indicating a decrease from 10.9 cm/yr at 3 months to 8.6 cm/yr at 12 months, which was comparable to the 8.5 cm/yr at 12 months observed with the 2.5 mg/kg semi-monthly dose of VRS-317. We believe the lower waning of height velocity over time with VRS-317 compared to daily rhGH suggests that a more consistent pattern of growth may be occurring in VRS-317 patients compared to patients on daily rhGH therapy.

After completion of 12 months of treatment in the Phase 2a stage and the Extension Study combined, all remaining patients in the Extension Study were switched to the 3.5 mg/kg semi-monthly dose, the selected pediatric Phase 3 dose. All patients completing the Phase 3 clinical trial, including those receiving daily rhGH therapy, will be offered the opportunity for treatment with the 3.5 mg/kg semi-monthly dose of VRS-317 in the Extension Study until market approval. These patients could potentially provide data to support the safety of switching patients from daily rhGH to VRS-317 therapy. The Extension Study may enroll up to 250 GHD children, and we anticipate that it will continue until any potential product launch of VRS-317, with patients receiving up to three or four years of VRS-317 therapy. This study could potentially provide long term safety and efficacy data in support of any application for global market registration.

Pediatric GHD Phase 3 clinical trial in the United States, Western Europe and Canada

In early 2015, we initiated a multicenter, randomized, open-label non-inferiority Phase 3 trial, which we refer to as the VELOCITY study, comparing the safety and efficacy of VRS-317 to daily rhGH in children with growth failure due to GHD. We have met with the FDA and corresponded with the EMA to develop our Phase 3 registration study for pediatric GHD. The study will take place in approximately 70 pediatric endocrinology centers in the United States, Western Europe and Canada using nearly identical inclusion and exclusion criteria to the Phase 2a stage of our Phase 1b/2a study and is expected to enroll comparable pre-pubertal naïve to treatment pediatric GHD patients. We expect to enroll up to 136 patients in a 3:1 randomization comparing 3.5 mg/kg semi-monthly dose of VRS-317 to 34 µg/kg/day of rhGH, which is the highest approved dose on the labels of Genotropin® and Norditropin®. VRS-317 will be administered utilizing a 30 gauge needle, which is comparable to the needle sizes typically used for daily rhGH products. A majority of patients will receive a single injection per dose. The primary endpoint for the study is non-inferiority between the two treatment groups based upon mean 12 month height velocity results. We anticipate having six month interim results in mid-2016 and final data in early 2017 to enable filing for marketing authorization in the United States, Europe and Canada. Assuming positive results from this Phase 3 study, we intend to file a BLA with the FDA, a Marketing Authorization Application, or MAA, with the EMA, and a New Drug Submission, or NDS with Health Canada.

Pediatric GHD Phase 2/3 clinical trial in Japan

We have also met with the PMDA in Japan regarding a registration trial for pediatric GHD patients. From the PMDA's feedback, we have designed a pediatric Phase 2/3 registration study and have submitted the study protocol and Clinical Trial Notification, or CTN, to the PMDA. In the Phase 2 stage of this study, 24 pre-pubertal naïve to treatment GHD children will be enrolled and administered a single dose of VRS-317 using a 30 gauge needle at one of three dose levels used in the completed Phase 1b stage of the Phase 1b/2a clinical trial conducted in U.S. GHD children. The PK/PD data from these Japanese GHD children will be compared to the PK/PD data from the U.S. GHD children administered the same dose of VRS-317. Once the PK/PD results are confirmed to be comparable between Japanese and U.S. GHD children, the Phase 3 stage of the study will begin and will be a single arm study evaluating 3.5 mg/kg VRS-317 semi-monthly in 48 GHD children. VRS-317 will be administered utilizing a 30 gauge needle, and a majority of patients will receive only a single injection per dose. Patients enrolled in the Phase 2 stage will be eligible to continue in the Phase 3 stage. The primary endpoint of the Phase 2/3 study is mean 12 month height velocity compared to historical controls. In addition, an Extension Study will be conducted in Japan to allow Phase 2/3 patients the option to continue treatment with VRS-317 for long-term safety and to obtain additional information on switching current daily rhGH treated GHD children to VRS-317 therapy. We are currently initiating clinical sites in Japan with an anticipation of enrolling pre-pubertal naïve to treatment GHD children in early 2015. The results of the Phase 2/3 study and the Extension Study in Japan will be combined with the pediatric GHD Phase 3 trial and Extension Study in the United States, Western Europe and Canada to support the submission of a Japan New Drug Application, or JNDA.

Adult GHD Phase 2/3 clinical trial

Adult GHD patients receive daily rhGH therapy at doses that are titrated to enable them to reach the normal range of IGF-I levels for their age and sex. The daily rhGH dose used in adult GHD patients ranges from 2 to 12 μg/kg/day. In our completed Phase 1a clinical trial in adult GHD patients, we demonstrated the potential for monthly dosing. We believe that over half of the adults diagnosed with GHD either refuse therapy or stop therapy due to the burden of daily injections. Reducing the dosing frequency from daily to monthly may increase compliance and maintain more patients on long-term therapy. Previous approvals of rhGH therapy for adult GHD patients required a primary endpoint of change in body composition (e.g., reduction in fat mass or truncal fat) compared to placebo.

In the first half of 2015, we intend to meet with the FDA and obtain advice from the EMA regarding our plans for a Phase 2/3 registration trial in GHD adults evaluating monthly dosing of VRS-317. We anticipate that this trial will be a randomized double blind placebo controlled study to assess the safety and efficacy of monthly VRS-317 in GHD adults. This trial will be conducted in the United States, Western Europe, Canada and Australasia, and we intend to begin enrollment in the second half of 2015. We believe that monthly VRS-317 dosing in GHD adults would offer a significant advantage in convenience and compliance over the weekly rhGH products in clinical development by other companies. VRS-317 will be dosed once a month as a single injection using a 30 gauge needle in this Phase 2/3 study of GHD adults.

rhGH market opportunity

The global rhGH market has largely been confined to the developed parts of the world, more particularly the United States, Europe and Japan. In 2013 the global rhGH market was estimated to be over $3 billion in annual sales, with the United States, Europe, Japan and Rest-of-World representing approximately 40%, 35%, 21% and 4% of the market, respectively. Global annual rhGH sales have historically grown each year, and based on market research, we believe that the market for daily rhGH products may continue to grow up to $4 billion by 2018.

As shown on the chart below, due to the lack of product differentiation among existing rhGH treatments, the global rhGH market is quite fragmented, with no brand achieving greater than 31% market share in 2013.

Importantly, rhGH manufacturers have attempted to develop a long-acting product using microsphere, PEGylation, fusion and alternative delivery technologies. Each of these approaches has not been successful due to regulatory, safety, efficacy or manufacturing issues, or a combination thereof. Nonetheless, primary and secondary market research continues to indicate a strong desire by patients, caregivers, physicians and payers to use an rhGH product that is safe and effective and requires less frequent dosing than daily subcutaneous injections.

Pediatric GHD market

Historically pediatric GHD use has dominated the rhGH market, accounting for approximately 50% of total annual sales. Of the over $3 billion global rhGH market, we believe that sales of rhGH products for pediatric GHD represent approximately $1.5 billion. We believe the United States and European markets for rhGH for pediatric GHD are approximately $450 million and $550 million, respectively. We believe that the Japanese market for rhGH for pediatric GHD is approximately $500 million, representing approximately one third of the global market of rhGH products for treatment of pediatric GHD.

Based on market research, we believe that the market for daily rhGH products can continue to grow up to $4 billion by 2018. Based on this research and assuming that the pediatric GHD market continues to constitute 50% of the total market, we believe that the pediatric GHD market could represent approximately $2.0 billion by 2018.

Adult GHD market

Treatment of GHD in adults was a natural expansion to the products already indicated for treating the same condition in children. Several studies were conducted in this area during the 1990s and many companies publicized their findings with respect to the effect of hormonal deficiency in adults on their quality of life during this period. Many adult patients face significant problems such as minimized social, mental and physical energy, reduced muscle and excess adipose tissues, reduced libido, elevated levels of cholesterol, higher cardiovascular disease rates, reduced quality of life and lower bone density.

We believe the adult GHD market is currently underpenetrated, yet it reached approximately $500 million in sales globally in 2013. Despite its current size, the adult GHD market remains largely untreated, making this population of patients with significant unmet needs an attractive additional indication for VRS-317. We believe that a therapy with more convenient dosing will expand the adult GHD market by encouraging patients not currently receiving rhGH therapy to seek treatment, as well as enhancing compliance among patients currently receiving daily therapy.

Future market expansion opportunities for VRS-317

Daily rhGH therapy is also currently approved for numerous other indications beyond GHD. More specifically, other indications currently approved in the United States for daily rhGH therapy include ISS, Turner Syndrome, Prader-Willi Syndrome, SGA, Noonan Syndrome and chronic renal insufficiency in children. ISS and Turner Syndrome comprise significant segments of the rhGH market and are likely potential indications for future VRS-317 clinical development. ISS is non-GHD short stature, defined by height that is more than two standard deviations below normal and growth rates that would not allow for attainment of adult height in the normal range, which has recognized benefits from rhGH therapy. In the United States only, ISS is an indication that is approved for rhGH therapy at the same dose as pediatric GHD. Turner Syndrome is the second most common genetic disorder, affecting 1 in 2,000 females. Short stature associated with Turner Syndrome is an approved indication for rhGH products. The rhGH dose required to treat short stature in Turner Syndrome patients is greater than the dose required for pediatric GHD patients. We may explore VRS-317 in further clinical trials to assess the appropriate dose of VRS-317 to achieve similar treatment outcomes to current daily rhGH therapy for ISS and Turner Syndrome.

Commercialization strategy

Industry research published in 2008 indicated that less than 36% of patients on treatment with rhGH therapy are compliant, resulting in some level of noncompliance in the majority of patients. In separately published research released in 2011, a lack of compliance to daily rhGH therapy results in suboptimal therapeutic outcomes. Market research indicates that frequency of administration ranks highest amongst the factors that affect adherence to this daily rhGH treatment. Our own market research indicates that the potential for VRS-317 to reduce the treatment burden of daily injections and thereby address the lack of compliance with their rhGH therapy will be of significant interest to pediatric endocrinologists. Based on a third-party market research report commissioned by us, a survey of 68 U.S. pediatric endocrinologists indicated a high level of interest in the profile of VRS-317 and a willingness to prescribe it to a majority of their patients if it is approved.

In light of our stage of development, we have not yet established a commercial organization or distribution capabilities. We generally expect to retain commercial rights for our products in territories where we believe it is possible to access the market through a focused, specialty sales force. If VRS-317 receives marketing approval, we plan to commercialize in the United States and Canada with our own focused, specialty sales force. We believe that the pediatric endocrinologists in the United States, who provide treatment for hGH deficiency in children, are sufficiently concentrated that we will be able to effectively promote VRS-317 to these specialists with a sales force of approximately 50 people. According to data published by the Journal of Pediatrics and the Pediatric Endocrine Society, there are approximately 800 pediatric endocrinologists in the United States. Similarly sized sales forces are effectively being utilized to address these pediatric endocrinologists and focus on the currently high-prescribing physicians, according to primary market research conducted by a third-party market research organization commissioned by us.

Manufacturing

We do not own or operate facilities for product manufacturing, storage and distribution, or testing nor do we expect to in the future. We currently rely, and expect to continue to rely, on Boehringer Ingelheim, or BI, for the manufacture of our drug substance and drug product for preclinical and clinical testing, as well as for commercial manufacture if our product candidate receives marketing approval. Additional contract manufacturers are used to label, package and distribute investigational drug product. We have experienced personnel to manage the third-party manufacturers.

We have an agreement with BI for the production of VRS-317 drug substance and drug product for our clinical trials. Under the agreement, we transferred our initial manufacturing process for VRS-317, including the expressing cell

line, to BI for further development, and BI will manufacture and supply VRS-317 to us for use in clinical trials, all in accordance with the project plan attached to the agreement. The agreement contains customary terms, such as delivery, inspection, acceptance and rejection, for the supply of the product. We have the right to cancel any manufacturing campaign for VRS-317 subject to the payment of a cancellation fee, which is a percentage of the total payment for the cancelled manufacturing campaign based on the time of cancellation. We have no exclusive relationship with BI for supply of our clinical materials. The agreement does not give BI any rights for commercial supply of VRS-317.

As of December 31, 2014, BI manufactures ten approved therapeutic proteins that are expressed in E. coli. VRS-317 is expressed in E. coli as a soluble protein. The XTEN sequences in VRS-317 confer improved pharmaceutical properties compared to rhGH alone. These properties include increased solubility and high net negative charge (low isoelectric point) at physiological pH enabling a straightforward purification process without the need for complex steps such as protein folding. The process for manufacturing VRS-317 drug substance consists of E. coli fermentation, initial purification to remove the majority of the E. coli components, secondary purification using three column chromatography steps and a final buffer exchange and concentration step. Because VRS-317 consists of rhGH genetically fused to XTEN, no additional steps to chemically modify the protein are required after the drug substance is produced. The VRS-317 drug substance is filtered and then VRS-317 drug product filling, labeling, packaging and testing is performed. Each of these steps involves a relatively common biotechnology process. The manufacturing process for VRS-317 is less complex than traditional rhGH manufacturing processes. The process is robust and reproducible, does not require specialized equipment, uses common and readily available materials and is readily transferable. The pharmaceutical properties of VRS-317 enable increased solubility compared to rhGH and increased stability due to the ability to reduce or eliminate the major degradation pathways typically observed in rhGH products. VRS-317 drug product is a stable liquid formulation stored refrigerated with short term stability at room temperature. We have contracted with Catalent, Inc. for the labeling, packaging and distribution of VRS-317 drug product for our clinical trials.

Under our agreement with BI, we obtain supplies and services on a purchase order basis from BI. The agreement may be terminated by either party for convenience upon 18 months' notice or earlier for certain scientific or technical reasons, material breach, bankruptcy, change of control or other business reasons. The VRS-317 used in our clinical trials was and is currently manufactured under current Good Manufacturing Practices, or cGMP, conditions. Sufficient material produced using the commercial process to complete the Phase 3 trial and Extension Study has already been produced, and preparations are underway to produce quantities required for our anticipated subsequent clinical trials. We expect that cost-of-goods-sold of VRS-317 will generally be less than that of other rhGH products. Changes in our requirements may require revalidation of the manufacturing process at a different scale and potentially at a different contractor depending on the necessary scale, infrastructure and technical capabilities. To ensure continuity in our supply chain, we plan to establish supply arrangements with alternative suppliers for certain portions of our supply chain, as appropriate.

The agreement assigns to us the ownership of all inventions and intellectual properties generated by BI that relate directly to VRS-317 and does not cover BI's background intellectual properties or improvements. In addition, upon expiration of the agreement or termination of the agreement by either party for convenience, or by us for business reasons or for BI's material breach, the agreement grants us a non-exclusive and royalty free license to use BI's background intellectual properties to the extent necessary for us to manufacture, use and exploit VRS-317. Upon termination of the agreement (other than for our breach or bankruptcy or technical reasons), BI will transfer to us the then-current manufacturing process for VRS-317, with the cost borne by us.

Research and development

We are evaluating the use of the XTEN technology on another therapeutic protein. We have recently initiated testing of this additional product candidate in animals. We plan to demonstrate proof of concept in the appropriate animal models and assess the potentially differentiated product attributes that could provide us with a superior product candidate to the current therapeutic protein. We will explore whether to proceed, and the optimal development path and product profile, upon obtaining the validating preclinical data.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, generic drug companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

The key competitive factors affecting the success of VRS-317, if approved, are likely to be its efficacy, safety, tolerability, frequency and route of administration, convenience and price, and the level of generic competition and the availability of coverage and reimbursement from government and other third-party payors. The method of administration of VRS-317, subcutaneous injection, is commonly used to administer rhGH therapy for the treatment of GHD and related indications. While daily rhGH therapy with subcutaneous injections is required for replacement therapy, a therapy that offers a less invasive method of administration might have a competitive advantage over one administered by subcutaneous injection, depending on the relative efficacy, safety and tolerability of the other method of administration.

In the United States, there are a variety of currently marketed rhGH therapies administered by daily subcutaneous injection and used for the treatment of GHD, principally Norditropin® (Novo Nordisk), Humatrope® (Eli Lilly), Nutropin-AQ® (Roche/Genentech), Genotropin® (Pfizer), Saizen® (Merck Serono), Tev-tropin® (Teva Pharmaceuticals) and Omnitrope® (Sandoz GmbH). These rhGH drugs are well-established therapies and are widely accepted by physicians, patients, caregivers and third-party payors as the standard of care for the treatment of GHD. Physicians, patients and third-party payors may not accept the addition of VRS-317 to their current treatment regimens for a variety of potential reasons, including:

·if they do not wish to incur any potential additional costs related to VRS-317; or
·if they perceive the use of VRS-317 to be of limited additional benefit to patients.

In addition to the currently approved and marketed daily rhGH therapies, there are a variety of experimental therapies that are in various stages of clinical development by companies both already participating in the rhGH market as well as potential new entrants, principally Aileron Therapeutics, Althea, Ambrx, Ascendis, Bioton S.A., Critical Pharmaceuticals, Dong-A, GeneScience, Hanmi, LG Life Science, OPKO Health, Inc. (via Prolor acquisition) and all of the existing global and regional rhGH franchises. However, based on publicly available data, these products have limitations. For example, an alternative PEGylation approach of reversible chemical linkage of rhGH to a large circulating PEG, which has not completed studies in GHD children, has reported adult data suggesting that the rhGH exposure and IGF-I response is less than one week. We believe all of the PEGylation and circulating PEG approaches will be more expensive to manufacture than current daily rhGH because they require additional manufacturing steps after the purified rhGH is produced. It is also unclear whether or not chronic administration of PEG will be safe because it was recently reported by one company that their PEGylated rhGH product candidate caused vacuoles to form in the brains of monkeys and published reports have indicated vacuole formation in the kidneys of rats upon chronic dosing of PEGylated proteins. A fusion protein approach is also under investigation using a glycosylated peptide hormone genetically fused to rhGH. Because of the glycosylation, this protein must be produced in mammalian cells, and a six step purification process has been reported. In addition, this fusion protein has been reported to have an rhGH exposure and IGF-I response of less than one week. This fusion protein is currently being studied in adult GHD Phase 3 clinical trial with weekly administration and in a Phase 2 clinical trial in children with weekly administration. Limited safety data is publicly available on this fusion protein.

Intellectual property

Our success depends, in part, upon our ability to protect our core technology. To establish and protect our proprietary rights, we rely on a combination of patents, patent applications, trademarks, copyrights, trade secrets and know-how, license agreements, confidentiality procedures, non-disclosure agreements with third parties, employee disclosure and invention assignment agreements, and other contractual rights.

In December 2008 we entered into a worldwide, exclusive license agreement with Amunix, which was amended and restated in December 2010 and subsequently amended in January 2013 and February 2014. The patents in-licensed under this agreement constitute the core of our intellectual property. The terms of this license are summarized below.

As of December 31, 2014, the in-licensed global patent portfolio consists of five granted U.S. patents, two granted patents by the European Patent Office, two granted patents in New Zealand, one granted patent in Australia, one granted patent in China and one granted patent in Mexico. In addition, the portfolio also includes 59 pending utility patent applications, ten of which are in the United States, and of those ten, two are provisional patent applications that were filed in 2014.

The in-licensed patent portfolio includes five main patent families, which we believe, if issued in their current form, would provide broad coverage for the XTEN (unstructured recombinant polypeptide, URP) technology, including methods for producing XTEN products, and various levels of more specific coverage for VRS-317. The portfolio

includes composition of matter, method of treatment and use claims.

The U.S. patents that have previously issued as of December 31, 2014 are U.S. Patent Nos. 7,855,279, 8,492,530 and 7,846,445. U.S. Patent Nos. 7,855,279 and 8,492,530 cover XTEN (URP) fusion proteins with increased half-life, including dependent claims directed to hGH-XTEN fusions. U.S. Patent No. 7,846,445 covers methods for extending the serum secretion half-life of a protein by producing XTEN fusions, including that of hGH. We estimate that these issued U.S. patents will expire between 2026 and 2027.

In addition, U.S. Patent Nos. 8,673,860 and 8,703,717 were recently granted in 2014 covering XTEN fusions of biologically active proteins, including hGH, and pharmaceutical compositions comprising such fusions, as well as methods for treating growth hormone-related conditions, such as GHD and ISS. We estimate that U.S. Patent No. 8,673,860 will expire in 2032 and U.S. Patent No. 8,703,717 will expire in 2031. A European patent that has been issued is currently being opposed by Novo Nordisk A/S and XL-protein GmbH. See “Risk factors—Risks related to intellectual property—We may become involved in legal proceedings to protect or enforce our intellectual property rights, which could be expensive, time-consuming and unsuccessful.”

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time the drug is under regulatory review.

Acquisitions and license agreements

Amunix

In December 2008 we entered into a worldwide, exclusive license agreement with Amunix, Inc., which was amended and restated in December 2010 and subsequently amended in January 2013 and February 2014. In March 2013, Amunix, Inc. was merged into Amunix Operating, Inc., or Amunix, which assumed all of the rights and obligations of Amunix, Inc. under the agreement. Under this agreement, Amunix granted us an exclusive (even as to Amunix) license under its patents and know-how related to the XTEN technology to develop and commercialize up to four licensed products for human use anywhere in the world, with each licensed product to consist of a selected target attached to an XTEN polypeptide. The license gives us rights with respect to two targets, namely hGH and another specified human protein. Certain of the licensed intellectual property was developed using government funding, and the exclusivity of our license is therefore subject to certain retained rights of the U.S. federal government. During the term of the agreement, which extends on a country-by-country basis until the later of the expiration of all licensed patents or ten years from the first commercial sale in such country, Amunix has exclusivity obligations to us. These obligations prohibit Amunix from using itself, or granting a license under, the patents and know-how related to the XTEN technology to exploit licensed products and selected targets that are, are derived from, have the same biological activity as, or are otherwise based on the licensed products and selected targets included in our exclusive license.

We are responsible for the development and commercialization of the licensed products under the agreement. Amunix has the right to terminate the agreement on a selected target-by-selected target basis if we do not use commercially reasonable efforts to develop and commercialize licensed products directed at such selected target, which requires that we use those efforts and resources used by a biotechnology company that is similarly situated for a product of similar market potential at a similar stage of its development or life. In addition to its right to terminate the agreement for our diligence failure, Amunix also has the right to terminate if we challenge any of the Amunix licensed patents.

If during any consecutive 18-month period our funding of research, development and commercialization activities with respect to licensed products directed at one of our selected targets is not at least $250,000, Amunix has the right to terminate the agreement unless we pay an additional $150,000 to Amunix to extend the 18-month period for an additional 24 months. Once we start commercializing a licensed product, we will owe to Amunix a royalty on net sales of the licensed products until the later of the expiration of all licensed patents or ten years from the first commercial sale in the relevant country. The royalty payable is one percent of net sales for the first two marketed products, but higher single-digit royalties are payable if we market additional products, or if we substitute one marketed product for another. If we elect to substitute one marketed product for another, in addition to royalties, we would also be required to make milestone and other payments totaling up to $40 million per marketed product. Amunix may terminate this agreement if we fail to comply with our payment obligations. We have the right to terminate this agreement without cause at any time upon prior notice to Amunix.

Amunix prosecutes and maintains the licensed patents, at our expense with respect to those licensed patents that are primarily applicable to our licensed products, and at our partial expense with respect to those licensed patents of broader applicability; provided, that if Amunix decides to abandon a licensed patent, we may elect to continue prosecution and maintenance. We have the first right to prosecute and control any action for infringement related to any product that does, or may, compete with one of our marketed licensed products and any claim within a licensed patent that covers or relates to such marketed licensed product.

In addition to the license agreement described above, we also entered into a Services Agreement with Amunix in March 2013. Under the services agreement, we retained Amunix to perform certain research, development and other services related to the licensed products, on a project-by-project basis pursuant to statement of works that the parties may negotiate and execute from time to time. We will pay for Amunix's services on a full-time equivalent, or FTE, basis plus additional fees as may be agreed by the parties in the statement of work. New inventions arising out of the services performed by Amunix, and all associated intellectual property rights, are generally owned by Amunix. This services agreement or any statement of work may be terminated by either party for the other party's uncured material breach. We also have the right to terminate this services agreement or any statement of work without cause at any time upon prior notice to Amunix. If not terminated, this services agreement will continue until the expiration or termination of the license agreement. Termination of the services agreement does not result in termination of the license agreement.

Government regulation

Government authorities in the United States, at the federal, state and local level, in the European Union and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

U.S. drug approval process

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

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

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's current good laboratory practice, or cGLP, regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practices, or cGCP, to establish the safety and efficacy of the proposed drug or biological product for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP, and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

Preclinical studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess its potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with cGCP requirements, which include the requirement that all research subjects provide their informed consent (assent, if applicable) in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an institutional review board, or IRB, at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Marketing approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. In most cases, the submission of a BLA is subject to a substantial application user fee. Under the new Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of the FDA's acceptance for filing of a standard non-priority BLA to review and act on the submission.

The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, plan to mitigate any identified or suspected serious risks. The REMS plan could include medication guides, physician communication plans, assessment plans and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept a BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews a BLA to determine, among other things, whether the drug is safe and effective and the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured, which is not under the control of the product sponsor. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all.

If the FDA's evaluation of the BLA and inspection of the manufacturing facilities are favorable, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the BLA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-approval requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of a BLA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies to determine compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend significant time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label, although doctors may prescribe drugs for off-label purposes. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states.

Hatch-Waxman exclusivity

Market and data exclusivity provisions under the FDCA can delay the submission or the approval of certain applications for competing products. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an Abbreviated New Drug Application, or ANDA, or a 505(b)(2) NDA submitted by another company that references the previously approved drug. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA or 505(b)(2) NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant, are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages, strengths or dosage forms of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Orphan drug designation and exclusivity

VRS-317 has received orphan drug designation for the treatment of GHD in the European Union at any dosing regimen less frequent than daily, as well as in the United States at once-a-month dosing.

In the United States, the Orphan Drug Act provides incentives for the development of products intended to treat rare diseases or conditions. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. If a sponsor demonstrates that a drug is intended to treat rare diseases or conditions, the FDA will grant orphan designation for that product for the orphan disease indication. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation, however, does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Orphan drug designation provides manufacturers with research grants, tax credits, and eligibility for orphan drug exclusivity. If a product that has orphan drug designation subsequently receives the first FDA approval of the active moiety for that disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which for seven years prohibits the FDA from approving another product with the same active ingredient for the same indication, except in limited circumstances. If a drug designated as an orphan product receives marketing approval for an indication broader than the orphan indication for which it received the designation, it will not be entitled to orphan drug exclusivity. Orphan exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to

be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Further, the FDA may approve more than one product for the same orphan indication or disease as long as the products contain different active ingredients. Moreover, competitors may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

In the European Union, the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in the European Union community. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug.

In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following drug approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of the regulatory review and approval process.

New legislation and regulations

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted or FDA regulations, guidance, policies or interpretations will be changed, or what the impact of such changes, if any, may be.

Foreign regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. The cost of establishing a regulatory compliance system for numerous varying jurisdictions can be very significant. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union and Japan, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, we must obtain approval from both the competent national authority of a European Union member state in which the clinical trial is to be conducted, and a favorable opinion from the competent ethics committee. Our clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents.

To obtain marketing approval of a drug under European Union regulatory systems, we may submit a Marketing Authorization Application, or MAA, either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. The centralized procedure is compulsory for specific products, including medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional. Under the centralized

procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the initial assessment of a drug. The CHMP also is responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is requested by the CHMP but has not yet been provided. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to applicants who wish to market a product in various European Union member states where such product has not previously received marketing approval in any European Union member state. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state designated by the applicant, known as the reference member state. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

In the European Union, new chemical entities qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the sponsor is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the drug if such company can complete a full MAA with a complete database of pharmaceutical test, preclinical tests and clinical trials and obtain marketing approval of its product.

Pharmaceutical coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we may obtain regulatory approval. Sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a third-party payor will provide coverage for a drug product typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that a payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the approved drugs for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Whether or not we conduct such studies, our product candidates may not be considered medically necessary or cost-effective. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of drug products and

medical services and questioning safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as our drug product candidates and could adversely affect our net revenue and results.

Pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements for any of our products.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. In particular, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, which we collectively refer to as the Affordable Care Act or ACA, contains provisions that have the potential to substantially change healthcare financing, including impacting the profitability of drugs. For example, the Affordable Care Act revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations and subjected manufacturers to new annual fees and taxes for certain branded prescription drugs. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare law and regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescribing of any product candidates for which we may obtain marketing approval. Our business operations and arrangements with investigators, healthcare professionals, consultants, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products that obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include, but are not limited to, the following:

- the federal healthcare Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal false claims laws and civil monetary penalties law impose penalties and provide for civil whistleblower or qui tam actions against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or making a false record or 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, or HIPAA, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare

benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without written authorization;

- 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 Affordable Care Act will require manufacturers of drugs, devices, biologics and medical supplies to report to the U.S. Department of Health and Human Services, or HHS, information related to payments and other transfers of value to physicians and teaching hospitals and certain physician ownership and investment interests; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to our business operations, including our sales or marketing arrangements, and claims involving healthcare items or services reimbursed by governmental third-party payors, and in some instances, also such claims reimbursed by non-governmental third-party payors, including private insurers.

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. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. 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 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/or administrative penalties, damages, fines, disgorgement, 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 are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

The Foreign Corrupt Practices Act

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

Employees

As of February 28, 2014, we had 33 full-time employees, including 15 employees engaged in research and development. None of our employees is represented by a labor union or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Facilities

Our principal facilities consist of office space in Menlo Park, California. We occupy approximately 12,900 square feet of office space under a lease that expires in August, 2017.

Legal proceedings

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should consider carefully the following risks, together with all the other information in this Form 10-K, including our consolidated financial statements and notes thereto. If any of the following risks actually materializes, our operating results, financial condition and liquidity could be materially adversely affected. As a result, the trading price of our common stock could decline and you could lose part or all of your investment.

Risks related to the development and commercialization of our product candidate

Our success depends heavily on the successful development, regulatory approval and commercialization of our only product candidate, VRS-317.

We do not have any products that have gained regulatory approval. Our only clinical-stage product candidate is VRS-317, a novel, long-acting recombinant human growth hormone. We have completed the Phase 2a stage of a Phase 1b/2a clinical trial in children with growth hormone deficiency, or GHD, and initiated our North American and European Phase 3 pediatric GHD clinical trial for VRS-317 in early 2015. We also plan to initiate a Phase 2/3 pediatric GHD clinical trial of VRS-317 in Japan in early 2015 and a Phase 2/3 adult GHD clinical trial of VRS-317 in the second half of 2015. As a result, our near-term prospects, including our ability to finance our operations and generate revenue, are substantially dependent on our ability to obtain regulatory approval for and, if approved, to successfully commercialize VRS-317 in a timely manner.

We cannot commercialize VRS-317 or any future product candidates in the United States without first obtaining regulatory approval for the product from the U.S. Food and Drug Administration, or FDA, nor can we commercialize VRS-317 or any future product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. The FDA review process typically takes years to complete and approval is never guaranteed. Before obtaining regulatory approvals for the commercial sale of VRS-317 for a target pediatric GHD indication or our future product candidates, we generally must demonstrate with substantial evidence gathered in preclinical and well-controlled clinical studies that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. We are pursuing the same regulatory pathway for VRS-317 followed by most of the approved rhGH products for pediatric GHD patients: a dose-finding study and a Phase 3 registration trial with a primary endpoint of 12 month mean height velocity. In addition, while the available growth data from published studies of approved rhGH therapy products suggest that three, six and twelve month mean height velocities are well correlated within the same clinical trial, it is possible that VRS-317, due to its unique properties, will produce different results. If 12 month mean height velocities that we observed for VRS-317 in the ongoing Extension Study do not correlate to 12 month mean height velocities that we ultimately observe in any Phase 3 clinical trial that we may conduct, VRS-317 may not achieve the required primary endpoint in the Phase 3 clinical trial, and VRS-317 may not receive regulatory approval.

Moreover, obtaining regulatory approval for marketing of VRS-317 in one country does not ensure we will be able to obtain regulatory approval in other countries, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

Even if VRS-317 or any of our future product candidates were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for VRS-317 in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue to fund our operations. Also, any regulatory approval of VRS-317 or our future

product candidates, once obtained, may be withdrawn. Furthermore, even if we obtain regulatory approval for VRS-317, the commercial success of VRS-317 will depend on a number of factors, including the following:

- development of our own commercial organization or establishment of a commercial collaboration with a commercial infrastructure;
- establishment of commercially viable pricing and obtaining approval for adequate reimbursement from third-party and government payors;
- the ability of our third-party manufacturers to manufacture quantities of VRS-317 using commercially viable processes at a scale sufficient to meet anticipated demand and reduce our cost of manufacturing, and that are compliant with current Good Manufacturing Practices, or cGMP, regulations;
- our success in educating physicians and patients about the benefits, administration and use of VRS-317;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- the effectiveness of our own or our potential strategic collaborators' marketing, sales and distribution strategy and operations;

- acceptance of VRS-317 as safe and effective by patients, caregivers and the medical community;
- a continued acceptable safety profile of VRS-317 following approval; and
- continued compliance with our obligations in our intellectual property licenses with third parties upon favorable terms.

Many of these factors are beyond our control. If we or our commercialization collaborators are unable to successfully commercialize VRS-317, we may not be able to earn sufficient revenues to continue our business.

VRS-317 is a new chemical entity, and although it contains the same rhGH composition used in currently approved rhGH products, it has been genetically modified to extend its half-life, creating uncertainty about its long-term safety profile.

VRS-317 utilizes the same rhGH amino acid sequence as in currently approved rhGH products, but combined with sequences of hydrophilic amino acids genetically fused to the rhGH protein to extend its half-life. This proprietary in-licensed half-life extension technology, XTEN, has been used in VRS-317 to potentially enable less frequent administration of rhGH. We have limited clinical data on product candidates utilizing XTEN technology indicating whether they are safe or effective for long-term treatment in humans. The long term safety and efficacy of the XTEN technology and the extended half-life and exposure profile of VRS-317 compared to currently approved rhGH products is unknown, and it is possible it may increase the risk of unforeseen reactions to VRS-317 following extended treatment relative to other currently approved rhGH products. Elevated levels of rhGH and IGF-I together can lead to acromegaly, a rare disease that occurs when the body produces excess growth hormone, leading to an increase in the size of bones and organs and which can result in disfigurement and other complications, with an associated increased cancer risk. It is unknown whether long-term repeated administration of VRS-317 could result in an increased immune response to rhGH, leading to a loss of efficacy or potential safety issues. If extended treatment with VRS-317 in our ongoing or future clinical trials results in any concerns about its safety or efficacy, we may be unable to successfully develop or commercialize VRS-317.

Because the results of preclinical testing and earlier clinical trials and the results to date in our Extension Study are not necessarily predictive of future results, VRS-317 may not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical testing and early clinical trials and the results to date in our Extension Study do not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier clinical trials. Despite the results to date in our ongoing Extension Study of VRS-317 in GHD children and the results reported in earlier trials, we do not know whether the clinical trials we are conducting, or may conduct, will demonstrate adequate efficacy and safety to result in regulatory approval to market VRS-317. Even if we believe that we have adequate data to support an application for regulatory approval to market our product candidates, the FDA, European Medicines Agency, or EMA, or other applicable foreign regulatory authorities may not agree and may require that we conduct additional clinical trials. If our Phase 3 clinical trial of VRS-317 in GHD children or other later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for VRS-317 may be adversely impacted.

There can be no assurance that VRS-317 will not exhibit new or increased safety risks in the Phase 3 clinical trial as compared to the Phase 1b/2a clinical trial or ongoing Extension Study. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many other companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for the marketing of their products.

In addition, we have not yet confirmed that the selected Phase 3 dose of VRS-317 administered for 12 months will provide adequate efficacy to support registration. There can be no guarantee that the dose studied in the Phase 3 clinical trial will be efficacious or, if it is, whether it will be the optimal dose. There cannot be any guarantee that any of these studies will be successful in determining a dose or dose regimen of VRS-317 suitable for marketing approval.

As an organization, we have never conducted a Phase 3 clinical trial or submitted an NDA or BLA before, and may be unsuccessful in doing so for VRS-317.

Although we have completed the Phase 2a stage of a Phase 1b/2a clinical trial of VRS-317, the conduct of our Phase 3 clinical trial and the submission of a successful Biologics License Application, or BLA, is a complicated process. As an organization, we have never conducted a Phase 3 clinical trial, have limited experience in preparing, submitting and prosecuting regulatory filings, and have not submitted a BLA before. Consequently, even though the Phase 2a stage of our Phase 1b/2a clinical trial was successful, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to BLA submission and approval of VRS-317. Failure to commence or complete, or delays in, our planned clinical trials would prevent us from or delay us in commercializing VRS-317.

Long-acting rhGH products and product candidates no longer in development or marketed have failed to generate commercial success or obtain regulatory approval, and we cannot predict whether VRS-317 will achieve success where others have failed.

Many attempts have been made to develop sustained release formulations of rhGH. For example, Nutropin Depot, a long-acting form of rhGH developed by Genentech that uses Alkermes' ProLease® injectable extended-release drug delivery system, was approved by the FDA in 1999 and withdrawn from the market in 2004 by Genentech and Alkermes due to the significant resources required to continue manufacturing and commercializing the product. Additional attempts at sustained release formulations have not yet led to globally marketed products, due to manufacturing, regulatory, efficacy and/or safety reasons. Even if we obtain all requisite regulatory approvals, no assurance can be given that VRS-317 will achieve commercial success or market adoption.

Delays in the enrollment of patients in any of our clinical studies could increase our development costs and delay completion of the study.

We may not be able to initiate or continue clinical studies for VRS-317 or any future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these studies as required by the FDA or other regulatory authorities. Even if we are able to enroll a sufficient number of patients in our clinical studies, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our studies may be delayed or our studies could become too expensive to complete.

For example, we enrolled 48 patients in the United States over approximately eight months in the Phase 1b stage of our Phase 1b/2a clinical trial of VRS-317. The last patient was enrolled in the Phase 2a stage of the study in November 2013, and the study was completed by mid-2014. As the outcome of the Phase 2a stage of the trial was successful, we intend to begin enrollment for a Phase 3 clinical trial in the United States, Western Europe and Canada in early 2015. As we expect to study only pre-pubertal naïve to treatment subjects in the Phase 3 clinical trial, we will need to seek participation of additional patients in that trial. We will need to activate new clinical study sites and enroll patients at forecasted rates at both new and existing clinical study sites. Our forecasts regarding the rates of clinical site activation and patient enrollment at those sites are based on a number of assumptions, including assumptions based on past experience with the Phase 1b stage of the Phase 1b/2a clinical trial. However, there can be no assurance that those forecasts will be accurate or that we will not face delays in our Phase 3 clinical trial. There may be concurrent competing pediatric GHD clinical trials that will inhibit or slow our enrollment in the Phase 3 clinical trial. If we experience delays in enrollment, our ability to complete our Phase 3 clinical trial could be impaired and the costs of conducting the study could increase, either of which could have a material adverse effect on our business.

If clinical studies of VRS-317 and any future product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, we may incur additional costs, experience delays in completing or ultimately fail in completing the development and commercialization of VRS-317 or our future product candidates.

Before obtaining regulatory approval for the sale of any product candidate, we must conduct extensive clinical studies to demonstrate the safety and efficacy of our product candidates in humans. Clinical studies are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more of our clinical studies could occur at any stage of testing.

We may experience numerous unforeseen events during, or as a result of, clinical studies that could delay or prevent our ability to receive regulatory approval or commercialize VRS-317 or any future product candidates, including the following:

- clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- the number of patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate or patients may drop out of these clinical studies at a higher rate than we anticipate;
- the cost of clinical studies or the manufacturing of our product candidates may be greater than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical studies of our product candidates for various reasons, including a finding that our product candidates have unanticipated serious side effects or other unexpected characteristics or that the patients are being exposed to unacceptable health risks;
- regulators may not approve our proposed clinical development plans;

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical study or conduct a clinical study at a prospective study site;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical studies of our product candidates may be insufficient or inadequate.

If we are required to conduct additional clinical studies or other testing of VRS-317 or any future product candidates beyond those that we contemplate, if we are unable to successfully complete clinical studies or other testing, if the results of these studies or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications that are not as broad as intended;
- have the product removed from the market after obtaining marketing approval;
- be subject to additional post-marketing testing requirements; or
- be subject to restrictions on how the product is distributed or used.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether any clinical studies will begin as planned, will need to be restructured or will be completed on schedule, or at all.

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

VRS-317 or our future product candidates may cause serious adverse side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any marketing approval.

Our product candidate, VRS-317, has not completed clinical development. The risk of failure of clinical development is high. It is impossible to predict when or if this or any future product candidates will prove safe enough to receive regulatory approval. Undesirable side effects caused by VRS-317 or any future product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority.

Pediatric subjects taking VRS-317 have reported certain adverse effects, such as mild and transient injection site discomfort, headaches and sore extremities, consistent with known adverse effects of rhGH therapy. No serious side effects have been reported to date. However, we cannot assure you that side effects from VRS-317 in current or future clinical trials will continue to be mild or that side effects in general will not prompt the discontinued development of VRS-317 or any future product candidates. As a result of these side effects or further safety or toxicity issues that we may experience in our clinical trials in the future, we may not receive approval to market VRS-317 or any future product candidates, which could prevent us from ever generating revenue or achieving profitability. Results of our trials could reveal an unacceptably high severity or prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Any drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may have a material adverse effect on our business, results of operations, financial condition, cash flows and future prospects.

Additionally, if VRS-317 or any of our future product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend the marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;

- the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of Risk Evaluation Mitigation Strategies, or REMS, or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to subjects or patients;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved.

Even if our clinical trials demonstrate acceptable safety and efficacy of VRS-317 for growth in pediatric GHD patients based on a semi-monthly dosing regimen, the FDA or similar regulatory authorities outside the United States may not approve VRS-317 for marketing or may approve it with restrictions on the label, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Assuming the success of our clinical trials, we anticipate seeking regulatory approval for VRS-317 in the United States, Europe and Canada for treatment of pediatric GHD patients based on a semi-monthly dosing regimen. It is possible that the FDA, the EMA or Health Canada may not consider the results of our clinical trials to be sufficient for approval of VRS-317 for this indication. In general, the FDA suggests that sponsors complete two adequate and well-controlled clinical studies to demonstrate effectiveness because a conclusion based on two persuasive studies will be more compelling than a conclusion based on a single study. Even if we achieve favorable results in our Phase 3 clinical trial, and considering that VRS-317 is a new chemical entity, the FDA may nonetheless require that we conduct additional clinical studies, possibly using a different clinical study design.

Moreover, even if the FDA or other regulatory authorities approve VRS-317 for treatment of pediatric GHD patients based on semi-monthly dosing, the approval may include additional restrictions on the label that could make VRS-317 less attractive to physicians and patients compared to other products that may be approved for broader indications, which could limit potential sales of VRS-317.

If we fail to obtain FDA or other regulatory approval of VRS-317 or if the approval is narrower than what we seek, it could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Even if VRS-317 or any future product candidates receive regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients, caregivers, healthcare payors and others in the medical community necessary for commercial success.

If VRS-317 or any future product candidates receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians, hospital administrators, patients, healthcare payors and others in the medical community. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including the following:

- the prevalence and severity of any side effects;
- their efficacy and potential advantages compared to alternative treatments;
- the price we charge for our product candidates;
- the willingness of physicians to change their current treatment practices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

· the strength of marketing and distribution support; and
· the availability of third-party coverage or reimbursement.

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For example, a number of companies offer therapies for treatment of pediatric GHD patients based on a daily regimen, and physicians, patients or their families may not be willing to change their current treatment practices in favor of VRS-317 even if it is able to offer less frequent dosing. If VRS-317 or any future product candidates, if approved, do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable on a sustained basis or at all.

VRS-317 has never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale. In addition, to successfully commercialize VRS-317, we must also design, manufacture, and gain regulatory approval of a delivery device to safely, effectively, and conveniently administer VRS-317 in relevant patient types.

VRS-317 has never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. Even if we could otherwise obtain regulatory approval for VRS-317, there is no assurance that our manufacturer will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. For example, in February 2014, the FDA notified us that it would require additional information before allowing us to use a newly manufactured lot of VRS-317 produced by our new manufacturer intended for our ongoing Extension Study. The FDA subsequently issued a partial clinical hold related to the use of any material produced by this new manufacturer and requested additional information prior to allowing us to use the newly manufactured lot. We responded to the FDA's requests, and the FDA ultimately lifted the partial clinical hold in June 2014, and the new supply is currently being used in the Extension Study. There can be no assurance, however, that we will not be subject to similar FDA actions in the future.

If our manufacturer is unable to produce sufficient quantities of the approved product for commercialization, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

VRS-317 is a biological molecule, or biologic, rather than a small molecule chemical compound, and as a result we face special uncertainties and risks associated with scaling up manufacturing. The manufacture of biologics involves complex processes, including developing cells or cell systems to produce the biologic, growing large quantities of such cells and harvesting and purifying the biologic produced by them. As a result, the cost to manufacture biologics is generally far higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is difficult to reproduce. VRS-317 was previously produced for us by a third-party contract manufacturer using a small-scale process that was too expensive and inefficient to support the dosages necessary for our ongoing and planned clinical trials. We have entered into an agreement with a new third-party manufacturer to develop a more efficient, larger-scale manufacturing process. However, scaling up and improving a biologic manufacturing process is a difficult and uncertain task, and we can give no assurance that we will be successful in developing and implementing this new process. Additionally, if we receive regulatory approval for VRS-317, in order to successfully commercialize VRS-317, we will need to manufacture quantities of VRS-317 using commercially viable processes at a scale sufficient to meet anticipated demand. Even if we are able to do so, if the therapeutically effective dosage of VRS-317 is higher than we anticipate or the obtainable sales price is lower than we anticipate, we may not be able to successfully commercialize VRS-317.

To commercialize VRS-317, we must design, manufacture, and gain regulatory approval of a delivery device to safely, effectively and conveniently administer VRS-317. We have engaged third-party manufacturers to design a suitable prototype for commercial purposes. There can be no assurance that these efforts will be successful. If we are unsuccessful in developing a suitable delivery device, our commercialization efforts would be impaired, which would

have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our failure to successfully identify, acquire, develop and commercialize additional products or product candidates could impair our ability to grow.

Although a substantial amount of our efforts will focus on the continued clinical testing and potential approval of our most advanced product candidate, VRS-317, a key element of our long-term growth strategy is to acquire, develop and/or market additional products and product candidates. We currently have one other potential product candidate that is in the preclinical study stage, but its development is at a preliminary stage and there can be no certainty that we will choose to advance it. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical product candidates and products. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure.

Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. Any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any products that we develop or approved products that we acquire will be manufactured profitably or achieve market acceptance.

We currently have no sales or distribution personnel and only limited marketing capabilities. If we are unable to develop a sales and marketing and distribution capability on our own or through collaborations or other marketing partners, we will not be successful in commercializing VRS-317 or other future products.

We do not have a significant sales or marketing infrastructure and have no experience in the sale, marketing or distribution of therapeutic products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. If VRS-317 is approved, we intend to commercialize it with our own specialty sales force in the United States, Canada and potentially other geographies.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We also may not be successful entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively and could damage our reputation. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new therapeutic products is highly competitive. We face competition with respect to VRS-317, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are several large pharmaceutical and biotechnology companies that currently market and sell rhGH therapies to our target patient group. These companies typically have a greater ability to reduce prices for their competing drugs in an effort to gain or retain market share and undermine the value proposition that we might otherwise be able to offer to payors. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of these competitors are attempting to develop therapeutics for our target indications.

We are developing our lead product candidate, VRS-317, for treatment of pediatric GHD patients based on a semi-monthly dosing regimen. The current standard of care for growth therapies for patients in the United States is a daily subcutaneous injection of rhGH. There are a variety of currently marketed daily rhGH therapies administered by daily subcutaneous injection and used for the treatment of GHD, principally Norditropin® (Novo Nordisk), Humatrope® (Eli Lilly), Nutropin-AQ® (Roche/Genentech), Genotropin® (Pfizer), Saizen® (Merck Serono), Tev-tropin® (Teva Pharmaceuticals), Omnitrope® (Sandoz GmbH) and Valtropin® (LG Life Science). These rhGH drugs, with the exception of Valtropin®, are well-established therapies and are widely accepted by physicians, patients, caregivers, third-party payors and pharmacy benefit managers, or PBMs, as the standard of care for the treatment of GHD. Physicians, patients, third-party payors and PBMs may not accept the addition of VRS-317 to their current treatment regimens for a variety of potential reasons, including concerns about incurring potential additional costs related to VRS-317, the perception that the use of VRS-317 will be of limited additional benefit to patients, or limited long-term safety data compared to currently available rhGH treatments.

In addition to the currently approved and marketed daily rhGH therapies, there are a variety of experimental therapies that are in various stages of clinical development by companies both already participating in the rhGH market as well as potential new entrants, principally Aileron Therapeutics, Althea, Ambrx, Ascendis, Bioton S.A., Critical Pharmaceuticals, Dong-A, GeneScience, Hanmi, LG Life Science, OPKO Health, Inc. (via Prolor acquisition) and all of the existing global and regional rhGH franchises.

Many of our competitors, including a number of large pharmaceutical companies that compete directly with us, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs.

We may form strategic alliances in the future, and we may not realize the benefits of such alliances.

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business. These relationships or those like them may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for VRS-317 or any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could also delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

If we are able to commercialize VRS-317 or any future product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, thereby harming

our business.

The regulations that govern marketing approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to commercialize VRS-317 or any future products successfully also will depend in part on the extent to which reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other organizations. 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. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for new products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. In some foreign countries, including major markets in the European Union and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take nine to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. Our business could be materially harmed if reimbursement of our approved products, if any, is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of VRS-317 and any future product candidates in human clinical studies and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical studies or cancellation of studies;
- significant costs to defend the related litigation;

· substantial monetary awards to patients;
· loss of revenue; and
· the inability to commercialize any products that we may develop.

We currently hold $5 million in product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks related to our financial condition and need for additional capital

We have a limited operating history and have incurred significant losses since our inception, and we anticipate that we will continue to incur substantial and increasing losses for the foreseeable future. We have only one product candidate and no commercial sales, which, together with our limited operating history, makes it difficult to evaluate our business and assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We do not have any products approved for sale, and to date we have focused principally on developing our only product candidate, VRS-317. Evaluating our performance, viability or future success will be more difficult than if we had a longer operating history or approved products on the market. We continue to incur significant research and development and general and administrative expenses related to our operations. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable. We have incurred significant operating losses in each year since our inception and expect to incur substantial and increasing losses for the foreseeable future. As of December 31, 2014, we had an accumulated deficit of $111.3 million.

To date, we have financed our operations primarily through private placements of our convertible preferred stock and, the initial public offering of our common stock in March 2014, and a follow-on offering or our common stock in January 2015. We have devoted substantially all of our efforts to research and development, including clinical studies, but have not completed development of any product candidate. We anticipate that our expenses will increase substantially as we:

- continue the research and development of our only product candidate, VRS-317, and any future product candidates;
- continue clinical studies of VRS-317, including the Phase 3 and Phase 2/3 clinical trials of VRS-317 that we initiated or expect to initiate in 2015, which will be our most expensive clinical trials to date;
- seek to discover or in-license additional product candidates;
- seek regulatory approvals for VRS-317 and any future product candidates that successfully complete clinical studies;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize VRS-317 or other future product candidates if they obtain regulatory approval, including process improvements in order to manufacture VRS-317 at commercial scale; and
- enhance operational, financial and information management systems and hire more personnel, including personnel to support development of VRS-317 and any future product candidates and, if a product candidate is approved, our commercialization efforts.

To be profitable in the future, we must succeed in developing and eventually commercializing VRS-317 as well as other products with significant market potential. This will require us to be successful in a range of activities, including advancing VRS-317 and any future product candidates, completing clinical studies of these product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We are only in the preliminary stages of some of these activities. We may not succeed in these activities and may never generate revenue that is sufficient to be profitable in the future. Even if we are profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our product candidates, market our product candidates, if approved, or continue our operations.

We currently have no source of product revenue and may never become profitable.

To date, we have not generated any revenues from commercial product sales, or otherwise. Even if we are able to successfully achieve regulatory approval for VRS-317 or any future product candidates, we do not know when any of these products will generate revenue from product sales for us. Our ability to generate revenue from product sales and achieve profitability will depend upon our ability, alone or with any future collaborators, to successfully commercialize products, including VRS-317 or any product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenue from product sales from VRS-317 or any future product candidates also depends on a number of additional factors, including our or any future collaborators' ability to:

- complete development activities, including our ongoing Extension Study and Phase 3 and Phase 2/3 clinical trials of VRS-317, successfully and on a timely basis;
- demonstrate the safety and efficacy of VRS-317 to the satisfaction of the FDA and obtain regulatory approval for VRS-317 and future product candidates, if any, for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;

- set a commercially viable price for our products;
- establish and maintain supply and manufacturing relationships with reliable third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- develop a commercial organization capable of sales, marketing and distribution of any products for which we obtain marketing approval in markets where we intend to commercialize independently;
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets;
- obtain coverage and adequate reimbursement from third-party payors, including government and private payors;
- achieve market acceptance of our products, if any;
- establish, maintain and protect our intellectual property rights and avoid third-party patent interference or patent infringement claims; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with pharmaceutical product development, including that VRS-317 or any future product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide to or are required by the FDA or foreign regulatory authorities to perform studies or trials in addition to those that we currently anticipate. Even if we are able to complete the development and regulatory process for VRS-317 or any future product candidates, we anticipate incurring significant costs associated with commercializing these products.

Even if we are able to generate revenues from the sale of VRS-317 or any future product candidates that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or shut down our operations.

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

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under any potential future collaboration and license agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to VRS-317 and any future product candidates, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing VRS-317 and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;

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the timing and outcomes of clinical studies for VRS-317 and any future product candidates or competing product candidates;

- changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of VRS-317 or any of our future product candidates;
- the level of demand for VRS-317 and any future product candidates, should they receive approval, which may fluctuate significantly and be difficult to predict;

- the risk/benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- competition from existing and potential future drugs that compete with VRS-317 or any of our future product candidates;
- our ability to commercialize VRS-317 or any future product candidate inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

We will need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs and other operations or commercialization efforts. Raising additional capital may subject us to unfavorable terms, cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates and technologies.

The completion of the development and the potential commercialization of VRS-317 and any future product candidates, should they receive approval, will require substantial funds. As of December 31, 2014, we had approximately $170.6 million in cash and cash equivalents. We believe that our existing cash and cash equivalents will be sufficient to sustain operations for at least the next 12 months based on our existing business plan. Our future financing requirements will depend on many factors, some of which are beyond our control, including the following:

- the rate of progress and cost of our clinical studies;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;
- the cost of preparing to manufacture VRS-317 on a larger scale;
- the costs of commercialization activities if VRS-317 or any future product candidate is approved, including product sales, marketing, manufacturing and distribution;
- the degree and rate of market acceptance of any products launched by us or future partners;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements;
- the emergence of competing technologies or other adverse market developments; and
- the costs of attracting, hiring and retaining qualified personnel.

We do not have any material committed external source of funds or other support for our development efforts. Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. Additional financing may not be available to us when we need it or it may not be available on favorable terms. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to VRS-317 or potential future product candidates, technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend one or more of our clinical studies or research and development programs or our commercialization efforts.

Risks related to our reliance on third parties

We rely on third parties to conduct our clinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such studies.

We do not independently conduct clinical studies of our lead product candidate. We rely on third parties, such as contract research organizations, or CROs, clinical data management organizations, medical institutions and clinical investigators, to perform this function. For example, we currently rely on ResearchPoint Global to oversee and manage the Extension Study of VRS-317. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of our clinical studies is conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical studies are protected. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We also rely on other third parties to store and distribute supplies for our clinical studies. Any performance failure on the part of our existing or future distributors could delay clinical development or regulatory approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We rely on third-party contract manufacturing organizations to manufacture and supply VRS-317. If our manufacturers and suppliers fail to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find a new supplier or manufacturer. We may also face delays in the development and commercialization of our product candidates.

We currently have limited experience in, and we do not own facilities for, clinical-scale manufacturing of our product candidates and we currently rely upon third-party contract manufacturing organizations to manufacture and supply drug product for our clinical studies of VRS-317. The manufacture of pharmaceutical products in compliance with the

FDA’s cGMPs requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced cGMP requirements, other federal and state regulatory requirements and foreign regulations. If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations to us or under applicable regulations, our ability to provide study drugs in our clinical studies would be jeopardized. Any delay or interruption in the supply of clinical study materials could delay the completion of our clinical studies, increase the costs associated with maintaining our clinical study programs and, depending upon the period of delay, require us to commence new studies at significant additional expense or terminate the studies completely. For example, in February 2014, the FDA notified us that it would require additional information before allowing us to use a newly manufactured lot of VRS-317 produced by our new manufacturer and intended for our ongoing Extension Study. The FDA subsequently issued a partial clinical hold related to the use of any material produced by this new manufacturer and requested additional information prior to allowing us to use the newly manufactured lot. We responded to the FDA’s requests, and the FDA ultimately lifted the partial clinical hold in June 2014, and the new supply is currently being used in the Extension Study.

All manufacturers of our product candidates must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall or withdrawal of product approval. If the safety of any product supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical studies, regulatory submissions, approvals or commercialization of our product candidates, entail higher costs or impair our reputation.

Our product candidate, VRS-317, is a biologic and therefore requires a complex production process. In October, 2012, we transferred production of VRS-317 to a new manufacturer, Boehringer Ingelheim. In connection with the transfer of production, we made certain changes to the manufacturing process in order to increase its scale and efficiency. We cannot assure that the FDA and the EMA will agree to the changes in the manufacturing process to support commercialization. In addition, current agreements with our manufacturer do not provide for the entire supply of the drug product necessary for full scale commercialization. If we and our manufacturer cannot agree to the terms and conditions necessary for our commercial supply needs, or if our manufacturer terminates the agreement in response to a material breach by us or otherwise becomes unable to fulfill its supply obligations, we would not be able to manufacture VRS-317 until a qualified alternative manufacturer is identified, which could also delay the development of, and impair our ability to commercialize, VRS-317.

The number of third-party manufacturers with the necessary manufacturing and regulatory expertise and facilities is limited, and it could be expensive and take a significant amount of time to arrange for alternative suppliers, which could have a material adverse effect on our business. New manufacturers of any product candidate would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the product candidate. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs that may be passed on to us.

Any future collaboration agreements we may enter into for VRS-317 or any other product candidate may place the development of VRS-317 or other product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

We may enter into additional collaboration agreements with third parties with respect to VRS-317 for the commercialization of this candidate outside the United States, or with respect to future product candidates for commercialization in or outside the United States. Our likely collaborators for any distribution, marketing, licensing or other collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We will have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend in part on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to any such collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical study results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical studies, provide insufficient funding for a clinical study program, stop a clinical study, abandon a product candidate, repeat or conduct new clinical studies or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;

- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

Any termination or disruption of collaborations could result in delays in the development of product candidates, increases in our costs to develop the product candidates or the termination of development of a product candidate.

Risks related to the operation of our business

Our future success depends on our ability to retain our chief executive officer and other key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on our chief executive officer and the other principal members of our executive team. Under the terms of their employment, our executives may terminate their employment with us at any time. The loss of the services of any of these people could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We expect to expand our development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of February 28, 2015, we had 33 employees. Over the next several years, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively, which we anticipate being conducted at numerous clinical sites;
- identifying, recruiting, maintaining, motivating and integrating additional employees with the expertise and experience we will require;

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managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;

- managing additional relationships with various strategic partners, suppliers and other third parties;
- improving our managerial, development, operational and finance reporting systems and procedures; and
- expanding our facilities.

Our failure to accomplish any of these tasks could prevent us from successfully growing our company. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We are an “emerging growth company,” and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) December 31, 2019, (2) the last day of the fiscal year (a) in which we have total annual gross revenue of at least $1.0 billion or (b) in which we are deemed to be a large accelerated filer, which means, among other things, that the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our corporate headquarters are located in California and certain clinical sites for our product candidate, operations of our existing and future partners are or will be located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant partners, suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural or manmade disaster.

If we obtain approval to commercialize VRS-317 outside the United States, we will be subject to additional risks.

If we obtain approval to commercialize any products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- 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 living or traveling abroad;

- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical study data from completed or ongoing clinical studies for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of any product candidates could be delayed.

Risks related to intellectual property

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 intellectual property license agreements with third parties, including with respect to VRS-317, and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements, in which event we may not be able to develop and market any product that is covered by these agreements. For example, we license substantially all of the intellectual property relating to VRS-317 from Amunix, and the loss of our license agreement with Amunix would therefore materially adversely affect our ability to proceed with any development or potential commercialization of our product candidates as currently planned. Amunix has the right to terminate the license upon 30 days' written notice with respect to a particular target and the related products if (i) during any consecutive 18 month period our cumulative funding of research, development and commercialization activities in respect of such target is not at least $250,000, in which case we would have the right to extend the applicable 18 month period by paying Amunix $150,000; or (ii) if we do not use commercially reasonable measures to develop and commercialize licensed products based on such target. Termination of this license, or reduction or elimination of our licensed rights under it or any other license, may result in our having to negotiate new or reinstated licenses on less favorable terms or our not having sufficient intellectual property rights to operate our business. The occurrence of such events could materially harm our business and financial condition.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we license, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could have a material adverse effect on our business. In some cases we do not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents. We are also required to reimburse Amunix for certain costs incurred in prosecuting, maintaining, defending and enforcing the licensed patents.

Our ability to successfully commercialize our technology and products may be materially adversely affected if we are unable to obtain and maintain effective intellectual property rights for our technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad.

Our success depends in large part on our and our licensors' ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and products.

We license substantially all of the intellectual property relating to VRS-317 from Amunix. We do not presently own any issued patents or pending patent applications, and our license agreement with Amunix provides that inventions relating to VRS-317 are owned by Amunix. We are therefore dependent on Amunix to apply for, prosecute, maintain, defend and, in some cases, enforce the patent rights necessary to conduct our business. However, we cannot be certain this will be done in a manner consistent with the best interests of our business. The process of applying for patents is expensive and time-consuming, and Amunix may not, or may not be able to, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or Amunix will fail to identify patentable aspects of our respective research and development output before it is too late to obtain patent protection. While Amunix has obtained a number of patents relating to the XTEN technology, and applied for a number of other patents relating to the XTEN technology in general, and VRS-317 in particular, we cannot assure you that the pending applications will result in issued patents, and the existing Amunix patents that we license, and any future patents they obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies. Under our license agreement with Amunix, we are obligated to use commercially reasonable efforts to develop and commercialize certain products that we license from Amunix and to maintain minimum rates of spending on research, development and commercialization. In exchange, we retain a limited, exclusive license to relevant patents and know-how related to XTEN technology. If we fail to fulfill our obligations under the agreement, Amunix could terminate the agreement.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unresolved. In recent years patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of the patent rights we rely on are highly uncertain. Pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of the patents we rely on or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that our licensors were the first to make the inventions claimed in our licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent.

Even if the patent applications we rely on issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and the patents we rely on may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

Finally, certain of Amunix’s activities have been funded, and may in the future be funded, by the U.S. government. When new technologies are developed with U.S. government funding, the government obtains certain rights in any

resulting patents, including the right to a nonexclusive license authorizing the government to use the invention. These rights may permit the government to disclose our confidential information to third parties and to exercise “march-in” rights to use or allow third parties to use Amunix’s patented technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the U.S. government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, U.S. government-funded inventions must be reported to the government, U.S. government funding must be disclosed in any resulting patent applications, and Amunix’s rights in such inventions may be subject to certain requirements to manufacture products in the United States.

We may become involved in legal proceedings to protect or enforce our intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe or otherwise violate the patents we rely on, or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent we are asserting is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patents we are asserting do not cover the technology in question. An adverse result in any litigation proceeding could put one or more patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Interference or derivation proceedings provoked by third parties or brought by the United States Patent and Trademark Office, or USPTO, or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to patents and patent applications. We or our licensers may become involved in proceedings, including oppositions, interferences, derivation proceedings inter partes reviews, patent nullification proceedings, or re-examinations, challenging our patent rights or the patent rights of others, and the outcome of any such proceedings are highly uncertain. For example, Novo Nordisk A/S and XL-protein GmbH filed oppositions to an issued European patent relating to the XTEN technology. An adverse determination in any such proceeding could reduce the scope of, or invalidate, important patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Our business also could be harmed if a prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we hold material service agreements with certain parties, including Amunix, and disagreements may therefore arise as to the ownership of any intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and/or management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology. Third parties may assert infringement claims against us based on existing or future intellectual property

rights. If we are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing and marketing our products and technology. We may also elect to enter into such a license in order to settle pending or threatened litigation. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and could require us to pay significant royalties and other fees. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above.

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, harming our business and competitive position.

In addition to our patented technology and products, we rely upon confidential proprietary information, including trade secrets, unpatented know-how, technology and other proprietary information, to develop and maintain our competitive position. Any disclosure to 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 the market. We seek to protect our confidential proprietary information, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. These agreements are designed to protect our proprietary information, however, we cannot be certain that our trade secrets and other confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets, or that technology relevant to our business will not be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. In addition, intellectual property laws in foreign countries may not protect trade secrets and confidential information to the same extent as the laws of the United States. If we are unable to prevent disclosure of the intellectual property related to our technologies to third parties, we may not be able to establish or maintain a competitive advantage in our market, which would harm our ability to protect our rights and have a material adverse effect on our business.

We may not be able to protect and/or enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive to us and to our licensors. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the United States. These products may compete with our products in jurisdictions where we or our licensors do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

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

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

- Others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we license;
- Our licensors or collaborators might not have been the first to make the inventions covered by an issued patent or pending patent application;
- Our licensors or collaborators might not have been the first to file patent applications covering an invention;
- Others may independently develop similar or alternative technologies or duplicate any of our or our licensors' technologies without infringing our intellectual property rights;

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

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid by us and/or our licensors to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the licensed patents and/or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and those technologies licensed to us and this circumstance would have a material adverse effect on our business.

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

In March 2013, under the America Invents Act, or AIA, the United States moved to a first-to-file system and made certain other changes to its patent laws. The effects of these changes are currently unclear as the USPTO must still implement various regulations, the courts have yet to address these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. Accordingly, it is not yet clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, all of which could have a material adverse effect on our business and financial condition.

If our third party licensor does not obtain a patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, if any, one or more of the U.S. patents covering our approved product(s) or the use thereof may be eligible for up to five years of patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. Nevertheless, we or our licensor may not be granted patent term extension either in the United States or in any foreign country because of, for example, we or our licensors failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such

extension, afforded by the governmental authority could be less than we request.

If we or our licensors are unable to obtain patent term extension or restoration, or the term of any such extension is less than requested, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Risks related to government regulation

The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor our collaboration partners are permitted to market our product candidates in the United States until we receive approval of a BLA from the FDA. Neither we nor our collaboration partners have submitted an application or received marketing approval for VRS-317 or any future product candidates. Obtaining approval of a BLA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including the following:

·warning letters;
·civil or criminal penalties and fines;
·injunctions;
·suspension or withdrawal of regulatory approval;
·suspension of any ongoing clinical studies;
·voluntary or mandatory product recalls and publicity requirements;
·refusal to accept or approve applications for marketing approval of new drugs or biologics or supplements to approved applications filed by us;
·restrictions on operations, including costly new manufacturing requirements; or
·seizure or detention of our products or import bans.

For example, in February 2014, the FDA notified us that it would require additional information before allowing us to use a newly manufactured lot of VRS-317 produced by our new manufacturer and intended for our ongoing Extension Study. The FDA subsequently issued a partial clinical hold related to the use of any material produced by this new manufacturer and requested additional information prior to allowing us to use the newly manufactured lot and the new supply is currently being used in the Extension Study. We responded to the FDA's requests, and the FDA ultimately lifted the partial clinical hold in June 2014. Prior to receiving approval to commercialize any of our product candidates in the United States or abroad, we and our collaboration partners must demonstrate with substantial evidence from well-controlled clinical studies, and to the satisfaction of the FDA and other regulatory authorities abroad, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical studies can be interpreted in different ways. Even if we and our collaboration partners believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any of our product candidates to humans may produce undesirable side effects, which could interrupt, delay or cause suspension of clinical studies of our product candidates and result in the FDA or other regulatory authorities denying approval of our product candidates for any or all targeted indications.

Regulatory approval of a BLA is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical studies, or perform additional preclinical studies and clinical studies. The number of preclinical studies and clinical studies that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. The FDA can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to, the following:

·a product candidate may not be deemed safe or effective;
·FDA officials may not find the data from preclinical studies and clinical studies sufficient;

- the FDA might not approve our or our third-party manufacturer's processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

If VRS-317 or any future product candidates fail to demonstrate safety and efficacy in clinical studies or do not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

Even if we receive regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.

Once regulatory approval has been granted, the approved product and its manufacturer are subject to continual review by the FDA and/or non-U.S. regulatory authorities. Any regulatory approval that we or any future collaboration partners receive for VRS-317 or any future product candidates may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and efficacy of the product. In addition, if the FDA and/or non-U.S. regulatory authorities approve VRS-317 or any future product candidates, we will be subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products. In addition, manufacturers of our drug products are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture our drug products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a third party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and/or other non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including the following:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical studies;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs or biologics or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

The regulatory requirements and policies may change and additional government regulations may be enacted with which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we are not able to maintain regulatory compliance, we may not be permitted to market our future products and our business may suffer.

Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.

We intend to seek a distribution and marketing partner for VRS-317 outside the United States and may market future products in international markets. In order to market our future products in regions such as the European Economic Area, or EEA, Asia Pacific, or APAC, and many other foreign jurisdictions, we must obtain separate regulatory approvals.

For example, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. Before granting the MA, the European Medicines Agency or the competent authorities of the member states of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. In Japan, the Pharmaceuticals and Medical Devices Agency, or the PMDA, of the Ministry of Health Labour and Welfare, or MHLW, must approve an application under the Pharmaceutical Affairs Act before a new drug product may be marketed in Japan.

We have had limited interactions with foreign regulatory authorities. The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Moreover, clinical studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and even if we file we may not receive necessary approvals to commercialize our products in any market.

Healthcare reform measures could hinder or prevent our product candidates' commercial success.

In the United States, there have been and we expect there will continue to be a number of legislative and regulatory changes to the healthcare system in ways that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the PPACA, was enacted in 2010. The PPACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The PPACA, among other things:

- imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs," effective 2011;
- increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%, effective 2011;
- could result in the imposition of injunctions;
- requires collection of rebates for drugs paid by Medicaid managed care organizations;
- requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- creates a process for approval of biologic therapies that are similar or identical to approved biologics.

While the U.S. Supreme Court upheld the constitutionality of most elements of the PPACA in June 2012, other legal challenges are still pending final adjudication in several jurisdictions. In addition, Congress has also proposed a number of legislative initiatives, including possible repeal of the PPACA. At this time, it remains unclear whether there will be any changes made to the PPACA, whether to certain provisions or its entirety. We cannot assure you that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals for spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, which triggered the legislation's automatic reduction to several government programs, including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by the sequestration

provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In March 2013, the President signed an executive order implementing sequestration, and in April 2013, the 2% Medicare reductions went into effect. We cannot predict whether any additional legislative changes will affect our business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of health care may adversely affect:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Further, changes in regulatory requirements and guidance may occur and we may need to amend clinical study protocols to reflect these changes. Amendments may require us to resubmit our clinical study protocols to Institutional Review Boards for reexamination, which may impact the costs, timing or successful completion of a clinical study. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Governmental Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the recall and withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products or require safety surveillance and/or patient education. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical studies and the drug approval process. Data from clinical studies may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate or suspend clinical studies before completion, or require longer or additional clinical studies that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Given the serious public health risks of high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk evaluation and mitigation strategies, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, without limitation:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce 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 the Medicare and Medicaid programs;
- indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities like us which provide coding and billing advice to customers;

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federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- 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;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

The PPACA, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Risks related to ownership of our common stock

Our stock price may be volatile, and investors in our common stock could incur substantial losses.

Our stock price has fluctuated in the past and may be volatile in the future. From March 21, 2014, the first date of trading of our common stock, through February 28, 2015 the reported sale price of our common stock has fluctuated between $16.15 and $36.86 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price for our common stock may be influenced by many factors, including the following:

- the success of competitive products or technologies;
- results of clinical studies of VRS-317 or future product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products;
- introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or product candidates;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- developments concerning our ability to bring our manufacturing processes to scale in a cost-effective manner;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- trading volume of our common stock;

- sales of our common stock by us or our stockholders;
- general economic, industry and market conditions; and
- the other risks described in this “Risk factors” section.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our 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, financial condition, results of operations and growth prospects.

Our executive officers, directors and principal stockholders will continue to maintain the ability to control or significantly influence all matters submitted to stockholders for approval.

As of February 28, 2015, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock, in the aggregate, beneficially own shares representing approximately 73% of our common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, will control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

We incur significant costs as a result of operating as a newly public company, and our management devotes substantial time to new compliance initiatives.

As a newly public company, we are incurring significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the other rules and regulations of the Securities and Exchange Commission, or SEC, and the rules and regulations of The NASDAQ Global Select Market, or NASDAQ. The expenses required in order to adequately prepare for being a public company have been and will be material, and compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. For example, the Sarbanes-Oxley Act and the rules of the SEC and national securities exchanges have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel are devoting and will continue to need to devote a substantial amount of time to these compliance initiatives. These rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees, or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, beginning with our annual report on Form 10-K for the fiscal year ended December 31, 2015. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K following the date on which we are no longer an emerging growth company. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense and expend significant management efforts. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate consolidated financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

In connection with our preparations for becoming a public company, we identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our consolidated financial statements. If we fail to remediate one or more of our material weaknesses in the future or if we fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements in accordance with U.S. generally accepted accounting principles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

Prior to the completion of our initial public offering, we were a private company with limited accounting personnel and other resources to address our internal control over financial reporting. During the course of preparing for our initial public offering, we determined that material adjustments to various accounts were necessary, which required us to restate the financial statements as of and for the years ended December 31, 2012 and 2011 and for the period from inception (December 10, 2008) through December 31, 2012 that had been previously audited by another independent audit firm. These adjustments leading to a restatement of those financial statements led us to conclude that we had a material weakness in internal control over financial reporting as of December 31, 2012. The material weakness that we identified was that we did not maintain a sufficient complement of resources with an appropriate level of accounting knowledge, experience and training commensurate with our structure and financial reporting requirements.

This material weakness contributed to adjustments to previously issued financial statements principally, but not limited to, the following areas: equity accounting in connection with our issuance of Series A and B convertible preferred stock and period-end cutoff for clinical trial related expenses.

For a discussion of our remediation plan and the actions that we have executed during 2013 and 2014, see Item 9A, Controls and Procedures, of Part II of this Form 10-K. The actions we have taken are subject to continued review, supported by confirmation and testing by management as well as audit committee oversight. While we have been successful in our efforts to remediate this particular material weakness we cannot assure you that we will be able to prevent or remediate any additional weaknesses in the future, which could impair our ability to accurately and timely report our financial position, results of operations or cash flows. If we are unable to successfully prevent or remediate any additional material weaknesses in the future, and if we are unable to produce accurate and timely consolidated financial statements, including our filing of quarterly reports with the SEC on a timely and accurate basis, our stock price may be adversely affected and we may be unable to maintain compliance with applicable NASDAQ listing requirements.

An active trading market for our common stock may not be maintained.

Our common stock is currently traded on NASDAQ, but we can provide no assurance that we will be able to maintain an active trading market for our shares on NASDAQ or any other exchange in the future. If there is no active market for our common stock, it may be difficult for our stockholders to sell shares without depressing the market price for the shares or at all.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts may cease to publish research on our company at any time in their discretion. If one or more of these analysts cease coverage of our company, or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline. In addition, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If our operating results fail to meet the forecast of analysts, our stock price would likely decline.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, 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. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include the following:

- our board of directors is divided into three classes with staggered three-year terms which may delay or prevent a change of our management or a change in control;
- our board of directors has the right to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- our stockholders are not able to act by written consent or call special stockholders' meetings; as a result, a holder, or holders, controlling a majority of our capital stock are not able to take certain actions other than at annual stockholders' meetings or special stockholders' meetings called by the board of directors, the chairman of the board, the chief executive officer or the president;
- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- our stockholders are required to provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and
- our board of directors are able to issue, without stockholder approval, shares of undesignated preferred stock, which makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our employment arrangements with our executive officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change in control of us, which could harm our financial condition or results.

Certain of our executive officers are parties to employment or other agreements or participants under plans that contain change in control and severance provisions providing for aggregate cash payments for severance and other benefits and acceleration of vesting of stock options in the event of a termination of employment in connection with a change in control of us. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be our stockholders' sole source of gain.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of existing or any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

Item 1B. Unresolved Staff Comments.

None

Item 2. Properties.

In March 2014, we entered into an operating facility lease agreement to lease 12,943 square feet in Menlo Park, California for our new headquarters building for a period of thirty-nine months. The total obligation for the Company under this lease is approximately $2.1 million as of December 31, 2014.

Item 3. Legal Proceedings.

We are not currently subject to any material legal proceedings

Item 4. Mine Safety Disclosures.

None

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market for Registrant's Common Equity

Our common stock has been listed on The NASDAQ Global Select Market under the symbol "VSAR" since March 21, 2014. The following table sets forth the quarterly range of high and low reported sale prices of our common stock on The NASDAQ Global Market for the periods indicated:

| | Price Range | |
|---|---|---|
| | High | Low |
| 2014 | | |
| First Quarter (beginning March 21, 2014) | $36.30 | $27.00 |
| Second Quarter | $36.86 | $23.51 |
| Third Quarter | $29.92 | $16.15 |
| Fourth Quarter | $23.41 | $16.69 |

On February 28, 2015, the last reported sale price of our common stock on The NASDAQ Global Select Market was $19.81 per share.

On February 28, 2015, there were 22 stockholders of record of our common stock, one of which was Cede & Co., a nominee for Depository Trust Company ("DTC"). All of the shares of our common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC and are therefore considered to be held of record by Cede & Co. as one stockholder.

Dividend Policy

We have not paid dividends on our common stock. We currently intend to retain any earnings for use in the development and expansion of our business. We, therefore, do not anticipate paying cash dividends on our common stock in the foreseeable future.

Sales of Unregistered Equity Securities and Use of Proceeds

Other than sales disclosed in previous quarterly reports on Form 10-Q or current reports on Form 8-K, there were no unregistered sales of equity securities by us during the year ended December 31, 2014.

We expect to continue to use the proceeds from our initial public offering in March 2014 and the follow-on offering in January 2015 to fund clinical trials of VRS-317 for the treatment of pediatric GHD, and for working capital and

general corporate purposes. There has been no material change in the planned use of proceeds from our follow-on offering as described in our prospectus dated January 21, 2015, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended.

Performance Graph

The following stock performance graph compares our total stock return with the total return for (i) the NASDAQ Composite Index and the (ii) the NASDAQ Biotechnology Index for the period from March 21, 2014 (the date our common stock commenced trading on the NASDAQ Global Select Market) through December 31, 2014. The figures represented below assume an investment of $100 in our common stock at the closing price of $31.37 on March 21, 2014 and in the NASDAQ Composite Index and the NASDAQ Biotechnology Index on March 21, 2014 and the reinvestment of dividends into shares of common stock. The comparisons in the table are required by the SEC, and are not intended to forecast or be indicative of possible future performance of our common stock. This graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

| $100 investment in stock or index | Ticker | March 21, 2014 | June 30, 2014 | September 30, 2014 | December 31, 2014 |
|---|---|---|---|---|---|
| Versartis, Inc. | VSAR | $100.00 | $89.39 | $ 60.54 | $ 71.58 |
| NASDAQ Composite Index | IXIC | $100.00 | $103.06 | $ 105.05 | $ 110.74 |
| NASDAQ Biotechnology Index | NBI | $100.00 | $104.24 | $ 110.93 | $ 123.28 |

Item 6. Selected Financial Data.

Selected financial statement data is consolidated for the year ended December 31, 2014 and include the accounts of Versartis, Inc. and its wholly-owned subsidiary, Versartis Cayman Holdings Company, established in 2014. All other selected financial statement data for the years ended December 31, 2013, 2012, and 2011 include only the accounts of Versartis, Inc.

The selected consolidated statements of operations data for the years ended December 31, 2014, 2013, and 2012 and the selected consolidated balance sheet data as of December 31, 2014 and 2013 are derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The selected consolidated statements of operations data for the year ended December 31, 2011 and the selected balance sheets data as of December 31, 2012 and 2011 are derived from our audited consolidated financial statements that are not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the selected historical financial data below in conjunction with the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| | 2014 | 2013 | 2012 | 2011 |
| Consolidated Statement of operations data: | | | | |
| Operating expenses | | | | |
| Research and development | $32,608 | $14,855 | $10,963 | $6,374 |
| General and administrative | 13,505 | 4,428 | 1,936 | 1,781 |
| Total operating expenses | 46,113 | 19,283 | 12,899 | 8,155 |
| Loss from operations | (46,113) | (19,283) | (12,899) | (8,155) |
| Interest income | 132 | 1 | - | 1 |
| Interest expense | — | (128) | (393) | (131) |
| Other income (expense), net | (11,532) | 913 | 75 | 1,118 |
| Net loss and comprehensive loss | (57,513) | (18,497) | (13,217) | (7,167) |
| Deemed dividend related to beneficial conversion feature of convertible preferred stock | (25,559) | - | - | - |
| Net loss attributable to common stockholders | $(83,072) | $(18,497) | $(13,217) | $(7,167) |
| Net loss per basic and diluted share attributable to common stockholders [1] | $(4.39) | $(41.10) | $(114.71) | $(7.37) |
| Weighted-average common shares used to compute basic and diluted net loss per share | 18,921,533 | 450,000 | 115,219 | 972,585 |

(1) See Notes 2 and 14 to our audited consolidated financial statements included elsewhere in the Annual Report on Form 10-K for an explanation of the calculations of basic and diluted net loss per share attributable to common stockholders.

| | As of December 31, | | | |
|---|---|---|---|---|
| | 2014 | 2013 | 2012 | 2011 |
| Consolidated Balance sheet data: | | | | |
| Cash and cash equivalents | $170,566 | $13,288 | $404 | $950 |
| Working capital (deficit) | 166,039 | 10,283 | (4,745) | 1,293 |
| Total assets | 174,294 | 14,683 | 2,189 | 3,118 |
| Total stockholders' equity (deficit) | 167,369 | (47,292) | (34,742) | (21,826) |

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with the section of this Form 10-K entitled "Selected Financial Data" and our consolidated financial statements and related notes included elsewhere in this Form 10-K. This discussion and other parts of this Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this Form 10-K entitled "Risk Factors." Test

Overview

We are an endocrine-focused biopharmaceutical company initially developing our novel long-acting recombinant human growth hormone, VRS-317, for growth hormone deficiency, or GHD, an orphan disease. A key limitation to current recombinant human growth hormone, or rhGH, products is that they impose the burden of daily injections over multiple years, often resulting in poor compliance, which in turn can lead to suboptimal treatment outcomes in GHD patients. VRS-317 is intended to reduce the burden of daily treatment by requiring significantly fewer dosing events and injections, potentially improving compliance and, therefore, treatment outcomes. We have completed the Phase 2a stage of our pediatric GHD clinical trial, have analyzed 12 month safety and efficacy data from our ongoing Extension Study and have received feedback from various authorities, including the FDA and the EMA, providing guidance on the design of our Phase 3 clinical trial. We have submitted to the FDA the protocol for a pediatric GHD Phase 3 registration trial, which we refer to as the VELOCITY study, and we initiated this Phase 3 trial in early 2015. We have received feedback from the Japanese regulatory agency, Pharmaceuticals Medicines and Devices Agency, or the PMDA, on our plans for a pediatric GHD Phase 2/3 registration trial in Japan. We have submitted to the PMDA the agreed upon protocol for the pediatric GHD Phase 2/3 trial and a complete Clinical Trial Notification, or CTN. We also intend to initiate this Phase 2/3 trial in early 2015. In the first half of 2015, we will seek input from the FDA and the EMA on our proposed Phase 2/3 registration trial in GHD adults, and we anticipate initiation of this study in the second half of 2015. We have global rights to VRS-317 and, if VRS-317 is approved, given the highly concentrated prescriber base, we intend to commercialize it with our own specialty sales force in the United States and Canada, and potentially other geographies.

VRS-317 is a fusion protein consisting of rhGH and a proprietary half-life extension technology known as XTEN, which we in-license from Amunix Operating, Inc., or Amunix. Amunix has granted us an exclusive license under its patents and know-how related to the XTEN technology to develop and commercialize up to four licensed products, including VRS-317. Once we start commercializing a licensed product, we will owe to Amunix a royalty on net sales of the licensed products until the later of the expiration of all licensed patents or ten years from the first commercial sale in the relevant country. The royalty payable is one percent of net sales for the first two marketed products, but higher single-digit royalties are payable if we market additional products, or if we substitute one marketed product for another. If we elect to substitute one marketed product for another, in addition to royalties, we would also be required to make milestone and other payments totaling up to $40 million per marketed product. See "Business—Acquisitions and license agreements—Amunix" for further information about our Amunix license agreement.

Financial overview

Summary

We have not generated net income from operations, and, at December 31, 2014, we had an accumulated deficit of $111.3 million, primarily as a result of research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments and research

and development payments in connection with potential future strategic partnerships, we have not yet generated any revenue. Although VRS-317 is at a late stage of development, it may never be successfully developed or commercialized. Accordingly, we expect to incur significant and increasing losses from operations for the foreseeable future as we seek to advance VRS-317 into a Phase 3 clinical trial, and there can be no assurance that we will ever generate significant revenue or profits.

Research and development expenses

We recognize both external and internal research and development expenses as incurred. Our external research and development expenses consist primarily of:

- the cost of acquiring and manufacturing clinical trial and other materials, including expenses incurred under agreements with contract manufacturing organizations;
- expenses incurred under agreements with contract research organizations, investigative sites, and consultants that conduct our clinical trials and a substantial portion of our preclinical activities; and
- other costs associated with development activities, including additional studies.

Internal research and development costs consist primarily of salaries and related fringe benefit costs for our employees (such as workers' compensation and health insurance premiums), stock-based compensation charges, travel costs, and allocated overhead expenses.

We expect to continue to incur substantial expenses related to our development activities for the foreseeable future as we transition to and initiate our pediatric GHD Phase 3 registration trial, or the VELOCITY study, as well as our Phase 2/3 registration trials in Japan and in GHD adults. As product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials, we expect that our research and development expenses will increase substantially in the future.

General and administrative expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not included in research and development. We anticipate general and administrative expenses will increase in future periods, reflecting an expanding infrastructure, other administrative expenses and increased professional fees associated with being a public reporting company.

Other income (expense), net

Other income (expense), net is comprised of changes in the fair value of the convertible preferred stock warrant and call option liabilities (which were incurred in historical periods through the completion of our initial public offering in March 2014). In addition, other income (expense), net includes any gains and losses on foreign currency transactions primarily related to third-party contracts with foreign based contract manufacturing organizations.

Critical accounting policies, significant judgments and use of estimates

Our management's discussion and analysis of financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our critical accounting policies and estimates. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Research and development expense

Research and development costs are expensed as incurred. Research and development expense includes payroll and personnel expenses; consulting costs; external contract research and development expenses; and allocated overhead, including rent, equipment depreciation and utilities, and relate to both company-sponsored programs as well as costs incurred pursuant to reimbursement arrangements. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed.

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing contracts and purchase orders, reviewing the terms of our license agreements, communicating with our applicable personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each consolidated balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees to:

·contract manufacturers in connection with the production of clinical trial materials;
·contract research organizations and other service providers in connection with clinical studies;
·investigative sites in connection with clinical studies;
·vendors in connection with preclinical development activities; and

· professional service fees for consulting and related services.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows and expense recognition. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. Our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting changes in estimates in any particular period. To date, there have been no material differences from our estimates to the amount actually incurred. However, due to the nature of these estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical studies or other research activity.

Stock-based compensation expense

For the years ended December 31, 2014, 2013 and 2012, stock-based compensation expense was $4.6 million, $0.2 million and $0.1 million, respectively. As of December 31, 2014, we had approximately $24.5 million of total unrecognized compensation expense, which we expect to recognize over a weighted-average period of approximately 3.1 years. The intrinsic value of all outstanding stock options as of December 31, 2014 was approximately $36.0 million, of which approximately $12.9 million related to vested options and approximately $23.1 million related to unvested options. We expect to continue to grant equity incentive awards in the future as we continue to expand our number of employees and seek to retain our existing employees, and to the extent that we do, our actual stock-based compensation expense recognized in future periods will likely increase. The stock-based compensation expense that we recognized beginning with the first quarter of 2014 and for each quarter thereafter through 2017 reflects our conclusion to calculate that expense based on a deemed fair value of our common stock that is higher than the exercise price of certain stock options granted during the first quarter 2014 prior to our initial public offering.

Stock-based compensation costs related to stock options granted to employees are measured at the date of grant based on the estimated fair value of the award, net of estimated forfeitures. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of stock-based awards is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the award. Stock options we grant to employees generally vest over four years.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions to estimate the fair value of stock-based awards. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per share of common stock could have been significantly different. These assumptions include:

· Fair value of our common stock: Prior to our initial public offering, because our stock was not publicly traded, we estimated its fair value.
· Expected volatility: As we do not have an extensive trading history for our common stock, the expected stock price volatility for our common stock was estimated by taking the average historical price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. Industry peers consist of several public companies in the biopharmaceutical industry that are similar in size, stage of life cycle and financial leverage. We did not rely on implied volatilities of traded options in our industry peers' common stock because the volume of activity was relatively low. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own common stock price becomes available, or unless circumstances change such that the identified companies are

no longer similar to us, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation.

- Expected term: We do not believe we are able to rely on our historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term for use in estimating the fair value-based measurement of our options. Therefore, we have opted to use the "simplified method" for estimating the expected term of options.
- Risk-free rate: The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected time to liquidity.
- Expected dividend yield: We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

See Note 10 to our audited consolidated financial statements included elsewhere in this Form 10-K for information concerning certain of the specific assumptions used in applying the Black-Scholes option-pricing model to determine the estimated fair value of employee stock options granted in 2014, 2013 and 2012. In addition to the assumptions used in the Black-Scholes option-pricing model, we must also estimate a forfeiture rate to calculate the stock-based compensation expense for our awards. We will continue to use judgment in evaluating the expected volatility, expected terms, and forfeiture rates utilized for our stock-based compensation expense calculations on a prospective basis.

Estimated fair value of convertible preferred stock warrant and call option liabilities

For historical periods prior to the completion of our initial public offering, we accounted for our convertible preferred stock warrants and call options as described below.

We accounted for our convertible preferred stock warrant liabilities as freestanding warrants for shares that are puttable or redeemable. These warrants are classified as liabilities on our consolidated balance sheets and are recorded at their estimated fair value. At the end of each reporting period, changes in estimated fair value during the period were recorded as a component of other income (expense), net. We adjusted these liabilities for changes in fair value up until the conversion of the preferred stock underlying the warrants into common stock upon the completion of our initial public offering, at which time the liabilities were be reclassified to additional paid in capital.

We estimate the fair values of our convertible preferred stock warrants using an option pricing model based on inputs as of the valuation measurement dates, including the fair value of our convertible preferred stock, the estimated volatility of the price of our convertible preferred stock, the expected term of the warrants and the risk-free interest rates.

We determined that our obligation to issue, and our investors' obligation to purchase, additional shares of convertible preferred stock represent a freestanding financial instrument, which we accounted for as a call option. The freestanding convertible preferred stock call option liability was initially recorded at fair value, with fair value changes recognized as increases or reductions to other income (expense), net. At the time of the exercise of the call option, any remaining value of the option was recorded as a capital transaction.

Income taxes

We file U.S. federal income tax returns and California state tax returns. To date, we have not been audited by the Internal Revenue Service or any state income tax authority; however, all tax years remain open for examination by federal and state tax authorities. We use the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is deemed more likely than not that some portion or all of a deferred tax asset will not be realized.

As of December 31, 2014, our total gross deferred tax assets were $36.6 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses and tax credit carryforwards. Utilization of net operating losses and tax credit carryforwards may be limited by the "ownership change" rules, as defined in Section 382 of the Internal Revenue Code (any such limitation, a "Section 382 limitation"). Similar rules may apply under state tax laws. We have performed an analysis to determine whether an "ownership change" occurred from inception through our initial public offering in March 2014. Based on

this analysis, management determined that we did experience historical ownership changes of greater than 50% during this period. Therefore, our ability to utilize a portion of our net operating losses and credit carryforwards is currently limited. However, these Section 382 limitations are not expected to result in a permanent loss of the net operating losses and credit carryforwards. As such, a reduction to our gross deferred tax asset for our net operating loss and tax credit carryforwards is not necessary prior to considering the valuation allowance. Since March 2014, we may have experienced an ownership change under Section 382, or may experience an ownership change as a result of future offerings or other changes in the ownership of our stock. In such event, the amount of net operating losses and research and development credit carryovers useable in any taxable year could be limited and may expire unutilized.

Results of operations

Comparison of the years ended December 31, 2014 and 2013

The following table summarizes our net loss during the periods indicated (in thousands, except percentages):

| | Year Ended December 31, | | Increase/ (Decrease) | | |
|---|---|---|---|---|---|
| | 2014 | 2013 | | | |
| Operating expenses: | | | | | |
| Research and development | $32,608 | $14,855 | $17,753 | 120% | |
| General and administrative | 13,505 | 4,428 | 9,077 | 205% | |
| Loss from operations | (46,113) | (19,283) | 26,830 | 139% | |
| Interest income | 132 | 1 | 131 | NM | (1) |
| Interest expense | — | (128) | (128) | NM | (1) |
| Other income (expense), net | (11,532) | 913 | 12,445 | NM | (1) |
| Not loss and comprehensive loss | $(57,513) | $(18,497) | $39,016 | 211% | |

(1) Not meaningful.

Research and development expense

Research and development expense increased $17.8 million, or 120%, from $14.9 million for 2013 to $32.6 million for 2014. The increase in research and development expense was primarily due to a $12.8 million increase related to manufacturing costs to support our ongoing Extension Study and prepare for our Phase 3 clinical trial. Additionally, clinical costs increased $5.0 million to wrap-up our Phase 2a clinical study, support our ongoing Extension Study, and plan for a Phase 3 study. For the years ended December 31, 2014 and 2013, substantially all of our research and development expense related to our VRS-317 drug development activity.

Included in the $17.8 million increase in research and development expense was an increase of $2.5 million in compensation and benefit expense related to new hires, from $1.8 million for 2013 to $4.3 million for 2014. Additionally, stock-based compensation expense increased $1.1 million, from $0.1 million for 2013 to $1.2 million for 2014.

General and administrative expense

General and administrative expense increased $9.1 million, or 205%, from $4.4 million for 2013 to $13.5 million for 2014. The increase in general and administrative expense was primarily due to additional payroll, including stock-based compensation of $3.3 million, consulting, and professional services expenses incurred during 2014 as we prepared for and completed our initial public offering and expanded our infrastructure to support additional public company requirements.

Interest income

Interest income increased $0.1 million, from $0.0 million for 2013 to $0.1 million for 2014. The increase in interest income was primarily due to interest earned on proceeds from our Series E issuance in February 2014 and our initial

public offering in March 2014.

Interest expense

Interest expense decreased $0.1 million, from $0.1 million for 2013 to zero for 2014. The decrease in interest expense was primarily due to interest expense associated with the October 2012 Convertible Loan Agreement, which converted into Series B convertible preferred stock in January 2013.

Other income (expense), net

Other income (expense), net decreased $12.4 million, from $0.9 million of other income for 2013 to $11.5 million of other expense for 2014. This decrease was primarily due to a change in the fair value of the preferred stock call option liability associated with the Series D convertible preferred stock financing of approximately $9.6 million as measured immediately prior to the Series D-2 financing completed in February 2014, and a $2.3 million change in the fair value of the warrant liability associated with the Series B convertible preferred stock financings in January and May 2012 as measured immediately prior to the close of our initial public offering on March 26, 2014.

Income taxes

As of December 31, 2014, we had net operating loss carryforwards of approximately $85.7 million and $55.1 million that may offset future federal and state income taxes, respectively, through 2034. Current federal and state tax laws include substantial restrictions on the utilization of net operating losses and tax credits in the event of an ownership change. Even if the carryforwards are available, they may be subject to annual limitations, lack of future taxable income, or future ownership changes that could result in the expiration of the carryforwards before they are utilized. At December 31, 2014, we recorded a 100% valuation allowance against our deferred tax assets of approximately $36.6 million, as at that time our management believed it was uncertain that they would be fully realized. We have performed an analysis to determine whether an “ownership change” occurred from inception to our initial public offering in March 2014. Based on this analysis, management determined that we did experience historical ownership changes of greater than 50% during this period. Therefore, our ability to utilize a portion of our net operating losses and credit carryforwards is currently limited. However, these Section 382 limitations are not expected to result in a permanent loss of the net operating losses and credit carryforwards.

Comparison of the years ended December 31, 2013 and 2012

The following table summarizes our net loss during the periods indicated (in thousands, except percentages):

| | Year Ended December 31, | | Increase/ (Decrease) | | |
|---|---|---|---|---|---|
| | 2013 | 2012 | | | |
| Operating expenses: | | | | | |
| Research and development | $14,855 | $10,963 | $3,892 | 36 | % |
| General and administrative | 4,428 | 1,936 | 2,492 | 129 | % |
| Loss from operations | (19,283) | (12,899) | 6,384 | 49 | % |
| Interest income | 1 | — | (1) | NM | (1) |
| Interest expense | (128) | (393) | (265) | 67 | % |
| Other income (expense), net | 913 | 75 | 838 | NM | (1) |
| Not loss and comprehensive loss | $(18,497) | $(13,217) | $5,280 | 40 | % |

(1) Not meaningful.

Research and development expense

Research and development expense increased $3.9 million, or 36%, from $11.0 million for 2012 to $14.9 million for 2013. The increase in research and development expense was primarily due to a $4.6 million increase in manufacturing costs related to the preparation for our Phase 2a clinical trial. The increase was partially offset by a $0.6 million decrease in clinical trial costs. For the years ended December 31, 2012 and 2013, substantially all of our research and development expense related to our VRS-317 drug development activity.

General and administrative expense

General and administrative expense increased $2.5 million, or 129%, from $1.9 million for 2012 to $4.4 million for 2013. The increase in general and administrative expense was primarily due to additional payroll, consulting, and professional services expenses incurred during the 2013 period as we prepared for our initial public offering.

Interest expense

Interest expense decreased $0.3 million, from $0.4 million for 2012 to $0.1 million for 2013. The decrease in interest expense was primarily due to interest expense associated with the October 2012 Convertible Loan Agreement, which converted into Series B convertible preferred stock in January 2013.

Other income (expense), net

Other income (expense), net increased $0.8 million, from $0.1 million in income for 2012 to $0.9 million in income for 2013. This increase was primarily due to a change in the fair value of the preferred stock call option liability associated with the Series C convertible preferred stock financing of approximately $1.0 million. Other income in 2012 was primarily attributable to the change in the fair value of $0.1 million of the liability associated with the Series B convertible preferred stock financings in January and May 2012.

Liquidity and capital resources

Since our inception and through December 31, 2014, we have financed our operations primarily through private placements of our equity securities, our initial public offering in March 2014, a follow-on public offering in January 2015, and debt financing. At December 31, 2014, we had cash and cash equivalents of $170.6 million, a majority of which is invested in money market funds at several highly rated financial institutions. We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of VRS- 317 and any additional product candidates. Specifically, we have incurred substantial expenses in connection with our Phase 1b/2a clinical trial and ongoing Extension Study, and we expect to continue to incur substantial expenses in connection with the Extension Study and the Phase 3 and Phase 2/3 clinical trials that we plan to conduct.

If our Phase 3 and Phase 2/3 clinical trials for VRS-317 are successful, we will continue to require additional financing to further develop our product candidates and fund operations for the foreseeable future, and we will continue to seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the rate of progress and cost of our clinical studies;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;
- the cost of preparing to manufacture VRS-317 on a larger scale;
- the costs of commercialization activities if VRS-317 or any future product candidate is approved, including product sales, marketing, manufacturing and distribution;
- the degree and rate of market acceptance of any products launched by us or future partners;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements; and
- the emergence of competing technologies or other adverse market developments.

If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others technologies or clinical product candidates or programs that we would prefer to develop and commercialize ourselves.

Cash flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| | (In thousands) | | |
| Net cash (used in) provided by: | | | |
| Operating activities | $(39,653) | $(17,090) | $(11,716) |
| Investing activities | (772) | (9) | - |
| Financing activities | 197,703 | 29,983 | 11,170 |
| Net increase (decrease) in cash and cash equivalents | $157,278 | $12,884 | $(546) |

Cash used in operating activities

Net cash used in operating activities was $39.7 million, $17.1 million and $11.7 million in 2014, 2013 and 2012, respectively, which was primarily due to the use of funds in our operations related to the development of our product candidates. Cash used in operating activities in 2014 of $39.7 million reflects a net loss of $57.5 million, offset by the non-cash remeasurement of convertible preferred stock in connection with our initial public offering in March 2014. Cash used in operating activities in 2014 increased compared to 2013, and increased in 2013 compared to 2012, primarily due to a higher net loss from operations as we continued to increase our research and development expenditures to develop VRS-317 and due to additional general and administrative expenditures as we prepared for and completed our initial public offering.

Cash used in investing activities

Cash used in investing activities consisted primarily of investment in equipment, furniture, and leasehold improvements related to our new corporate headquarters in Menlo Park, California.

Cash provided by financing activities

Net cash provided by financing activities was $197.7 million, $30.0 million and $11.2 million in 2014, 2013 and 2012, respectively. Net cash provided by financing activities in 2014 resulted primarily from $132.1 million in net proceeds from our initial public offering, and net proceeds of $64.8 million in net proceeds from the issuance of convertible preferred stock. Cash provided by financing activities in 2013 resulted primarily from $30.0 from the issuance of convertible preferred stock. Net cash provided by financing activities in 2012 resulted primarily from $5.8 million in net proceeds from the issuance of convertible preferred stock and $4.5 million in net proceeds from the issuance of convertible preferred notes.

As of December 31, 2014, we had cash and cash equivalents of approximately $170.6 million. We believe that our existing cash and cash equivalents will be sufficient to sustain operations for at least the next 12 months based on our existing business plan. If our potential Phase 3 and Phase 2/3 clinical trials are successful, we will need to raise additional capital in order to further advance our product candidates towards regulatory approval and potential commercialization.

Contractual obligations and commitments

At December 31, 2014, we had lease obligations consisting of an operating lease for our operating facility that commenced in June 2014 for approximately 12,943 square feet.

In the table below, we set forth our enforceable and legally binding obligations and future commitments at December 31, 2014, as well as obligations related to contracts that we are likely to continue, regardless of the fact that they were cancellable at December 31, 2014. Some of the figures that we include in this table are based on management's estimates and assumptions about these obligations, including their duration, the possibility of renewal, anticipated actions by third parties and other factors. Because these estimates and assumptions are necessarily subjective, the obligations we will actually pay in future periods may vary from those reflected in the table.

The following table summarizes our contractual obligations, including open payables, as of December 31, 2014:

| | Payments due by period | | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 year | 1 to 3 years | 4 to 5 years | After 5 years |
| | (In thousands) | | | | |
| Lease obligations | $2,075 | $765 | $1,310 | $— | $— |
| Manufacturing related commitments | 19,270 | 16,358 | 1,367 | 1,089 | 456 |
| Clinical trial and other related commitments | 15,772 | 7,751 | 7,592 | 429 | — |
| Total [(1)] | $37,117 | $24,874 | $10,269 | $1,518 | $456 |

(1) Includes cancellable amounts in the aggregate of approximately $27.2 million.

We are obligated to make future payments to third parties under in-license agreements, including sublicense fees, royalties, and payments that become due and payable on the achievement of certain development and commercialization milestones. As the amount and timing of sublicense fees and the achievement and timing of these milestones are not probable and estimable, such commitments have not been included on our balance sheet or in the contractual obligations tables above.

Off-balance sheet arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

JOBS Act accounting election

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have chosen to “opt out” of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

The primary objective of our investment activities is to preserve our capital to fund our operations. We also seek to maximize income from our cash and cash equivalents without assuming significant risk. To achieve our objectives, we invest our cash and cash equivalents in money market funds. As of December 31, 2014, we had cash and cash equivalents of $170.6 million consisting of cash and investments in several highly liquid U.S. money market funds. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates.

Item 8. Financial Statements and Supplementary Data.

The following consolidated financial statements of the registrant, related notes and report of independent registered public accounting firm are set forth beginning on page F-1 of this report.



Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

A company’s internal control over financial reporting is a process designed by, or under the supervision of, a company’s principal executive and principal financial officers, or persons performing similar functions, and effected by a company’s board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate. In connection with our preparation for our initial public offering, we concluded that there was a material weakness in our internal control over financial reporting that caused the restatement of our previously issued financial statements as of and for the years ended December 31, 2012 and 2011 and for the period from inception (December 10, 2008) through December 31, 2012. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company’s annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness that we identified was that we did not maintain a sufficient complement of resources with an appropriate level of accounting knowledge, experience and training commensurate with our company’s structure and financial reporting requirements.

During the fourth quarter of 2013 and in preparation for our initial public offering, we initiated various remediation efforts, including hiring additional resources with the appropriate public company and technical accounting expertise and taking other actions that are more fully described below. As such remediation efforts were still ongoing as of December 31, 2013 and into 2014, we concluded that the material weakness had not been remediated as of December

31, 2013. However, our remediation efforts throughout 2014 have led to the remediation of our material weakness as of December 31, 2014. Our remediation efforts included the following:

Addition of employee resources. Our finance team has been expanded to include a Chief Financial Officer and a corporate controller, both with significant public company and biotechnology industry experience, as well as other qualified personnel which enabled us to timely close our books and prepare accurate consolidated financial statements and related footnote disclosures.

Other actions to strengthen the internal control environment. As a result of the additional resources added to the finance function, we are allowing for separate preparation and review of the reconciliations and other account analyses. In addition, these additional finance resources are allowing us to develop a more structured close process, including enhancing our existing policies and procedures, to improve the completeness, timeliness and accuracy of our financial reporting and disclosures including, but not limited to, those regarding proper consolidated financial statement classification, recognition of accruals to ensure proper period-end cutoff of expenses and assessing more judgmental areas of accounting.

The actions that have been taken were subject to continued review, supported by confirmation and testing by management as well as audit committee oversight.

This annual report does not include a report of management’s assessment regarding internal control over financial reporting or an attestation report of the company’s registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies

Item 9B. Other Information

None.

PART III

Certain information required by Part II is omitted from this Annual Report on Form 10-K because we intend to filed our definitive proxy statement for our 2015 annual meeting of shareholders, or the 2015 Proxy Statement, pursuant to Regulation 14A of the Exchange Act, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in the Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this Item will be included in the 2015 Proxy Statement, under the sections labeled “Item 1—Election of Directors” and “Compliance with Section 16(a) of the Securities Exchange Act of 1934”, and is incorporated herein by reference. The 2015 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year to which this report relates.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees, officers, and directors, including those officers responsible for financial reporting. Our code of business conduct and ethics is available on our website at www.versartis.com. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website. You may also request a printed copy of our code of ethics, without charge, by writing to us at 4200 Bohannon Drive, Suite 250, Menlo Park, CA 94025, Attn: Investor Relations

Item 11. Executive Compensation.

Information required by this Item will be included in the sections labeled “Compensation of Executive Officers” “Summary Compensation Table”, “Grants of Plan-Based Awards”, “Outstanding Equity Awards as of December 31, 2014”, “Option Exercises and Shares Vested” and “Compensation of Directors” appearing in our 2015 Proxy Statement, and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by this Item will be included in the sections labeled “Stock Ownership” and “Equity Compensation Plan Information” appearing in our 2015 Proxy Statement, and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this Item will be included in the section labeled “Transactions with Related Persons” appearing in our 2015 Proxy Statement, and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

Information required by this Item will be included in the section labeled “Item 2—Appointment of Independent Registered Public Accounting Firm” appearing in our 2015 Proxy Statement, and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedule.

(1) Consolidated Financial Statements;
See Index to Consolidated Financial Statements at page F-1 of this report.

(2) Financial Statement Schedule
Schedule II is included on page F-33 of this report. All other schedules are omitted because they are not required or the required information is included in the consolidated financial statements or notes thereto.
(3) Exhibits:
The exhibits listed in the accompanying index to exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Versartis, Inc.

Date: March 6, 2015 By: /s/ Jeffrey L. Cleland
Jeffrey L. Cleland
Chief Executive Officer

(Principal Executive Officer)

Date: March 6, 2015 By: /s/ Joshua T. Brumm
Joshua T. Brumm
Chief Financial Officer

(Principal Financial Officer and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ Jeffrey L. Cleland, Ph.D.<br>Jeffrey L. Cleland, Ph.D. | Chief Executive Officer and Director<br>(Principal Executive Officer) | March 6, 2015 |
| /s/ Joshua T. Brumm<br>Joshua T. Brumm | Chief Financial Officer (Principal Financial and Accounting Officer) | March 6, 2015 |
| /s/ Jay P. Shepard<br>Jay P. Shepard | Chairman of the Board of Directors | March 6, 2015 |
| /s/ Srinivas Akkaraju, M.D., Ph.D.<br>Srinivas Akkaraju, M.D., Ph.D. | Director | March 6, 2015 |
| /s/ R. Scott Greer<br>R. Scott Greer | Director | March 6, 2015 |

| | | |
|---|---|---|
| /s/ Edmon R. Jennings<br>Edmon R. Jennings | Director | March 6, 2015 |
| /s/ Shahzad Malik<br>Shahzad Malik | Director | March 6, 2015 |
| /s/ Anthony Y. Sun, M.D.<br>Anthony Y. Sun, M.D. | Director | March 6, 2015 |
| /s/ John Varian<br>John Varian | Director | March 6, 2015 |

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Versartis, Inc.

In our opinion, the accompanying balance sheets and the related statements of operations and comprehensive loss, of convertible preferred stock and stockholders' equity (deficit) and of cash flows present fairly, in all material respects, the financial position of Versartis, Inc. and its subsidiary (a development stage company) at December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014 and, cumulatively, for the period from December 10, 2008 (date of inception) to December 31, 2014 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 6, 2015

VERSARTIS, INC.

(A development stage company)

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

| | December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | $170,566 | $13,288 |
| Prepaid expenses and other current assets | 2,398 | 978 |
| Total current assets | 172,964 | 14,266 |
| Other assets | 616 | 396 |
| Property and equipment, net | 714 | 21 |
| Total assets | $174,294 | $14,683 |
| Liabilities, convertible preferred stock and stockholders' equity (deficit) | | |
| Current liabilities | | |
| Accounts payable | $1,259 | $315 |
| Accrued liabilities | 5,666 | 3,668 |
| Total current liabilities | 6,925 | 3,983 |
| Convertible preferred stock warrant liability | — | 474 |
| Convertible preferred stock call option liability | — | 21 |
| Total liabilities | 6,925 | 4,478 |
| Commitments and contingencies (Note 7) | | |
| Convertible preferred stock, $0.0001 par value; 5,000,000, and 135,816,462 shares authorized at December 31, 2014 and December 31, 2013, respectively; zero and 120,648,174 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively; zero and $60,392 liquidation preference at December 31, 2014 and December 31, 2013, respectively | — | 57,497 |
| Stockholders' equity (deficit) | | |
| Common stock, $0.0001 par value, 50,000,000 and 15,652,174 shares authorized at December 31, 2014 and December 31, 2013, respectively; 24,245,437 and 1,257,311 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively | 2 | — |
| Additional paid-in capital | 278,626 | 6,454 |
| Deficit accumulated during the development stage | (111,259) | (53,746) |
| Total stockholders' equity (deficit) | 167,369 | (47,292) |

| | | |
|---|---|---|
| Total liabilities, convertible preferred stock and stockholders' equity (deficit) | $174,294 | $14,683 |

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

VERSARTIS, INC.

(A development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

| | Year Ended December 31, | | | Cumulative Period From December 10, 2008 (Date of Inception) to December 31, |
|---|---|---|---|---|
| | 2014 | 2013 | 2012 | 2014 |
| Operating expenses | | | | |
| Research and development | $32,608 | $14,855 | $10,963 | $ 78,481 |
| General and administrative | 13,505 | 4,428 | 1,936 | 23,646 |
| Total operating expenses | 46,113 | 19,283 | 12,899 | 102,127 |
| Loss from operations | (46,113) | (19,283) | (12,899) | (102,127) |
| Interest income | 132 | 1 | - | 135 |
| Interest expense | — | (128) | (393) | (863) |
| Other income (expense), net | (11,532) | 913 | 75 | (9,502) |
| Net loss and comprehensive loss | (57,513) | (18,497) | (13,217) | (112,357) |
| Deemed dividend related to beneficial conversion feature of convertible preferred stock | (25,559) | — | — | (25,559) |
| Accretion of Series A preferred stock to redemption value, net of extinguishment | — | — | — | 1,098 |
| Net loss attributable to common stockholders | $(83,072) | $(18,497) | $(13,217) | $ (136,818) |
| Net loss per basic and diluted share attributable to common stockholders | $(4.39) | $(41.10) | $(114.71) | |
| Weighted-average common shares used to compute basic and diluted net loss per share | 18,921,533 | 450,000 | 115,219 | |

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

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VERSARTIS, INC.

(A development stage company)

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share and per share amounts)

| | Convertible Preferred Stock | | Common Stock | | Additional Paid-In Capital | Deficit Accumulated During the Development Stage | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | |
| Balances at inception (December 10, 2008) | — | $— | — | $ — | $ — | $ — | $ — |
| Issuance of Series A convertible preferred stock valued at $0.0001 per share in consideration for research and development license in December 2008 | 11,000,000 | 1 | — | — | — | — | — |
| Accretion to redemption value of convertible preferred stock | — | 10,999 | — | — | — | (10,999) | (10,999) |
| Issuance of Series A convertible preferred stock for cash at $1.00 per share, net of issuance costs of $3, in May and December 2009 and April 2010 | 11,000,000 | 10,997 | — | — | — | — | — |
| Accretion to redemption value of convertible preferred stock-offering costs | | 3 | — | — | — | (3) | (3) |
| Issuance of common stock upon exercise of options subject to repurchase | — | — | 127,536 | — | — | — | — |
| Extinguishment of Series A convertible preferred stock | — | (12,100) | — | — | — | 12,100 | 12,100 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| (Refer to Note 8) | | | | | | | |
| Issuance of Series B convertible preferred stock in February 2011 at $0.45, net of issuance costs of $210 and convertible preferred stock call option liability of $1,388 | 21,805,693 | 8,215 | — | — | — | — | — |
| Conversion of notes payable and accrued interest into Series B convertible preferred stock at $0.45 per share in February 2011 | 10,238,444 | 4,607 | — | — | — | — | — |
| Issuance of common stock upon exercise of options | — | — | 2,261 | — | 3 | — | 3 |
| Vesting of options subject to repurchase | — | — | — | — | 11 | — | 11 |
| Stock-based compensation | — | — | — | — | 192 | — | 192 |
| Net loss | — | — | — | — | — | (23,130) | (23,130) |
| Balances at December 31, 2011 | 54,044,137 | 22,722 | 129,797 | — | 206 | (22,032) | (21,826) |
| Issuance of Series B convertible preferred stock in January 2012 at $0.45, net of issuance costs of $23 and convertible preferred stock call option liability of $129 | 6,430,555 | 2,999 | — | — | — | — | — |
| Issuance of Series B convertible preferred stock in May 2012 at $0.45, net of convertible preferred stock call option liability of $132 | 6,430,555 | 3,026 | — | — | — | — | — |
| Issuance of Series B convertible preferred stock upon exercise of Series B convertible preferred stock warrants in January and May 2012 | 2,000,000 | 900 | — | — | 152 | — | 152 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Issuance of common stock upon exercise of options | — | — | 3,910 | — | 5 | — | 5 |
| Vesting of options subject to repurchase | — | — | — | — | 3 | — | 3 |
| Stock-based compensation | — | — | — | — | 141 | — | 141 |
| Net loss | — | — | — | — | — | (13,217) | (13,217) |
| Balances at December 31, 2012 | 68,905,247 | 29,647 | 133,707 | — | 507 | (35,249) | (34,742) |
| Issuance of Series B convertible preferred stock on conversion of notes in January 2013 | 10,195,552 | 4,588 | — | — | — | — | — |
| Issuance of Series C convertible preferred stock in January and July 2013 at $0.56, net of issuance costs of $335 and convertible preferred stock call option liability of $864 | 36,444,444 | 19,301 | — | — | — | — | — |
| Issuance of Series D-1 convertible preferred stock at $0.56 per share in October 2013, net of issuance costs of $209 and convertible preferred stock call option liability of $126 | 17,777,777 | 9,665 | — | — | — | — | — |
| Conversion of Series B convertible preferred stock into common stock | (12,674,846) | (5,704) | 1,102,160 | — | 5,704 | — | 5,704 |
| Issuance of common stock upon exercise of options | — | — | 21,444 | — | 27 | — | 27 |
| Vesting of options subject to repurchase | — | — | — | — | 1 | — | 1 |
| Stock-based compensation | — | — | — | — | 215 | — | 215 |
| Net loss | — | — | — | — | — | (18,497) | (18,497) |
| Balances at December 31, 2013 | 120,648,174 | 57,497 | 1,257,311 | — | 6,454 | (53,746) | (47,292) |
| Issuance of Series D-2 convertible preferred stock at $0.76 per share in February 2014, net of issuance | 13,168,291 | 9,977 | — | — | — | — | — |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| costs of $23 | | | | | | | |
| Issuance of Series E convertible preferred stock in February 2014 at $1.13, net of issuance costs of $184 | 48,758,857 | 54,816 | — | — | — | — | — |
| Reclassification of warrant liability upon closing of IPO | — | — | — | — | 2,752 | — | 2,752 |
| Reclassification of call option liability upon closing of IPO | — | — | — | — | 9,581 | — | 9,581 |
| Conversion of convertible preferred stock into common stock upon IPO | (182,575,322) | (122,290) | 15,876,104 | 2 | 122,288 | — | 122,290 |
| Issuance of common stock upon exercise of warrants | — | — | 158,179 | — | 572 | — | 572 |
| Issuance of common stock upon IPO, net of issuance costs of $2,620 | — | — | 6,900,000 | — | 132,137 | — | 132,137 |
| Issuance of common stock upon exercise of options | — | — | 44,822 | — | 59 | — | 59 |
| Issuance of common stock under employee benefit plans | — | — | 9,021 | — | 142 | — | 142 |
| Beneficial conversion feature related to the issuance of Series E preferred stock | — | (25,559 ) | — | — | 25,559 | — | 25,559 |
| Deemed dividend related to beneficial conversion feature of Series E preferred stock | — | 25,559 | — | — | (25,559 ) | — | (25,559 ) |
| Stock-based compensation | — | — | — | — | 4,641 | — | 4,641 |
| Net loss | — | — | — | — | — | (57,513 ) | (57,513 ) |
| Balances at December 31, 2014 | — | — | 24,245,437 | 2 | 278,626 | (111,259) | 167,369 |

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

VERSARTIS, INC.

(A development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

| | Year Ended December 31, | | | Cumulative Period From December 10, 2008 (Date of Inception) to December 31, |
|---|---|---|---|---|
| | 2014 | 2013 | 2012 | 2014 |
| Cash flows from operating activities | | | | |
| Net loss | $(57,513) | $(18,497) | $(13,217) | $(112,357) |
| Adjustments to reconcile net loss to net cash used in operating activities | | | | |
| Depreciation and amortization | 107 | 17 | 21 | 200 |
| Loss on disposition of assets | 26 | — | — | 35 |
| Reserve for uncollectible receivables | — | — | — | 54 |
| Stock-based compensation expense | 4,641 | 215 | 141 | 5,189 |
| Amortization of debt discount | — | 121 | 312 | 666 |
| Non-cash interest expense | — | 7 | 81 | 195 |
| Non-cash research and development expense | — | — | — | 1 |
| Remeasurement of convertible preferred stock call option liability | 9,560 | (969) | (89) | 7,463 |
| Remeasurement of convertible preferred stock warrant liability | 2,279 | 41 | — | 2,239 |
| Changes in assets and liabilities | | | | |
| Accounts receivable | | 84 | 491 | — |
| Prepaid expenses and other assets | (1,695) | 299 | (128) | (3,013) |
| Accounts payable | 944 | (675) | 413 | 1,259 |
| Accrued liabilities and other liabilities | 1,998 | 2,267 | 259 | 5,665 |
| Net cash used in operating activities | (39,653) | (17,090) | (11,716) | (92,404) |
| Cash flows from investing activities | | | | |
| Proceeds from sale of property and equipment | — | — | — | 10 |
| Purchase of property and equipment | (827) | (9) | — | (1,012) |
| Security deposit for facility lease | 55 | — | — | — |
| Net cash used in investing activities | (772) | (9) | - | (1,002) |
| Cash flows from financing activities | | | | |
| Proceeds from issuance of common stock in initial public offering, net of issuance costs | 132,137 | — | — | 132,137 |
| Proceeds from sale of option for Series A preferred stock purchase rights | — | — | — | 1,000 |

| | | | | |
|---|---|---|---|---|
| Proceeds from issuance of convertible preferred stock, net of issuance costs | 64,793 | 29,956 | 5,765 | 120,113 |
| Proceeds from exercise of convertible preferred stock warrants | 572 | — | 900 | 1,472 |
| Proceeds from issuance of common stock in connection with employee benefit plans | 201 | 27 | 5 | 250 |
| Proceeds from issuance of convertible notes payable | — | — | 4,500 | 9,000 |
| Net cash provided by financing activities | 197,703 | 29,983 | 11,170 | 263,972 |
| Net increase (decrease) in cash and cash equivalents | 157,278 | 12,884 | (546) | 170,566 |
| Cash and cash equivalents at beginning of period | 13,288 | 404 | 950 | — |
| Cash and cash equivalents at end of period | $170,566 | $13,288 | $404 | $170,566 |
| Supplemental disclosure | | | | |
| Cash paid for interest | $— | $— | $— | $2 |
| Supplemental disclosure of noncash items | | | | |
| Conversion of notes payable and accrued interest to preferred stock | $— | $4,588 | $— | $9,195 |
| Conversion of preferred stock call option liability to additional paid in capital | $9,581 | $— | $— | $— |
| Conversion of preferred stock warrant liability to additional paid in capital | $2,752 | $— | $— | $— |
| Conversion of preferred stock to common stock and additional paid in capital | $122,290 | $— | $— | $— |
| Issuance of warrants for preferred stock in connection with convertible notes | $— | $— | $433 | $666 |
| Accretion of Series A convertible preferred stock to redemption value | $— | $— | $— | $11,002 |
| Issuance of call options related to convertible preferred stock | $— | $1,116 | $— | $3,504 |
| Extinguishment of Series A convertible preferred stock | $— | $— | $— | $12,100 |

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

VERSARTIS, INC.

(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Formation and Business of the Company

Versartis, Inc., (the "Company") a development stage company, was incorporated on December 10, 2008 in the State of Delaware. The Company is an endocrine-focused biopharmaceutical company initially developing long-acting recombinant human growth hormone for the treatment of growth hormone deficiency. The Company is developing drug candidates that it has licensed from Amunix Operating, Inc. ("Amunix").

The Company's headquarters and operations are in Menlo Park, California. Since incorporation, the Company has been primarily performing research and development activities, including early clinical trials, filing patent applications, obtaining regulatory approvals, hiring personnel, and raising capital to support and expand these activities.

Initial Public Offering

In March 2014, the Company completed its initial public offering of shares of its common stock, or IPO, pursuant to which the Company issued 6,900,000 shares of common stock, which includes shares issued pursuant to the underwriters' exercise of their over-allotment option, and received net proceeds of approximately $132.1 million, after underwriting discounts, commissions and offering expenses. In addition, in connection with the completion of the Company's IPO, all convertible preferred stock converted into common stock. Effective with the closing of the IPO, the Company's Amended and restated Certificate of Incorporation authorizes the Company to issue 50.0 million shares of common stock and 5.0 million shares of preferred stock.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of the accompanying consolidated financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

The accompanying financial statements are consolidated for the year ended December 31, 2014 and include the accounts of Versartis, Inc. and its wholly-owned subsidiary, Versartis Cayman Holdings Company, established in 2014. All intercompany accounts and transactions have been eliminated. The U.S. dollar is the functional currency for all of the Company's consolidated operations. All other accompanying financial statements for the years ended December 31, 2013 and 2012 include only the accounts of Versartis, Inc.

Since inception, the Company has incurred net losses and negative cash flows from operations. At December 31, 2014, the Company had a deficit accumulated during the development stage of $111.3 million and working capital of $166.0 million. The Company expects to continue to incur losses from costs related to the continuation of research and development and administrative activities for the foreseeable future. Although management has been successful in raising capital in the past, most recently in January 2015, there can be no assurance that the Company will be successful or that any needed financing will be available in the future at terms acceptable to the Company.

Segments

The Company operates in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. All long-lived assets are maintained in the United States of America.

Reclassification

Certain amounts within the consolidated balance sheet for the prior period have been reclassified to conform with the current period presentation. These reclassifications had no impact on the Company’s previously reported financial position.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Reverse Stock Split

On March 6, 2014, the Company effected a 1-for-11.5 reverse stock split of the Company's issued and outstanding shares of common stock. The par value of the common stock was not adjusted as a result of the reverse stock split. All issued and outstanding common stock share and per share amounts included in the accompanying consolidated financial statements have been adjusted to reflect this reverse stock split for all periods presented, and the conversion ratio of the preferred stock was adjusted accordingly.

Concentration of credit risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. All of the Company's cash and cash equivalents are held at four financial institutions that management believes are of high credit quality. Such deposits may, at times, exceed federally insured limits.

Risk and Uncertainties

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's potential drug candidates, uncertainty of market acceptance of the Company's products, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals and sole source suppliers.

Products developed by the Company require clearances from the U.S. Food and Drug Administration ("FDA") or other international regulatory agencies prior to commercial sales. There can be no assurance that the products will receive the necessary clearances. If the Company was denied clearance, clearance was delayed or the Company was unable to maintain clearance, it could have a materially adverse impact on the Company.

The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to complete clinical studies and launch and commercialize any product candidates for which it receives regulatory approval. There can be no assurance that such financing will be available or will be at terms acceptable by the Company.

Cash and cash equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. At December 31, 2014 the Company's cash and cash equivalents were held in four institutions in the United States and include deposits in money market funds which were unrestricted as to withdrawal or use. At December 31, 2013, the Company's cash and cash equivalents were held in an institution in the United States and include deposits in a money market fund which was unrestricted as to withdrawal or use. Included in cash and cash equivalents at December 31, 2014 and December 31, 2013 was approximately $0.1 million of restricted cash held by a bank as security for the Company's credit cards.

Property and equipment, Net

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets, generally between three and five years. Leasehold improvements are amortized on a straight-line basis over the lesser of their useful life or the term of the lease. Maintenance and repairs are charged to expense as incurred, and improvements are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the consolidated balance sheet and any resulting gain or loss is reflected in operations in the period realized.

Impairment of Long-Lived Assets

The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by the comparison of the carrying amount to the future net cash flows which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value (i.e. determined through estimating projected discounted future net cash flows or other acceptable methods of determining fair value) arising from the asset. There have been no such impairments of long-lived assets as of December 31, 2014 and 2013 and the cumulative period from December 10, 2008 (date of inception) to December 31, 2014.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Fair Value of Financial Instruments

The carrying value of the Company's cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to the short-term nature of these items. Convertible preferred stock call option liability and convertible preferred stock warrant liability were carried at fair value.

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

| | |
|---|---|
| Level I | Unadjusted quoted prices in active markets for identical assets or liabilities; |
| Level II | Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and |
| Level III | Unobservable inputs that are supported by little or no market activity for the related assets or liabilities. |

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The Company's financial instruments consist of Level I assets as of December 31, 2014 and 2013 and Level III liabilities as of December 31, 2013. Level I securities is comprised of highly liquid money market funds. Level III liabilities that are measured at fair value on a recurring basis consist of convertible preferred stock warrant liability and convertible preferred stock call option liability. The fair values of these instruments are measured using an option pricing model. Inputs used to determine estimated fair market value include the estimated fair value of the underlying stock at the valuation measurement date, the remaining expected term of the instrument, risk-free interest rates, expected dividends and the expected volatility.

Preclinical and Clinical Trial Accruals

The Company's clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations ("CROs") that conduct and manage clinical trials on the Company's behalf.

The Company estimates preclinical and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on its behalf. In accruing service fees, the Company estimates the time period over which services will be

performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

Convertible Preferred Stock Warrants

The Company accounted for its convertible preferred stock warrants as liabilities based upon the characteristics and provisions of each instrument. Convertible preferred stock warrants classified as derivative liabilities were recorded on the Company's consolidated balance sheet at their fair value on the date of issuance and revalued on each subsequent consolidated balance sheet, with fair value changes recognized as increases or reductions to other income (expense), net in the consolidated statements of operations.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Prior to the IPO in March 2014, the Company had outstanding warrants which were classified as a liability and remeasured to fair value each reporting period. The Company had estimated the fair value of these liabilities using an option pricing model and assumptions that were based on the individual characteristics of the warrants on the valuation date, as well as assumptions for expected volatility, expected life, dividends, and risk-free interest rate. Immediately prior to the completion of the Company's IPO in March 2014, all of the warrants were either exercised for cash or automatically net exercised for a total issuance of 158,179 shares of common stock, pursuant to the terms of the warrants. Just prior to the exercises, all outstanding warrants, covering 173,910 shares, were remeasured using the intrinsic value of the warrant computed as the difference between the $21.00 per share IPO price and the $5.17 per share exercise price of the warrant. The remeasurement of the fair value of these warrants from December 31, 2013 through the date of the conversion to a common stock warrant and following exercise resulted in a $2.3 million expense recorded to other income (expense), net in the consolidated statement of operations and comprehensive loss. The resulting fair value of approximately $2.8 million was reclassified to additional paid in capital upon completion of the IPO.

Convertible Preferred Stock Call Option

The Company determined that the Company's obligation to issue, and the investors' obligation to purchase, additional shares of the Company's convertible preferred stock represented a freestanding financial instrument. The freestanding convertible preferred stock call option liability was initially recorded at fair value, with fair value changes recognized as increases or reductions to other income (expense), net in the consolidated statement of operations and comprehensive loss. At the time of the deemed exercise of the call option, the remaining value of the option was reclassified to additional paid in capital. Immediately prior to the Series D-2 financing completed in February 2014, the Company remeasured the fair value of the preferred stock call option liability associated with the Series D convertible preferred stock financing and recorded other expense of approximately $9.6 million in the consolidated statement of operations and comprehensive loss. Fair value was computed using a discount from the Company's public offering price less the liquidation value of the underlying Series D convertible preferred stock.

Convertible Preferred Stock

The Company classified the convertible preferred stock as temporary equity on the balance sheets due to certain change in control events that are outside the Company's control, including liquidation, sale or transfer of the Company, as holders of the convertible preferred stock can cause redemption of the shares. Upon the IPO in March 2014, all of the outstanding shares of convertible preferred stock automatically converted into 15,876,104 shares of common stock.

In February 2014, the Company issued 48,758,857 shares of its Series E convertible preferred stock at a purchase price of $1.128 per share for an aggregate purchase price of approximately $55.0 million. The shares of convertible preferred stock automatically converted into 4,239,984 shares of common stock upon completion of the Company's IPO. Pursuant to Accounting Standards Codification 470-20, Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios, to Certain Convertible Instruments, the Company recorded a deemed dividend of approximately $25.6 million, which reflected a beneficial conversion feature on the underlying Series E preferred stock, in connection with the closing of the IPO on March 26, 2014.

Research and development

Research and development costs are charged to operations as incurred. Research and development costs include, but are not limited to, payroll and personnel expenses, laboratory supplies, consulting costs, external research and development expenses and allocated overhead, including rent, equipment depreciation, and utilities. Costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use are expensed to research and development costs when incurred.

Income taxes

The Company accounts for income taxes under the asset and liability approach. Under this method, deferred tax assets and liabilities are determined based on the difference between the consolidated financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

Stock-Based compensation

For stock options granted to employees, the Company recognizes compensation expense for all stock-based awards based on the grant-date estimated fair value. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The fair value of stock options is determined using the Black-Scholes option pricing model. The determination of fair value for stock-based awards on the date of grant using an option pricing model requires management to make certain assumptions regarding a number of complex and subjective variables.

Stock-based compensation expense related to stock options granted to nonemployees is recognized based on the fair value of the stock options, determined using the Black-Scholes option pricing model, as they are earned. The awards generally vest over the time period the Company expects to receive services from the nonemployee.

Consolidated Statement of Operations and Comprehensive Loss

Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. There have been no items qualifying as other comprehensive loss and, therefore, for all periods presented, the Company's comprehensive loss was the same as its reported net loss.

Net Loss per Share of Common Stock

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, convertible preferred stock, convertible notes payable, stock options and convertible preferred stock warrants are considered to be potentially dilutive securities. Because the Company has reported a net loss for the years ended December 31, 2014, 2013 and 2012, diluted net loss per common share is the same as basic net loss per common share for those periods.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise

discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

In June 2014, the Financial Accounting Standards Board issued Accounting Standards Update 2014-10, Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation, or ASU 2014-10, which eliminates the definition of a development stage entity, the development stage presentation and disclosure requirements under ASC 915, Development Stage Entities, and amends provisions of existing variable interest entity guidance under ASC 810, Consolidation. As a result of the changes, the financial statements of entities which meet the former definition of a development stage entity will no longer: (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. Furthermore, ASU 2014-10 clarifies disclosures about risks and uncertainties under ASC Topic 275, Risks and Uncertainties that apply to companies that have not commenced planned principal operations. Finally, variable interest entity rules no longer contain an exception for development stage entities and, as a result, development stage entities will have to be evaluated for consolidation in the same manner as non-development stage entities. These changes are effective for annual periods beginning after December 15, 2015 for public companies and are effective for annual periods beginning after December 15, 2016 for nonpublic entities. Early adoption is permitted for any annual reporting period or interim period for which the entity's financial statements have not yet been issued (public business entities) or made available for issuance (other entities). The Company has elected not to early adopt and is currently evaluating the impact of adopting ASU 2014-10, but does not expect there to be any impact on its financial position, results of operations or cash flows.

In August 2014, the FASB issued new guidance related to the disclosures around going concern. The new standard provides guidance around management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted. The Company will apply the guidance and disclosure provisions of the new standard upon adoption.

3. Balance Sheet Components

Prepaid expenses and other current assets (in thousands)

| | December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Preclinical and clinical | $2,216 | $847 |
| Other | 182 | 131 |
| Total | $2,398 | $978 |

Property and equipment, net (in thousands)

| | December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Equipment and furniture | $706 | $50 |
| Buildings, leasehold and building improvements | 132 | 21 |
| Construction-in-progress | — | — |
| | 837 | 71 |
| Less: Accumulated depreciation and amortization | (124) | (50) |
| Property and equipment, net | $714 | $21 |

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Accrued liabilities (in thousands)

| | December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Payroll and related | $1,737 | $539 |
| Preclinical and clinical | 3,259 | 1,726 |
| Professional services | 411 | 1,265 |
| Other | 259 | 138 |
| Total | $5,666 | $3,668 |

4. Fair Value Measurements

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

| | Fair Value Measurements at December 31, 2014 | | | |
|---|---|---|---|---|
| | Total | Level 1 | Level 2 | Level 3 |
| Assets | | | | |
| Money market funds | $160,125 | $160,125 | $ — | $— |

| | Fair Value Measurements at December 31, 2013 | | | |
|---|---|---|---|---|
| | Total | Level 1 | Level 2 | Level 3 |
| Assets | | | | |
| Money market funds | $12,761 | $12,761 | $ — | $— |
| Liabilities | | | | |
| Convertible preferred stock warrant liability | $474 | $— | $ — | $474 |
| Convertible preferred stock call option liability | 21 | — | — | 21 |

| | | | | |
|---|---|---|---|---|
| Total liabilities | $495 | $— | $ — | $495 |

The fair value measurement of the convertible preferred stock warrant liability and convertible preferred stock call option liability is based on significant inputs not observed in the market and thus represents a Level 3 measurement. Level 3 instruments are valued based on unobservable inputs that are supported by little or no market activity and reflect the Company's assumptions in measuring fair value. The Company's estimated fair value of the convertible preferred stock warrant liability is calculated using an option pricing model and key assumptions including the probabilities of settlement scenarios, enterprise value, time to liquidity, risk-free interest rates, discount for lack of marketability and volatility. The Company's estimated fair value of the preferred stock call option liability is calculated using an option pricing model and key assumptions including the estimated fair value of the Company's preferred stock, risk-free interest rates and volatility and the probability of the closing of the future financing tranche. The estimates are based, in part, on subjective assumptions and could differ materially in the future.

During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at fair value using Level 3 inputs. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the years ended December 31, 2014 or 2013.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instruments as follows:

| | Convertible preferred stock call option liability | Convertible preferred stock warrant liability |
|---|---|---|
| Balance at January 1, 2014 | $ 21 | $ 474 |
| Fair value of call option liability recognized upon issuance of preferred stock | — | — |
| Change in fair value recorded in other income (expense), net | 9,560 | 2,278 |
| Conversion of preferred stock into common stock and reclassification to permanent equity | (9,581) | (2,752) |
| Balance at December 31, 2014 | $ — | $ — |

| | Convertible preferred stock call option liability | Convertible preferred stock warrant liability |
|---|---|---|
| Balance at January 1, 2013 | $ — | $ 433 |
| Issuance of financial instruments | 1,116 | — |
| Fair value of call option liability recognized upon issuance of preferred stock | (126) | — |
| Change in fair value recorded in other income (expense), net | (969) | 41 |
| Balance at December 31, 2013 | $ 21 | $ 474 |

5. Convertible Notes Payable

In 2010, the Company entered into convertible notes payable agreements ("2010 Notes") with investors, in two tranches, for a total of $4.5 million. The terms of each of the 2010 Notes bear a fixed interest rate of 5%. In November 2010, the Company extended the maturity date of the 2010 Notes by two months to February 2011. The Company analyzed the amendment under the modification accounting guidance and concluded that the amendment did not result in a substantial modification. In February 2011, the outstanding 2010 Notes and accrued interest of $4.6 million were converted into 10,238,444 shares of Series B convertible preferred stock.

In October 2012, the Company entered into convertible notes payable agreements ("2012 Notes") with investors for a total of $4.5 million. The 2012 Notes bear a fixed interest rate of 8% accruing from the date of the issuance of 2012

Notes, with principal and unpaid interest payable on January 31, 2013. The 2012 Notes are convertible into shares of the next preferred stock financing at the purchase price of those shares, or into shares of Series B convertible preferred stock at $0.45 per share, at the option of the holder, or may be paid in cash in the event of a default.

In January 2013, the holders of 2012 Notes converted principal of $4.5 million and $88,000 of accrued interest, into 10,195,552 shares of Series B preferred convertible stock at a price of $0.45 per share.

6. Convertible Preferred Stock Warrants

In connection with the convertible note purchase agreements (“2010 Notes”), the Company issued convertible preferred stock warrants equal to 20% of the shares issuable upon conversion of the 2010 Notes. Using an option pricing model with a volatility of 85%, term of 1.75 years and a risk-free interest rate of 0.53%, the fair value of the warrants was determined to be approximately $233,000 and was recorded as warrant liability and a debt discount against the 2010 Notes and amortized to interest expense over the term of the 2010 Notes. The convertible preferred stock warrants were exercised in 2012 for 2.0 million shares of Series B convertible preferred stock at an exercise price of $900,000.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

In connection with the convertible note purchase agreements ("2012 Notes"), the Company issued convertible preferred stock warrants equal to 20% of the shares issuable on conversion of the 2012 Notes. The convertible preferred stock warrants were exercisable into shares of the same class of convertible preferred stock issued upon conversion of the related 2012 Notes. The convertible preferred stock warrants had a five-year term and an expiration date of October 12, 2017. The estimated fair value of these warrants of $433,000 at issuance was recorded as a debt discount on the 2012 Notes, and amortized to interest expense using the effective interest method through the original maturity date in 2013. The convertible preferred stock warrants were valued using an option pricing model with a risk-free interest rate of 0.21%, volatility of 90%, and an expected life equal to 1.5 years. As of December 31, 2013, the fair value of the warrants was estimated to be $474,000.

The 2012 warrants remained unexercised as of December 31, 2013. The terms of the warrants provided that they would expire at the earlier of (i) the closing of an initial public offering, (ii) a sale of the company or (iii) October 12, 2017; provided that if a holder of the warrants does not notify us of the holder's intent to exercise or not to exercise the warrant prior to the expiration date, and the fair market value of the underlying shares on the expiration date is greater than the exercise price, then the holder will be deemed to have net exercised the warrant immediately prior to the expiration date. Upon the closing of the Company's IPO, the warrants were exercised for a total of 158,179 shares of common stock.

Prior to the IPO in March 2014, the Company had outstanding warrants which were classified as a liability and remeasured to fair value each reporting period. The Company had estimated the fair value of these liabilities using an option pricing model and assumptions that were based on the individual characteristics of the warrants on the valuation date, as well as assumptions for expected volatility, expected life, dividends, and risk-free interest rate. Immediately prior to the completion of the Company's IPO in March 2014, all of the warrants were either exercised for cash or automatically net exercised for a total issuance of 158,179 shares of common stock, pursuant to the terms of the warrants. Just prior to the exercises, all outstanding warrants, covering 173,910 shares, were remeasured using the intrinsic value of the warrant computed as the difference between the $21.00 per share IPO price and the $5.17 per share exercise price of the warrant. The remeasurement of the fair value of these warrants from December 31, 2013 through the date of the conversion to a common stock warrant and following exercise resulted in a $2.3 million expense recorded to other income (expense), net in the consolidated statement of operations and comprehensive loss. The resulting fair value of approximately $2.8 million was reclassified to additional paid in capital upon completion of the IPO.

The assumptions used to value the convertible preferred stock warrants were as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Expected term (in years) | - | 1.1 |

| | | |
|---|---|---|
| Expected volatility | - | 75.00% |
| Risk-free interest rate | - | 0.13 % |
| Dividend yield | - | 0 % |

7. Commitments and Contingencies

Facility Leases

In August 2011, the Company signed an operating facility lease for its corporate office that includes approximately 5,740 square feet of office space in Redwood City, California. The lease term is for thirty months, commencing on October 16, 2011. The Company paid a security deposit of $55,000 for this facility lease in 2011, which was returned in 2014.

In March 2014, the Company entered into an operating facility lease agreement to lease 12,943 square feet in Menlo Park, California for its new headquarters building for a period of thirty-nine months. The total obligation for the Company under this lease is approximately $2.1 million as of December 31, 2014.

Rent expense was $520,000, $241,000 and $218,000 for the years ended December 31, 2014, 2013 and 2012, respectively, and $1,120,000 for the period from December 10, 2008 (inception) to December 31, 2014.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

As of December 31, 2014, the aggregate future minimum lease payments under the noncancellable operating lease arrangements are as follows (in thousands):

| Year Ended December 31, 2014 | |
|---|---|
| 2015 | $765 |
| 2016 | 781 |
| 2017 | 529 |
| 2018 | — |
| 2019 | — |
| Thereafter | — |
| | $2,075 |

Purchase Commitments

The Company conducts research and development programs through a combination of internal and collaborative programs that include, among others, arrangements with contract manufacturing organizations and contract research organizations. The Company had contractual arrangements with these organizations including license agreements with milestone obligations and service agreements with obligations largely based on services performed.

In the normal course of business, the Company enters into various firm purchase commitments related to certain preclinical and clinical studies. At December 31, 2014 the noncancellable portion of these commitments, in aggregate, totaled approximately $7.9 million.

Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company’s exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

As of December 31, 2014 the Company is contingently committed to make development and sales-related milestone payments of up to $30.0 million under certain circumstances, and other payments of $10.0 million, as well as royalties relating to potential future product sales under the License Agreement with Amunix. The amount, timing and likelihood of these payments are unknown as they are dependent on the occurrence of future events that may or may not occur, including approval by the FDA of potential drug candidates.

Indemnification

In accordance with the Company’s amended and restated Certificate of Incorporation and amended and restated bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company’s request in such capacity. There have been no claims

to date and the Company has a director and officer insurance policy that may enable it to recover a portion of any amounts paid for future claims.

Litigation

The Company may from time to time be involved in legal proceedings arising from the normal course of business. There are no pending or threatened legal proceedings as of December 31, 2014.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

8. Convertible Preferred Stock

Convertible preferred stock ("preferred stock") as of December 31, 2013 consisted of the following (in thousands, except share and per share data):

At December 31, 2013 -

| Series | Shares Authorized | Outstanding | Per Share Liquidation Preference | Carrying Value |
|---|---|---|---|---|
| Series A | 22,000,000 | 22,000,000 | $ 0.45 | $9,900 |
| Series B | 46,425,950 | 44,425,953 | 0.45 | 18,631 |
| Series C | 36,444,444 | 36,444,444 | 0.56 | 19,301 |
| Series D-1 | 17,777,777 | 17,777,777 | 0.56 | 9,665 |
| Series D-2 | 13,168,291 | — | 0.76 | — |
| | 135,816,462 | 120,648,174 | | $57,497 |

Issuance of Series A preferred stock

In December 2008, the Company entered into a stock purchase agreement with Amunix and other investors to issue 22,000,000 shares of Series A preferred stock at a purchase price of $1.00 per share in multiple closings.

In consideration of Amunix entering into the License Agreement (Refer to Note 11) with the Company, the Company issued 11,000,000 shares of Series A convertible preferred stock in December 2008 to Amunix pursuant to the terms of the Series A Purchase Agreement and granted to Amunix the pro-rata right to participate in a future Series A closing if, at the sole discretion of certain investors, it is determined the Company has satisfied certain milestones, and the Board of Directors determines that the Company requires additional capital, for 2,500,000 shares at $1.00 per share. The pro rata right to participate in future Series A closing was determined to be issued to an entity under common control and as such the value of the option was initially recorded at a carrying value of $0. This right was waived by Amunix in 2010.

The Company issued an aggregate of 8,000,000 shares of Series A preferred stock in May and December 2009 at a purchase price of $1.00 per share and further issued 3,000,000 shares in April 2010 as part of the third closing pursuant to the Series A convertible preferred stock purchase agreement.

Issuance of Series B convertible preferred stock

In February 2011, the Company entered into a Series B convertible preferred stock purchase agreement with certain investors. The Company issued 21,805,693 shares of Series B convertible preferred stock at a purchase price of $0.45 per share totaling $9.8 million in gross proceeds. Further, the 2010 convertible notes converted into 10,238,444 shares of Series B preferred upon the conversion of principal of $4.5 million and accrued interest of $107,300.

In January and May 2012, the Company issued 12,861,110 shares of Series B convertible preferred stock at a purchase price of $0.45 per share in two subsequent closings and raised approximately $5.8 million in gross proceeds. The Company issued additional 2,000,000 shares of Series B convertible preferred stock upon the exercise of Series B convertible preferred stock warrants in exchange for $900,000.

Issuance of Series C convertible preferred stock

In January 2013, the Company entered into a Series C convertible preferred stock purchase agreement with certain investors. The Company issued 14,222,222 shares of Series C convertible preferred stock at a purchase price of $0.56 per share and raised approximately $8.0 million in gross proceeds.

The Company issued additional 22,222,222 shares of Series C preferred stock in July 2013 at a price of $0.56 per share and raised $12.5 million in gross proceeds.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Issuance of Series D convertible preferred stock

In October 2013, the Company entered into a stock purchase agreement with investors to sell shares of Series D convertible preferred stock in two tranches. In accordance with the terms of the Series D purchase agreement, the Company authorized the sale and issuance of up to 30,946,068 shares of Series D stock. The Company issued 17,777,777 shares of Series D-1 at a purchase price of $0.56 per share and raised approximately $10.0 million in gross proceeds. In February 2014, the Company issued 13,168,291 shares of Series D-2 at a purchase price of $0.76 per share and received approximately $10.0 million in gross proceeds.

Convertible preferred stock call option liability

The preferred stock purchase agreements for Series A, B, C and D provided the investors the right to participate in future rounds of the respective series funding at a fixed price equal to the original issue price. These rights were provided concurrently with the issuance of the original preferred stock agreement (Series A convertible preferred stock had a separate option agreement). These liability classified convertible preferred stock call options have been determined to be freestanding financial instruments because they are freely transferable and separately exercisable.

Series A convertible preferred stock call option liability

On December 10, 2008, the Company sold a convertible preferred stock call option right to investors to participate in four future rounds of Series A convertible preferred financing. The Company recorded an initial call option liability in December 2008 and remeasured the convertible preferred stock liability immediately prior to exercise as well as at each balance sheet date. The convertible preferred stock call option right was exercised in three rounds of financing and was waived at the fourth round financing. The impact of the remeasurement of the option was negligible on a cumulative basis from December 10, 2008 to December 31, 2010.

Series B convertible preferred stock call option liability

The Company has recorded an initial convertible preferred stock call option liability in February 2011 upon the initial closing of the financing. Using an option pricing model with a volatility of 71%, expected term of 1 year and a risk-free interest rate of 0.28%, the fair value of the call option was determined to be approximately $1.4 million and was recorded as convertible preferred stock call option liability and netted against the issuance of Series B convertible preferred stock.

The Company remeasured the convertible preferred stock call option liability at $349,000 at December 31, 2011 and recorded the change in fair value of $1.0 million in other income (expense), net. In 2012, the Company remeasured the convertible preferred stock call option liability immediately before exercise and recorded $88,000 in other income (expense), net and reclassified the fair value of $260,000 into preferred stock upon issuance of subsequent tranches of Series B convertible preferred stock.

Series C convertible preferred stock call option liability

The Company has recorded an initial convertible preferred stock call option liability in January 2013 upon the initial close of the financing. Using the option pricing model with a volatility of 56%, expected term of 0.5 years and a risk-free interest rate of 0.11%, the fair value of the convertible preferred stock call option was determined to be approximately $990,000 and was recorded as a call option liability and netted against the issuance of Series C convertible preferred stock.

The investors exercised their right to participate in subsequent tranches in 2013 and accordingly the Company remeasured the convertible preferred stock call option liability just before exercise and recorded $864,000 in other income (expense), net and reclassified the fair value of $126,000 into preferred stock upon issuance of subsequent tranches of Series C preferred stock.

Series D convertible preferred stock call option liability

The Company has recorded an initial convertible preferred stock call option liability in October 2013 upon the initial close of the financing. Using the option pricing model with a volatility of 60%, expected term of 0.3 years and a risk-free interest rate of 0.2%, the fair value of the convertible preferred stock call option was determined to be approximately $126,000 and was recorded as a call option liability and netted against the issuance of Series D-1 convertible preferred stock. As of December 31, 2013, the fair value of the call option was determined to be $21,000, and the change in the fair value of $105,000 was recorded in other income (expense), net in the consolidated statement of operations and comprehensive loss.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Modification to Series A rights and preferences

In February 2011, the Company entered into an agreement with new investors to sell shares of Series B convertible preferred stock. In addition, the Company sold the rights to develop one of its two product candidates to Diartis in exchange for a $1.0 million note receivable. In connection with the Series B convertible preferred stock financing, the liquidation preference of the Series A convertible preferred stock was reduced from $1.00 per share to $0.45 per share, and the conversion ratio of Series A convertible preferred stock was reduced from $11.50 per share to $5.17 per share, the redemption feature was eliminated and a down-round feature was added to the rights and preferences of Series A convertible preferred stockholders. The Company considers an amendment which adds, deletes or significantly changes a material contractual term or fundamentally changes the nature of the preferred shares to be in the nature of an extinguishment. As there were significant changes in the liquidation preference and conversion rate, the removal of the Series A holder-controlled contingent redemption feature, and addition of down-round protection, the Company has considered these changes to be substantially different. At the time of the extinguishment, the Company removed the carrying value of the preferred stock of $22.0 million, and recorded the deemed fair value of the Series A convertible preferred stock after the change in the rights and preferences of $9.9 million, resulting in a net reduction of $12.1 million in the Series A preferred stock carrying value and an increase to deficit accumulated during the development stage.

Accretion of preferred stock

The Company recorded the convertible preferred stock at fair value on the dates of issuance. The Company classifies the convertible preferred stock outside of stockholders' deficit because the shares contain liquidation features that are not solely within the Company's control.

The Series A shares were originally issued (before modification of rights and preferences upon issuance of Series B) with a contingent redemption feature, which allowed the holders to redeem their shares five years following the issuance date of the Series A preferred shares. As such, the Company has chosen to accrete Series A for change in redemption value with a change to accumulated deficit at the end of each reporting period. Accordingly, the Company has accreted $11.0 million during the cumulative periods ended December 31, 2010.

During the years ended December 31, 2012 and 2013, the Company did not adjust the carrying values of the convertible preferred stock to the redemption values of such shares since a liquidation event was not probable. Subsequent adjustments to increase the carrying values to the ultimate redemption values will be made only when it becomes probable that such a liquidation event will occur.

The rights, preferences and privileges of the convertible preferred stock as of December 31, 2013 are as follows:

Dividends

The holders of the Company's convertible preferred stock are entitled to receive noncumulative dividends of $0.036 per share (as adjusted for stock splits, combinations, and reorganizations) per annum on each outstanding share of Series A and B preferred stock, and $0.045 per share for each outstanding share of Series C and D-1 preferred stock. Such dividends shall be payable only when and if declared by the Board of Directors. No dividends have been

declared to date.

Conversion

Preferred stock is convertible, at the option of the holder, at any time, into fully paid, non-assessable shares of common stock at an initial conversion ratio of 11.5-to-one.

The convertible preferred stock will automatically convert into common stock, at the then applicable conversion rate, in the event of either (i) the consent of a majority of certain holders of the then outstanding preferred stock, voting together as a class, or, if earlier, (ii) immediately before the closing of an underwritten initial public offering of the Company's common stock pursuant to a registration statement on Form S-1 under the Securities Act of 1933, as amended, with aggregate proceeds of at least $50.0 million at a public offering price of at least $17.48 per share (adjusted for intervening common stock splits, stock dividends, combination, subdivision, recapitalizations or the like).

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Voting Rights

The holders of convertible preferred stock will be entitled to that number of votes on all matters presented to stockholders equal to the number of shares of common stock then issuable upon conversion of such preferred stock.

Liquidation

In the event of any sale of substantially all of the assets, a merger, or liquidation, dissolution or winding up of the Company, the holders of Series A, B, C and D-1 convertible preferred stock will be entitled to receive in preference to the holders of common stock, $0.45, $0.45, $0.56 and $0.56 respectively, per share (as adjusted for stock splits, combinations, and reorganizations) plus declared and unpaid dividends, if any. Thereafter, the remaining assets of the Company will be distributed ratably to the holders of preferred stock and common stock on a pro rata basis.

Deemed Liquidation

A merger, acquisition, sale or lease of all or substantially all of the assets of the Company which will result in the Company's stockholders immediately prior to such transaction not holding at least 50% of the voting power of the surviving, continuing or purchasing entity, shall be deemed to be a liquidation, dissolution or winding up. Upon this event, holders of convertible preferred stock shall receive their liquidation preference including any accrued and unpaid dividends as of the liquidation date.

Protective Provisions

Without first obtaining the approval of the Company's board of directors, which approval must include the approval of a majority of the directors designated by certain holders of preferred stock, the Company will not (i) make specified investment, compensation or operating decisions; (ii) take certain actions involving the Company's intellectual property and related agreements; (iii) consummate or consent to a liquidation event; (iv) increase or decrease the total number of authorized shares of any series or sub-series of preferred stock or of common stock or take certain other actions that may adversely affect the rights, preferences and privileges of the Company's outstanding capital stock; (v) amend, waive, alter or repeal any provision of the Company's certificate of incorporation or the company's bylaws; (vi) purchase or redeem (or permit any subsidiary to purchase or redeem) or pay or declare a dividend or make any distribution on the capital stock of the Company, except in certain circumstances; (vii) purchase or acquire any other business or entity or create any subsidiary; (viii) incur specified types of indebtedness, (ix) adopt or amend any stock option scheme or any other equity incentive plan; (x) enter into certain transactions concerning the Company's assets and intellectual property; (xi) enter into any transaction with any officer, director or other affiliate of the Company without required approvals; or (xii) change the authorized number of directors constituting the board of directors.

Without first obtaining the written consent or affirmative vote of the holders of at least 66 2/3% of the then outstanding shares of Series D preferred stock, consenting or voting separately as a class, the Company will not: (i) amend, alter, or repeal any provision of the Company's certificate of incorporation or bylaws in a manner that adversely affects the rights, preference or privileges of the Series D preferred stock; (ii) take certain other actions that may adversely affect the rights, preferences and privileges of the Series D preferred stock; (iii) declare or pay any dividend on any capital stock; (iv) consummate or consent to a liquidation event except in certain circumstances; or

(v) increase or decrease the authorized number of shares of the Series D preferred stock.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Without first obtaining the written consent or affirmative vote of certain stockholders specified in the certificate of incorporation, the Company will not: (i) consummate or consent to a liquidation event; (ii) amend, alter, or repeal any provision of the Company's certificate of incorporation or bylaws; (iii) create, or authorize the creation of, or issue or obligate itself to issue shares of, any additional class or series or sub-series of capital stock (or any security convertible into or exercisable for any such capital stock) that ranks senior to or pari passu with any series or sub-series of preferred stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Company, the payment of dividends and rights of redemption; (iv) increase or decrease the authorized number of shares of common stock or preferred stock; (v) purchase or redeem (or permit any subsidiary to purchase or redeem) or pay or declare a dividend or make any distribution on the capital stock of the company, except in certain circumstances; (vi) incur or guarantee specified types of indebtedness; (vii) increase or decrease the size of the board of directors; (viii) increase the number of shares reserved for issuance under the Company's equity incentive plans; (ix) alter or change the rights, preferences or privileges of any series or sub-series of preferred stock; (x) adopt or amend any stock option scheme or any other equity incentive plan; (xi) enter into certain transactions concerning the Company's intellectual property; (xii) enter into any transaction with any officer, director or other affiliate of the Company without required approval; or (xiii) make any loan or advance, or grant any credit, to any employee or director of the Company or any subsidiary, except advances for travel expenses and similar expenditures to be incurred on behalf of the Company in the ordinary course of business.

9. Common Stock

The Certificate of Incorporation, as amended, authorizes the Company to issue 50,000,000 shares of common stock. Common stockholders are entitled to dividends as and when declared by the Board of Directors, subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date. The holder of each share of common stock is entitled to one vote.

The Company had reserved common stock for future issuances as follows:

| | December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Conversion of convertible preferred stock | — | 10,491,140 |
| Issuance of equity based awards under stock plan | 991,401 | 9,533 |
| Issuance upon exercise of options under stock plan | 2,723,366 | 1,403,655 |
| Issuance of restricted stock units under stock plan | 185,514 | — |
| Issuance upon exercise of warrants to purchase Series B convertible preferred stock | — | 173,912 |
| Total | 3,900,281 | 12,078,240 |

10. Stock Based Awards

2009 Equity Incentive Plan

In February 2009, the Company adopted the Versartis, Inc. 2009 Stock Plan, which was amended in June 2011 (“2009 Plan”) for eligible employees, outside directors and consultants. The 2009 Plan provides for the granting of incentive stock options, non-statutory stock options, and stock purchase rights to acquire restricted stock. Terms of the stock option agreements, including vesting requirements, are determined by the board of directors, subject to the provisions in the 2009 Plan. Options granted by the Company generally vest over a period of four years and expire no later than ten years after the date of grant. Options may be exercised prior to vesting, subject to a right of repurchase by the Company. The board of directors determines the fair value of the underlying common stock at the time of the grant of each option. Upon the exercise of options, the Company issues new common stock from its authorized shares.

Options under the 2009 Plan may be granted for periods of up to ten years. All options issued to date have had a ten year life. The exercise price of an ISO shall not be less than 100% of the estimated fair value of the shares on the date of grant, as determined by the Board of Directors. The exercise price of an ISO and NSO granted to a 10% shareholder shall not be less than 110% of the estimated fair value of the shares on the date of grant, respectively, as determined by the board of directors. The exercise price of a NSO shall not be less than the par value per share of common stock. To date, options granted generally vest over four years and vest at a rate of 25% upon the first anniversary of the issuance date and 1/36th per month thereafter.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Upon adoption of the 2014 Equity Incentive Plan described below, no further grants will be made under the 2009 Plan.

2014 Equity Incentive Plan

In March 2014, the Company's board of directors adopted, and the Company's stockholders approved, the 2014 Equity Incentive Plan, or the 2014 Plan. The 2014 Plan became effective at the time of the initial public offering and is the successor to the 2009 Plan. The 2014 Plan provides for the grant of ISOs to employees and for the grant of NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, performance-based cash awards and other forms of equity compensation to employees, directors and consultants. Additionally, the 2014 Plan provides for the grant of performance cash awards to employees, directors and consultants.

Initially, the aggregate number of shares of common stock that may be issued pursuant to stock awards under the 2014 Plan after the initial public offering is approximately 4.1 million, which includes options outstanding under the 2009 Plan. The number of shares of common stock reserved for issuance under the 2014 Plan will automatically increase on January 1 of each year, beginning on January 1, 2015 (assuming the 2014 Plan becomes effective in 2014) and ending on and including January 1, 2024, by 4.5% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under the 2014 Plan is 12,000,000.

The Company's board of directors, or a duly authorized committee of the board of directors, will administer the 2014 Plan. The board of directors may also delegate to one or more of the Company's officers the authority to (i) designate employees (other than officers) to receive specified stock awards, and (ii) determine the number of shares of our common stock to be subject to such stock awards. Subject to the terms of our 2014 Plan, the board of directors has the authority to determine the terms of awards, including recipients, the exercise, purchase or strike price of stock awards, if any, the number of shares subject to each stock award, the fair market value of a share of the Company's common stock, the vesting schedule applicable to the awards, together with any vesting acceleration, and the form of consideration, if any, payable upon exercise or settlement of the award and the terms of the award agreements. Options granted under the 2014 Plan have a contractual life of ten years and generally vest over four years and vest at a rate of 25% upon the first anniversary of the issuance date and 1/36$^{th}$ per month thereafter. The exercise price shall not be less than 100% of the fair market value of the shares on the date of grant.

As of December 31, 2014, a total of 991,401 shares of common stock are available for future grant under the 2014 Plan.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Activity under the Company's stock option plans is set forth below:

| | Shares Available for Grant | Number of Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (in years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|---|
| Balance at January 1, 2013 | 168,571 | 462,471 | $ 1.31 | | |
| Additional shares authorized | 803,590 | — | — | | |
| Options granted | (974,459) | 974,459 | 2.16 | | |
| Options exercised | — | (21,444) | 1.27 | | |
| Options cancelled | 11,831 | (11,831) | 1.30 | | |
| Balances, December 31, 2013 | 9,533 | 1,403,655 | $ 1.90 | | |
| Additional shares authorized | 2,531,915 | — | — | | |
| Options granted | (1,471,142) | 1,471,142 | 18.68 | | |
| Restricted stock units granted | (185,514) | — | — | | |
| Options exercised | — | (44,822) | 1.32 | | |
| Options cancelled | 106,609 | (106,609) | 18.43 | | |
| Balances, December 31, 2014 | 991,401 | 2,723,366 | $ 10.33 | 8.8 | $ 36,006 |
| Vested and expected to vest as of December 31, 2014 | — | 2,651,182 | $ 10.27 | 8.8 | $ 35,141 |
| Exercisable as of December 31, 2014 | — | 648,058 | $ 3.04 | 7.7 | $ 12,858 |

The intrinsic values of outstanding, vested and exercisable options were determined by multiplying the number of shares by the difference in exercise price of the options and the fair value of the common stock. The intrinsic value of stock options exercised during the years ended December 31, 2014, 2013, and 2012 was $0.8 million, zero, and zero, respectively.

The following table summarizes information with respect to stock options outstanding and currently exercisable and vested as of December 31, 2014:

| Options Outstanding | | | Options Exercisable and Vested | |
|---|---|---|---|---|
| | Weighted Average | | | Weighted Average |

| Range of Exercise Prices | Number Outstanding | Remaining Contractual Life (in Years) | Number Outstanding | Remaining Contractual Life (in Years) |
|---|---|---|---|---|
| $1.27 - $1.61 | 769,755 | 7.5 | 471,420 | 7.5 |
| 2.53 | 570,927 | 9.0 | 146,484 | 9.0 |
| 3.34 - 18.66 | 576,987 | 9.2 | 1,087 | 9.2 |
| 18.73 - 31.96 | 795,697 | 9.6 | 29,067 | 9.6 |
| 34.00 | 10,000 | 9.5 | — | 9.5 |
| | 2,723,366 | | 648,058 | |

Stock Options Granted to Employees

During the years ended December 31, 2014, 2013, and 2012 the Company granted stock options to employees to purchase shares of common stock with a weighted-average grant date fair value of $16.90, $1.60, and $1.04 per share, respectively. The fair value is being expensed over the vesting period of the options, which is usually 4 years on a straight line basis as the services are being provided. No tax benefits were realized from options and other share-based payment arrangements during the periods.

As of December 31, 2014, total unrecognized employee stock-based compensation was $20.2 million, which is expected to be recognized over the weighted-average remaining vesting period of 3.1 years.

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(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

The fair value of employee stock options was estimated using the following weighted average assumptions:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| Expected volatility | 84.9% | 89.1% | 91.3% |
| Risk-free interest rate | 1.9% | 1.7% | 1.1% |
| Dividend yield | 0.0% | 0.0% | 0.0% |
| Expected life (in years) | 6.1 | 6.1 | 6.1 |

Determining Fair Value of Stock Options

The fair value of each grant of stock options was determined by the Company using the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

Expected Volatility – The expected stock price volatility assumption was determined by examining the historical volatilities of a group of industry peers, as the Company did not have any trading history for the Company's common stock. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available.

Expected Term – The expected term of stock options represents the weighted average period the stock options are expected to be outstanding. For option grants that are considered to be "plain vanilla", the Company has opted to use the simplified method for estimating the expected term as provided by the Securities and Exchange Commission. The simplified method calculates the expected term as the average time-to-vesting and the contractual life of the options. For other option grants, the expected term is derived from the Company's historical data on employee exercises and post-vesting employment termination behavior taking into account the contractual life of the award.

Risk-Free Interest Rate – The risk free rate assumption was based on the U.S. Treasury instruments with terms that were consistent with the expected term of the Company's stock options.

Expected Dividend – The expected dividend assumption was based on the Company's history and expectation of dividend payouts.

Forfeiture Rate – Forfeitures were estimated based on historical experience.

Fair Value of Common Stock – The fair value of the shares of common stock underlying the stock options has historically been the responsibility of and determined by the Company's board of directors. Because there had been no public market for the Company's common stock prior to the initial public offering, the board of directors determined the fair value of common stock at the time of grant of the option by considering a number of objective and subjective factors including independent third-party valuations of the Company's common stock, sales of convertible preferred stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock and general and industry specific economic outlook, amongst other factors. Since the initial public offering in March 2014, the fair value of the underlying common stock is based upon quoted prices on the NASDAQ Global Select Market.

Stock-based compensation expense, net of estimated forfeitures, is reflected in the statements of operations and comprehensive loss as follows (in thousands):

| | Year Ended December 31, | | | Cumulative Period From December 10, 2008 (Date of Inception) to December 31, |
|---|---|---|---|---|
| | 2014 | 2013 | 2012 | 2014 |
| Operating Expenses | | | | |
| Research and development | $1,230 | $124 | $91 | $ 1,599 |
| General and administrative | 3,411 | 91 | 50 | 3,590 |
| Total | $4,641 | $215 | $141 | $ 5,189 |

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

2014 Employee Stock Purchase Plan

The board of directors adopted, and the Company's stockholders approved, the 2014 Employee Stock Purchase Plan, or the ESPP, in March 2014. The ESPP became effective on March 20, 2014.

The maximum aggregate number of shares of common stock that may be issued under the ESPP is 150,000 shares (subject to adjustment to reflect any split of our common stock). Additionally, the number of shares of common stock reserved for issuance under the ESPP will increase automatically each year, beginning on January 1, 2015 and continuing through and including January 1, 2024, by the lesser of (i) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year; and (ii) 300,000 shares of common stock (subject to adjustment to reflect any split of our common stock). The board of directors may act prior to the first day of any calendar year to provide that there will be no January 1 increase or that the increase will be for a lesser number of shares than would otherwise occur. Shares subject to purchase rights granted under the ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under the ESPP.

An employee may not be granted rights to purchase stock under the ESPP if such employee (i) immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of the Company's common stock, or (ii) holds rights to purchase stock under the ESPP that would accrue at a rate that exceeds $25,000 worth of our stock for each calendar year that the rights remain outstanding.

The administrator may approve offerings with a duration of not more than 27 months, and may specify one or more shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of common stock will be purchased for the employees who are participating in the offering. The administrator, in its discretion, will determine the terms of offerings under the ESPP.

The ESPP permits participants to purchase shares of our common stock through payroll deductions with up to 15% of their earnings. The purchase price of the shares will be not less than 85% of the lower of the fair market value of our common stock on the first day of an offering or on the date of purchase.

We estimated the fair value of our employees' stock purchase rights under the ESPP using the Black-Scholes model with the following weighted-average assumptions:

| | Year Ended December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Expected volatility | 54.9% | - |
| Risk-free interest rate | 0.06% | - |
| Dividend yield | 0.00% | - |
| Expected life (in years) | 0.5 | - |

Restricted Stock Units

Restricted stock units are shares of common stock which are forfeited if the employee leaves the Company prior to vesting. These stock units offer employees the opportunity to earn shares of the Company's stock over time, rather than options that give the employee the right to purchase stock at a set price. As a result of these restricted stock units, the Company recognized $0.5 million in compensation expense during the year ended December 31, 2014. As all of the restricted stock vests through 2015 and beyond, the Company will continue to recognize stock based compensation expense related to the grants of these restricted stock units. If all of the remaining restricted stock units that were granted in 2014 vest, the Company will recognize approximately $4.3 million in compensation expense over a weighted average remaining period of 3.5 years. However, no compensation expense will be recognized for restricted stock units that do not vest.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

A summary of the Company's restricted stock activity is presented in the following tables:

| | Number of Shares | Weighted Average Grant Date Fair Value |
|---|---|---|
| Restricted Stock Units | | |
| Unvested at December 31, 2013 | — | $ — |
| Granted | 185,514 | 26.77 |
| Vested | — | — |
| Forfeited/canceled | — | — |
| Unvested at December 31, 2014 | 185,514 | $ 26.77 |

11. Related Party Transactions

Since inception the Company has entered into multiple agreements with Amunix which (i) with its affiliates, owns 10% of the Company's preferred stock outstanding at December 31, 2013, and (ii) is represented on the Company's Board of Directors. These agreements between the Company and Amunix include the following:

- License Agreement effective December 29, 2008, as amended, ("License Agreement"), pursuant to which the Company has the right to develop three products, with the option to develop up to three additional products in exchange for certain additional financial considerations. Amunix granted the Company a worldwide, exclusive, revocable sub-licensable right and licensed its intellectual property for the Company to research, test and develop these products. The License Agreement obligates the Company to pay to Amunix certain future royalties related to these products. One of these products, and the option to develop one additional product, were sold to Diartis on December 30, 2010. The agreement was further amended at the close of the Company's Series C preferred stock financing on January 7, 2013, to clarify the technology included in the License Agreement;
  The Company will pay Amunix additional consideration, in either cash or the Company's stock, for additional targets selected by the Company. The Company will also pay up to $30.0 million of milestone payments to Amunix, under certain circumstances;
- Joint Research Agreement effective November 13, 2009, as amended and combined with the License Agreement, establishing the process by which new targets will be identified and subsequently developed by the parties. In particular, the respective ownership of new inventions by the parties under various scenarios is contemplated. Overall, during the term of this agreement, the Company agreed to assign to Amunix its rights to all joint patents, and all the Company's patents that are directed to compositions, processes and methods of use or recombinant PEGylation ("rPEG") technology and/or targets comprising rPEG;

- Service Agreement ("Service Agreement") effective December 29, 2008, as amended, setting forth the terms under which Amunix has agreed to make covered products and marketed products for the Company as contemplated by the Licensing Agreement. Under the Service Agreement, Amunix agreed to undertake and complete the research, development and other services related to the covered products and marketed products as are reasonably requested by the Company from time to time. The specific milestones, deliverables, specifications and other terms with respect to any particular services project are to be detailed in mutually agreeable statements of work, which the parties are to negotiate (reasonably and in good faith) and execute promptly after the Company's request for services;
- Office sublease effective September 15, 2009 which expired in November 2011;
- Employee Cost Sharing Agreement, effective January 19, 2010, for the term of one year, whereby the Company makes certain employees available to Amunix to perform business development and finance services with respect to a Consulting Agreement. Amunix, Inc. will reimburse the Company a percentage of the employees' salary and benefits. This Agreement expired on February 1, 2012.

The aggregate operating expenses included in the consolidated statements of operations and comprehensive loss pertaining to these agreements were approximately $0, $0, and $74,000 for the years ended December 31, 2014, 2013 and 2012, respectively, and $7.4 million for the period from December 10, 2008 (date of inception) to December 31, 2014. There were no amounts receivable or payable at December 31, 2014 pertaining to these agreements.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Effective May 12, 2009, the Company entered into a consulting agreement with Mark de Boer, Ph.D. Mr. de Boer (i) is a partner with Index Ventures which owns 24% of the Company's preferred stock outstanding at December 31, 2013, and (ii) had served as Chairman of the Company's Board of Directors. The consulting fees were incurred in the ordinary course of business, and were zero for the year ended December 31, 2012 and $120,000 for the period from December 10, 2008 (date of inception) to December 31, 2014. The consulting agreement terminated on December 10, 2010 and Mr. de Boer left the Board of Directors on February 14, 2011. In May 2011, the Company declined to repurchase unvested option shares from Mr. de Boer, thereby accelerating the vesting of 10,185 shares of common stock. The Company recognized an additional $1,000 of stock compensation expense in 2011 related to this transaction.

The Company entered into a Services Agreement with Diartis dated February 14, 2011 for a term equal to the term of the Amunix License Agreement (see above). Under this agreement, the Company provided certain administrative services to Diartis related to the management of its Phase 1a Human Clinical Trial for the treatment of certain metabolic diseases, as a clinical research organization.

In March 2013, the Company ended its relationship with Diartis and terminated the Services Agreement between the companies.

The aggregate operating expenses included in the consolidated statements of operations and comprehensive loss pertaining to these agreements were approximately $0, $0, and $1.4 million for the years ended December 31, 2014, 2013 and 2012, respectively, and $3.9 million for the period from December 10, 2008 (inception) to December 31, 2014. There were no receivables due from Diartis or accounts payable to third parties related to the conduct of business for Diartis at December 31, 2014 or December 31, 2013.

12. Income Taxes

There is no provision for federal income taxes in 2014, 2013 and 2012 and for the period from December 10, 2008 (date of inception) to December 31, 2013, respectively.

Income (loss) before income taxes is attributed to the following geographic locations for the year ended December 31, 2014, 2013 and 2012 (in thousand):

| | December 31, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| United States | $(49,850) | $(18,497) | $(13,217) |
| Foreign | (7,663) | — | — |
| Income (loss) before income taxes | $(57,513) | $(18,497) | $(13,217) |

Income tax expense in 2014, 2013 and 2012 differed from the amount expected by applying the statutory federal tax rate to the income or loss before taxes as summarized below:

| | December 31, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| Federal tax benefit at statutory rate | 34 % | 34 % | 34 % |
| State tax benefit net of federal effect | — | — | — |
| Change in valuation allowance | (23)% | (42)% | (33)% |
| Research and development credits | 2 % | 9 % | — |
| Non-deductible warrant | (7)% | — | — |
| Foreign loss not benefitted | (5)% | — | — |
| Non-deductible expenses and other | (1)% | (1)% | (1)% |
| Total | 0 % | 0 % | 0 % |

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Deferred income taxes reflect the net tax effects of net operating loss and tax credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred tax assets at December 31, 2014 and 2013 are as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Net operating loss carry forwards | $ 32,143 | $ 21,414 |
| Research and development tax credits | 2,776 | 2,414 |
| Accruals and reserves | 1,693 | 47 |
| Depreciation and amortization | 33 | 89 |
| Total deferred tax assets | 36,645 | 23,964 |
| Less: Valuation allowance | (36,645) | (23,964) |
| Net deferred tax assets | $ — | $ — |

The Company's accounting for deferred taxes involves the evaluation of a number of factors concerning the realizability of its net deferred tax assets. The Company primarily considered such factors as its history of operating losses, the nature of the Company's deferred tax assets, and the timing, likelihood and amount, if any, of future taxable income during the periods in which those temporary differences and carryforwards become deductible. At present, the Company does not believe that it is more likely than not that the deferred tax assets will be realized; accordingly, a full valuation allowance has been established and no deferred tax asset is shown in the accompanying balance sheets.

The valuation allowance increased by approximately $12.7 million and $9.1 million in 2014 and 2013, respectively.

At December 31, 2014, the Company has net operating loss carryforwards for federal income tax purposes of approximately $85.7 million and federal research and development tax credits of approximately $840,000, which begin to expire in 2029. The Company also has net operating loss carryforwards for state income tax purposes of approximately $55.1 million, which begin to expire in 2029, and state research and development tax credits of approximately $698,000 which have no expiration date. Additionally, the Company has an Orphan Drug Credit of approximately $1.8 million for federal income tax purposes, which begins to expire in 2033.

Utilization of net operating losses and tax credit carryforwards may be limited by the "ownership change" rules, as defined in Section 382 of the Internal Revenue Code (any such limitation, a "Section 382 limitation"). Similar rules may apply under state tax laws. The Company has performed an analysis to determine whether an "ownership change" occurred from inception to the Company's initial public offering in March 2014. Based on this analysis, management determined that the Company did experience historical ownership changes of greater than 50% during this period. Therefore, the utilization of a portion of the Company's net operating losses and credit carryforwards is currently limited. However, these Section 382 limitations are not expected to result in a permanent loss of the net operating losses and credit carryforwards. As such, a reduction to the Company's gross deferred tax asset for its net operating loss and tax credit carryforwards is not necessary prior to considering the valuation allowance. In the event the Company experiences any subsequent changes in ownership, the amount of net operating losses and research and

development credit carryforwards useable in any taxable year could be limited and may expire unutilized.

The Company follows the provisions of FASB Accounting Standards Codification 740-10 (ASC 740-10), Accounting for Uncertainty in Income Taxes. ASC 740-10 prescribes a comprehensive model for the recognition, measurement, presentation and disclosure in consolidated financial statements of uncertain tax positions that have been taken or expected to be taken on a tax return. No liability related to uncertain tax positions is recorded in the consolidated financial statements. At December 31, 2014, 2013 and 2012, the Company's reserve for unrecognized tax benefits is approximately $332,000, $287,000 and $73,000, respectively. Due to the full valuation allowance at December 31, 2014, current adjustments to the unrecognized tax benefit will have no impact on the Company's effective income tax rate; any adjustments made after the valuation allowance is released will have an impact on the tax rate. The Company does not anticipate any significant change in its uncertain tax positions within 12 months of this reporting date. The Company includes penalties and interest expense related to income taxes as a component of other expense and interest expense, respectively, as necessary.

Because the statute of limitations does not expire until after the net operating loss and credit carryforwards are actually used, the statute is open for all tax years from inception, that is, for the period from December 10, 2008 (date of inception) to December 31, 2014 and forward for federal and state tax purposes.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

| | Amount |
|---|---|
| Balance at January 1, 2012 | $ 62 |
| Increase/(Decrease) of unrecognized tax benefits related to current year | 11 |
| Balance at December 31, 2012 | $ 73 |
| Increase/(Decrease) of unrecognized tax benefits taken in prior years | 31 |
| Increase/(Decrease) of unrecognized tax benefits related to current year | 183 |
| Balance at December 31, 2013 | $ 287 |
| Decreases based on tax positions taken during a prior period | (102 ) |
| Increases based on tax positions taken during a current period | 147 |
| Balance at December 31, 2014 | $ 332 |

All tax years remain open for examination by federal and state tax authorities.

13. Defined Contribution Plan

The Company sponsors a 401(k) Plan, which stipulates that eligible employees can elect to contribute to the 401(k) Plan, subject to certain limitations of eligible compensation. The Company may match employee contributions in amounts to be determined at the Company's sole discretion. To date, the Company has not made any matching contributions.

14. Net loss per share

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company (in thousands, except per share data):

| | December 31, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| Net loss attributable to common stockholders - basic and diluted | $(83,072 ) | $(18,497 ) | $(13,217 ) |
| Weighted-average shares outstanding | 18,921,533 | 450,061 | 130,718 |
| Less: weighted average shares subject to repurchase | — | (61 ) | (15,499 ) |

| | | | |
|---|---|---|---|
| Weighted-average shares used to compute basic and diluted net loss per share | 18,921,533 | 450,000 | 115,219 |
| Basic and diluted net loss per common share | $(4.39) | $(41.10) | $(114.71) |

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

Basic net loss attributable to common stockholders per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted net loss attributable to common stockholders per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period, determined using the treasury-stock method and the as-if converted method, for convertible securities, if inclusion of these is dilutive. Because the Company has reported a net loss for the years ended December 31, 2014, 2013 and 2012, diluted net loss per common share is the same as basic net loss per common share for those years.

The following potentially dilutive securities outstanding at the end of the years presented have been excluded from the computation of diluted shares outstanding:

| | December 31, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| Convertible preferred stock | — | 10,491,140 | 5,991,757 |
| Warrants to purchase convertible preferred stock (1) | — | 173,912 | 173,912 |
| Options to purchase common stock | 2,723,366 | 1,403,655 | 462,471 |
| Convertible notes | — | — | 885,024 |
| Restricted stock units | 185,514 | — | — |

(1) Assumes exercise of warrants to purchase convertible preferred stock at $5.17 per share.

15. Subsequent Event

In January 2015, the Company completed a secondary public offering of shares of its common stock, pursuant to which the Company issued 4,999,999 shares of common stock, which includes shares issued pursuant to the underwriters' exercise of their over-allotment option, and received net proceeds of approximately $80.3 million, after underwriting discounts, commissions and estimated offering expenses.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

16. Quarterly Results (Unaudited)

The following table is in thousands, except per share amounts:

| | Quarters Ended | | | |
|---|---|---|---|---|
| | March 31, 2014 | June 30, 2014 | September 30, 2014 | December 31, 2014 |
| Consolidated Statement of operations data: | | | | |
| Operating expenses | | | | |
| Research and development | $4,869 | $5,622 | $10,515 | $11,602 |
| General and administrative | 2,714 | 2,877 | 3,577 | 4,338 |
| Total operating expenses | 7,583 | 8,499 | 14,092 | 15,940 |
| Loss from operations | (7,583) | (8,499) | (14,092) | (15,940) |
| Interest income | — | 40 | 50 | 43 |
| Interest expense | — | — | — | — |
| Other income (expense), net | (11,843) | (141) | 208 | 244 |
| Net loss and comprehensive loss | (19,426) | (8,600) | (13,834) | (15,653) |
| Deemed dividend related to beneficial conversion feature of convertible preferred stock | (25,559) | - | - | - |
| Net loss attributable to common stockholders | $(44,985) | $(8,600) | $(13,834) | $(15,653) |
| Net loss per basic and diluted share attributable to common stockholders | $(16.13) | $(0.36) | $(0.57) | $(0.65) |
| Weighted-average common shares used to compute basic and diluted net loss per share | 2,788,087 | 24,194,808 | 24,194,808 | 24,215,018 |

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| | March 31, 2013 | June 30, 2013 | September 30, 2013 | December 31, 2013 |
| Statement of operations data: | | | | |
| Operating expenses | | | | |
| Research and development | $3,499 | $3,326 | $4,576 | $3,454 |
| General and administrative | 682 | 656 | 685 | 2,405 |
| Total operating expenses | 4,181 | 3,982 | 5,261 | 5,859 |
| Loss from operations | (4,181) | (3,982) | (5,261) | (5,859) |

| | | | | |
|---|---|---|---|---|
| Interest income | — | — | — | 1 |
| Interest expense | (128) | — | — | — |
| Other income (expense), net | 290 | 327 | 252 | 44 |
| Net loss and comprehensive loss | (4,019) | (3,655) | (5,009) | (5,814) |
| Deemed dividend related to beneficial conversion feature of convertible preferred stock | - | - | - | - |
| Net loss attributable to common stockholders | $(4,019) | $(3,655) | $(5,009) | $(5,814) |
| Net loss per basic and diluted share attributable to common stockholders | $(30.23) | $(24.74) | $(19.98) | $(4.62) |
| Weighted-average common shares used to compute basic and diluted net loss per share | 132,969 | 147,713 | 250,745 | 1,257,250 |

VERSARTIS, INC.

Schedule II: Valuation and Qualifying Accounts

(in thousands)

| | Balance at beginning of period | Additions/charged to expense | Deductions | Balance at end of period |
|---|---|---|---|---|
| Year ended December 31, 2014 | | | | |
| Valuation allowances for deferred tax assets | $ 23,964 | $ 12,681 | $ — | $ 36,645 |
| Year ended December 31, 2013 | | | | |
| Valuation allowances for deferred tax assets | $ 14,852 | $ 9,112 | $ — | $ 23,964 |
| Year ended December 31, 2012 | | | | |
| Valuation allowances for deferred tax assets | $ 9,681 | $ 5,171 | $ — | $ 14,852 |

Exhibit Index

| Exhibit Number | Description |
|---|---|
| 3.1 | Amended and Restated Certificate of Incorporation. (1) |
| 3.2 | Amended and Restated Bylaws. (2) |
| 4.1 | Form of Stock Certificate. (3) |
| 10.1 | Fourth Amended and Restated Investors' Right Agreement by and among the Company and the parties thereto, dated as of February 14, 2014. (4) |
| 10.2 | Lease by and between the Company and CA-Shorebreeze Limited Partnership, dated as of August 31, 2011. (5) |
| 10.3* | 2009 Stock Plan, as amended.(6) |
| 10.4* | Form of Notice of Stock Option Grant and Incentive Stock Option Agreement under 2009 Stock Plan. (7) |
| 10.5* | Form of Notice of Stock Option Grant and Non-Statutory Stock Option Agreement under 2009 Stock Plan. (8) |
| 10.6* | 2014 Equity Incentive Plan. (9) |
| 10.7* | Form of 2014 Equity Incentive Plan Stock Option Grant Notice and Stock Option Agreement. (10) |
| 10.8* | Form of 2014 Equity Incentive Plan Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement. (11) |
| 10.9* | Change in Control Severance Plan. (12) |
| 10.10* | 2014 Employee Stock Purchase Plan. (13) |
| 10.11* | Form of Indemnification Agreement by and between the Company and each of its directors and officers. (14) |
| 10.12† | Technology Transfer and Clinical Supply Agreement by and between the Company and Boehringer Ingelheim RCV GmbH & Co KG, dated as of October 23, 2012. (15) |
| 10.13† | Amendment No. 1 to the Technology Transfer, Clinical Supply Agreement by and between the Company and Boehringer Ingelheim RCV GmbH & Co KG, effective as of October 1, 2013. (16) |
| 10.14† | Assignment of Technology Transfer and Clinical Supply Agreement by and between the Company and Boehringer Ingelheim RCV GmbH & Co KG, effective as of January 1, 2014. (17) |
| 10.15† | |

| | |
|---|---|
| | Services Agreement by and between the Company and Amunix Operating Inc., dated as of March 18, 2013. (18) |
| 10.16† | Second Amended and Restated Licensing Agreement by and between the Company and Amunix Operating, Inc., dated as of December 30, 2010. (19) |
| 10.17† | Letter Agreement by and between the Company and Amunix Operating, Inc., dated as of February 3, 2011. (20) |
| 10.18† | Amendment No. 1 to the Second Amended and Restated Licensing Agreement by and between the Company and Amunix Operating, Inc., dated as of January 7, 2013. (21) |
| 10.19 | Amendment No. 2 to Second Amended and Restated Licensing Agreement by and between the Company and Amunix Operating, Inc., dated as of February 25, 2014. (22) |
| 10.20* | Offer letter between the Company and Jeffrey L. Cleland, Ph.D., dated as of December 20, 2010. (23) |
| 10.21* | Offer letter between the Company and Joshua T. Brumm, dated as of November 8, 2013. (24) |
| 10.22* | Amended and restated offer letter between the Company and Paul Westberg, dated as of February 10, 2011. (25) |
| 10.23 | Office Lease by and between the Company and Kilroy Realty, L.P., dated as of February 27, 2014. (26) |
| 21.1 | List of Subsidiaries |
| 23.1 | Consent of Independent Registered Public Accounting Firm |
| 24.1 | Power of Attorney (included in the signature page hereto) |

| Exhibit Number | Description |
|---|---|
| 31.1 | Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |

† Registrant has been granted confidential treatment for certain portions of this agreement. The omitted portions have been filed separately with the SEC.

* Indicates management contract or compensatory plan.

(1) Incorporated herein by reference to the same numbered exhibit of our current report on Form 8-K (File No. 001-36361), as filed with the SEC on March 26, 2014.

(2) Incorporated herein by reference to Exhibit 3.4 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 6, 2014.

(3) Incorporated herein by reference to the same numbered exhibit of our quarterly report on Form 10-Q (File No. 001-36361), for the quarterly period ended March 31, 2014, as filed with the SEC on May 14, 2014.

(4) Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014.

(5) Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014.

(6) Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014.

(7) Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014.

(8) Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014.

(9) Incorporated herein by reference to Exhibit 3.4 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 6, 2014.

(10) Incorporated herein by reference to Exhibit 99.5 of our registration statement on Form S-8 (File No. 333-194949), as filed with the SEC on April 1, 2014.

(11)

Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361), as filed with the SEC on April 17, 2014.

(12) Incorporated herein by reference to Exhibit 10.7 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 10, 2014.

(13) Incorporated herein by reference to Exhibit 10.9 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 6, 2014.

(14) Incorporated herein by reference to Exhibit 10.10 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 6, 2014.

(15) Incorporated herein by reference to Exhibit 10.11 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 19, 2014.

(16) Incorporated herein by reference to Exhibit 10.12 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 19, 2014.

(17) Incorporated herein by reference to Exhibit 10.13 of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014.

(18) Incorporated herein by reference to Exhibit 10.14 of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014.

(19) Incorporated herein by reference to Exhibit 10.15 of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014.
(20) Incorporated herein by reference to Exhibit 10.16 of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014.
(21) Incorporated herein by reference to Exhibit 10.17 of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014.
(22) Incorporated herein by reference to Exhibit 10.21 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 06, 2014.
(23) Incorporated herein by reference to Exhibit 10.18 of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014.
(24) Incorporated herein by reference to Exhibit 10.19 of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014.
(25) Incorporated herein by reference to Exhibit 10.20 of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014.
(26) Incorporated herein by reference to Exhibit 10.22 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 06, 2014.