Revance Therapeutics, Inc.
Form S-1/A
June 16, 2014
Table of Contents

As filed with the Securities and Exchange Commission on June 16, 2014

Registration No. 333-196582

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1

to

Form S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

Revance Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	2834	77-0551645
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

7555 Gateway Boulevard

Newark, California 94560

(510) 742-3400

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

L. Daniel Browne

President and Chief Executive Officer

Revance Therapeutics, Inc.

7555 Gateway Boulevard

Newark, California 94560

(510) 742-3400

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Mark B. Weeks	L. Daniel Browne	Bruce K. Dallas
Gordon K. Ho	President and Chief Executive Officer	Davis Polk & Wardwell LLP
Cooley LLP	Revance Therapeutics, Inc.	1600 El Camino Real
3175 Hanover Street	7555 Gateway Boulevard	Menlo Park, California 94025
Palo Alto, California 94304	Newark, California 94560	(650) 752-2000
(650) 843-5000	(510) 742-3400	

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ¨

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

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

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

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JUNE 16, 2014

PRELIMINARY PROSPECTUS

3,000,000 Shares

Revance Therapeutics, Inc.

Common Stock

We are offering 3,000,000 shares of our common stock. We have granted the underwriters an option for a period of 30 days to purchase an additional 450,000 shares of our common stock. Our common stock is listed on The NASDAQ Global Market under the symbol RVNC. On June 13, 2014, the last reported sale price of our common stock on The NASDAQ Global Market was $30.01 per share.

Investing in our common stock involves risk. See Risk Factors beginning on page 13.

We are an emerging growth company under applicable Securities and Exchange Commission rules and will be eligible for reduced public company disclosure requirements.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public Offering Price	$	$
Underwriting Discount[(1)]	$	$
Proceeds to Revance (before expenses)	$	$

(1) See Underwriting for additional disclosure regarding underwriting commissions and expenses.

The underwriters expect to deliver the shares to purchasers on or about , 2014, through the book-entry facilities of The Depository Trust Company.

Cowen and Company **Piper Jaffray**

BMO Capital Markets **William Blair**

The date of this prospectus is , 2014.

Table of Contents

TABLE OF CONTENTS

We have not, and the underwriters have not, authorized anyone to provide you with information different than that contained or incorporated by reference in this prospectus or any free writing prospectus that we have authorized for use in connection with this offering. If anyone provides you with different or inconsistent information, you should not rely on it. You should assume that the information appearing in this prospectus, the documents incorporated by reference in this prospectus, and in any free writing prospectus that we have authorized for use in connection with this offering is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus, the documents incorporated by reference in this prospectus, and any free writing prospectus that we have authorized for use in connection with this offering in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections of this prospectus entitled Where You Can Find More Information and Incorporation of Certain Information by Reference.

Neither we nor the underwriters have done anything that would permit this offering, or possession or distribution of this prospectus, in any jurisdiction where action for that purpose is required, other than in the United States. Persons who come into possession of this prospectus and any applicable free writing prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus and any such free writing prospectus applicable to that jurisdiction.

Table of Contents

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere or incorporated by reference in this prospectus and does not contain all of the information that you should consider in making your investment decision. You should read and consider carefully the more detailed information in this prospectus, including the factors described under the heading Risk Factors in this prospectus beginning on page 13 and the financial and other information included and incorporated by reference in this prospectus, as well as the information included in any free writing prospectus that we have authorized for use in connection with this offering, before making an investment decision. Unless the context otherwise requires, we use the terms Revance, company, we, us and our in this prospectus to refer to Revance Therapeutics, Inc. and, where appropriate, our consolidated subsidiary.

Our Company

We are a clinical stage specialty biopharmaceutical company focused on the development, manufacturing and commercialization of novel botulinum toxin products for multiple aesthetic and therapeutic applications. Our objective is to become a leading commercial dermatology company by leveraging our patented TransMTS® peptide technology across our proprietary portfolio of botulinum toxin formulations to address unmet needs in the multi-billion dollar, and growing, global botulinum toxin market. We have worldwide rights to our proprietary TransMTS technology, which is a broad platform that enables both delivery of large macromolecules across skin and more targeted delivery of botulinum toxin when injected.

Our lead product candidate, RT001, is a topical formulation of botulinum toxin type A, which we believe has the potential to be the first approved non-injectable botulinum toxin product. We believe RT001 has significant advantages over existing injectable products and could significantly expand the botulinum toxin market beyond existing users. Our second product candidate, RT002, is a novel injectable formulation of botulinum toxin type A designed to be more targeted and longer lasting than currently available botulinum toxin injectable products. Both of our product candidates combine our purified botulinum toxin with our proprietary TransMTS® peptide technology. We own the worldwide rights to both of our product candidates.

Our initial focus is in aesthetics and therapeutic dermatology market, which is today, and which we believe in the future will remain, the largest single addressable market for botulinum toxin products. The worldwide botulinum toxin market for cosmetic and therapeutic applications has grown at a compound annual growth rate of approximately 11% from 2004 to 2012, and is projected to be approximately $4.3 billion by 2018, according to the market research firm Global Industry Analysts, Inc., or GIA. We believe the aesthetics and therapeutic dermatology market is ideally suited for multiple dose forms of botulinum toxin because different indications are best served by different delivery methods. For example, topical formulations are better suited than injectable formulations for treatment of superficial muscle groups, such as those responsible for lateral canthal lines, the wrinkles around the eyes which are commonly referred to as crow s feet lines, and injectable formulations are more appropriate for treatment of deeper muscles, such as those in glabellar area responsible for frown lines.

We are evaluating RT001 in a broad clinical program that includes aesthetic indications such as crow s feet lines, and therapeutic indications such as hyperhidrosis, or excessive sweating, chronic migraine headache and allergic rhinitis, or inflammation of the mucous membrane inside the nose. RT001 has the potential to be the first approved non-injectable botulinum toxin product. RT001 s primary advantages include painless topical administration, ease of use and limited dependence on administration technique by physicians and medical staff. These advantages should improve the experience of patients undergoing botulinum toxin procedures and make RT001 more suitable for many more indications than currently approved injectable botulinum toxin products.

We are in a Phase 3 clinical development program of RT001 in North America for the treatment of crow s feet lines, and we plan to initiate and complete an additional Phase 3 clinical trial in Europe and a second Phase 3 clinical trial in the United States in 2015. We recently initiated an open label Phase 3 safety clinical trial for RT001. We expect to receive primary efficacy data from the first of our pivotal Phase 3 clinical trials of RT001 late in the second half of 2014. We plan to complete the Phase 3 program for the treatment of crow s feet lines and file for regulatory approvals

Table of Contents

in the United States and Europe in the second half of 2016. To date, we have conducted fourteen clinical trials for RT001, with a total of over 1,400 subjects, for the treatment of crow s feet lines.

We are also developing RT001 for therapeutic applications where botulinum toxin has shown efficacy and that are particularly well suited for needle-free treatments. We have successfully completed initial Phase 2 clinical trials for the treatment of primary axillary, or underarm, hyperhidrosis, and for the prevention of migraine headache. We expect to initiate additional clinical trials for the development of RT001 for these and other indications.

We are developing RT002, our injectable formulation of botulinum toxin type A, for indications where deeper delivery of the botulinum toxin is required and a longer lasting effect is desired. Our RT002 clinical program includes aesthetic indications such as glabellar lines, or the vertical lines between the eyebrows and above the nose, and potential therapeutic indications such as blepharospasm, or uncontrolled blinking of the eye. We believe RT002 can provide more targeted delivery of botulinum toxin to intended treatment sites while reducing the unwanted spread of botulinum toxin to adjacent areas. We believe, and our preclinical and clinical studies indicate, that targeted delivery permits safe administration of higher targeted doses of botulinum toxin and can result in a longer lasting effect.

Our Product Candidates

We plan to develop RT001 and RT002 for multiple aesthetic and therapeutic applications. The table below summarizes the phases of development for the indications we are currently pursuing for our two product candidates:

RT001 Our Topical Formulation of Botulinum Toxin

RT001, our lead product candidate, is a topical gel formulation of botulinum toxin type A in a proprietary single-use administration apparatus. RT001 is applied to the skin and uses our proprietary TransMTS® peptide technology to enable delivery of botulinum toxin across the skin, eliminating the need for injections. Our initial focus is to develop and commercialize RT001 for indications where topical application provides a meaningful advantage over injectable administration. In our Phase 2 clinical trials, RT001 has demonstrated a statistically significant and clinically meaningful reduction in crow s feet lines that is visible to both physicians and patients. These and other studies have also indicated that RT001 is well tolerated with no serious adverse events related to study drug or study treatment procedures or other safety concerns.

Table of Contents

RT002 Our Injectable Formulation of Botulinum Toxin

RT002 is a new injectable botulinum toxin option that is designed to offer more targeted delivery of botulinum toxin to intended treatment sites while reducing the spread beyond the site of local injection. We have completed pre-clinical studies and an initial Phase 1/2 open label clinical trial of RT002 for the treatment of glabellar lines. Data from these studies indicated that RT002 has the potential to significantly increase duration of effect of botulinum toxin. Preclinical studies, which involved higher, more targeted doses of injectable botulinum toxin compared to a commercially available botulinum toxin product, demonstrated an increase in duration of effect ranging from 50-100% depending on the intended result and also indicated less unwanted spread of botulinum toxin. Our Phase 1/2 study indicated a median duration of effect of 7.3 months, which aligns with the data from our preclinical studies.

Based upon the data analyzed, we plan to further develop RT002 for the treatment of glabellar lines by initiating an active comparative Phase 2 clinical trial against a commercially available botulinum. Results of this study are expected in 2015. In addition, we plan to study RT002 in therapeutic indications already approved for botulinum toxin, such as blepharospasm, or uncontrolled blinking of the eye, an indication that requires deeper delivery of the botulinum toxin.

The Opportunity for Botulinum Toxins for Aesthetic Indication

Today s culture places significant value on physical appearance, leading to widespread adoption of anti-aging and aesthetic treatments. The aesthetic market has grown dramatically in the United States, driven by a large population of consumers who are looking to delay signs of aging and improve general appearance. In 2013, consumers spent $12.3 billion on 11.4 million physician-administered surgical and non-surgical aesthetic procedures in the United States, according to American Society for Aesthetic Plastic Surgery annual statistics. A strong consumer preference for non-surgical options and the increasing availability of effective alternatives have prompted adoption of non-surgical aesthetic procedures by a broader patient population. These trends have made non-surgical procedures the primary driver of growth in the aesthetic medicine market, accounting for 83.5% of the total number of procedures performed in 2013.

Injectable botulinum toxin treatments are the single largest cosmetic procedure in the United States and the rest of the world. According to GlobalData, in 2012 clinicians spent an estimated $1.3 billion globally on injectable botulinum toxin for aesthetic procedures and such spending is expected to grow at a compounded annual growth rate of 14% from 2011 through 2018.

We believe the botulinum toxin market could expand further with the introduction of a topical formulation such as RT001. Based on our market research, a topical treatment would address key consumer barriers for injectable botulinum toxin products such as fear of frozen face, needle aversion and aversion to injecting a toxin in their bodies. We believe that a topical treatment could expand the use of botulinum toxin to a wider range of physicians and allow those physicians who currently perform botulinum toxin procedures to do so on a larger number of patients. Additionally, our research indicates that a topical treatment can improve the profitability of physicians practices by increasing the number of procedures per patient.

We also believe there are market growth opportunities with the introduction of an injectable botulinum toxin product with a longer duration of effect such as RT002. Physicians have indicated to us that duration of effect is an important attribute and that a product with a longer duration of effect would cause them to use RT002. Physicians have also indicated to us that the need for repeated treatments is a key reason why men accounted for only 10% of injectable botulinum toxin procedures in 2013. We therefore believe an injectable botulinum toxin product with a longer duration of effect such as RT002 could potentially expand the market for botulinum toxin procedures among men.

Table of Contents

Crow s Feet Lines Our Lead Indication for RT001

The first indication we are pursuing for RT001 is in the field of aesthetic dermatology. According to GlobalData, the largest use for botulinum toxins is in aesthetic dermatology, which is estimated to generate approximately $1.7 billion in worldwide sales in 2014. If approved, we believe RT001 can expand the overall botulinum toxin aesthetic market by adding new patients who would prefer a needle-free approach to treatment. The aesthetic dermatology market is attractive because we believe that patients in this market tend to be open to trying new products and are willing to pay for aesthetic procedures out of pocket, reducing reliance on reimbursement. We are focused on this market not only because of its size and growth potential but also because, in the United States and Europe, this market can be easily accessed by a small specialty sales force and distributor network.

Crow s feet lines are skin wrinkles in the outer corner of the eye area, which are commonly caused by aging. Consumers in general, and women in particular, believe that the eye area is the first place where they notice the signs of aging. Consumers also believe that the perception of aging is affected by the quality of the skin. A large segment of the anti-aging topical cosmeceutical market is targeted towards improvement in skin texture and luminosity of the skin in the eye area. Despite the fact that until September 2013 there were no botulinum toxin products approved for crow s feet lines, we believe that there has been significant use of botulinum toxin for this indication given the desire of consumers to address the condition.

We believe that RT001 provides the following benefits to patients and physicians for treatment of crow s feet lines, as compared to traditional botulinum toxin treatments that are administered by injection:

- The RT001 procedure is painless and has not shown any evidence of bruising, swelling or any of the other adverse events associated with injections. RT001 has been shown to be well tolerated with no significant safety concerns;
- RT001 relaxes the crow s feet wrinkles appearance at rest, when the face is in a neutral expression, while still allowing a natural smile;
- Consumers who indicated that they were averse to injecting toxin into their bodies found the concept of a topical treatment appealing;
- RT001 is simple to use and results are not technique dependent. RT001 comes in a pre-filled applicator that contains the proper dose for the treatment of crow s feet lines; and
- RT001 is very appealing to both key physicians and practice groups who perform the majority of cosmetic procedures in the United States and physicians who have less injectable botulinum toxin experience.

We have conducted fourteen clinical trials for RT001, with a total of over 1,400 subjects, for the treatment of crow s feet lines. RT001 was shown to be safe, with statistically significant and clinically meaningful results in our Phase 1 and Phase 2 clinical trials. In all concentrations of peptide and botulinum toxin studied, RT001 was well tolerated with no serious adverse events related to study drug or study treatment procedures or safety concerns.

We have completed three Phase 2b clinical trials of RT001 to evaluate a 25 ng/mL dose of botulinum toxin for the treatment of moderate to severe crow s feet lines. Two of these trials were double-blind, randomized, placebo-controlled clinical trials. RT001 met the primary efficacy and all secondary endpoints in both trials. After completing these Phase 2b clinical trials, we modified the diluent formulation to improve stability. We then conducted a Phase 3 clinical trial of RT001, but saw no improvement from baseline in either the placebo or RT001 group using the new diluent formulation. Subsequently, we obtained stability data to confirm that the original Phase 2b formulation has adequate commercial stability. We have since returned to the original Phase 2b diluent formulation and have conducted a two-cohort Phase 2 double-blind, randomized, placebo-controlled clinical trial. The combined data for the first and second cohorts showed statistical significance in wrinkle severity from baseline comparable to that observed in our previous Phase 2b clinical trials. Additionally, we

Table of Contents

initiated an open label Phase 3 clinical trial in the first quarter of 2014 to evaluate the long term safety and efficacy of repeat administration of RT001. We currently expect to enroll up to 1,800 subjects in the study.

Based on our discussions with the United States Food and Drug Administration, or the FDA, the European Medicines Agency and other regulatory authorities, we believe that three Phase 3 pivotal clinical trials and the Phase 3 open label safety clinical trial, if successful, will provide the efficacy and safety data to support our regulatory filing for approval of RT001 for the treatment of crow s feet lines in the United States, Europe and other countries.

Glabellar Lines Our Lead Indication for RT002

The first indication we are pursuing for RT002 is in the field of aesthetic dermatology. According to the American Society of Aesthetic Plastic Surgery annual statistics, injectable botulinum toxins are the leading aesthetic procedure in the United States with over 3.7 million procedures performed in 2013, a 16% increase over 2012. This also represents a 127% increase since 2002, the year in which botulinum toxins were first approved for an aesthetic indication. We believe RT002 can further expand this market for the treatment of glabellar lines. Physicians have indicated to us that, even among their patients who are satisfied with current botulinum toxin procedures for the treatment of glabellar lines, there is a desire for a longer duration of effect. Physicians have also indicated to us that the lack of a longer duration of effect is a key reason why relatively few men pursue botulinum toxin procedures for the treatment of glabellar lines. We believe we would be able to leverage our specialty sales force by adding RT002 to our product offerings. Because different indications within the aesthetics dermatology market are best served by different delivery methods, we believe an injectable botulinum toxin product such as RT002 would be complementary to RT001.

The Opportunity for Topical Botulinum Toxins for Therapeutic Indications

While currently approved botulinum toxin products may be better known for their aesthetic applications, according to GIA the worldwide injectable botulinum toxin market has grown from $1.1 billion in 2004 to over $2.4 billion in 2012 and the fastest growing segment of that market in the United States and Europe is for therapeutic indications. This growth for therapeutic indications has been driven largely by the approval of injectable botulinum toxin products in new indications such as preventive treatment of migraine headache in 2010 and overactive bladder in 2011, in addition to other therapeutic indications including hyperhidrosis, movement disorders, such as cervical dystonia and upper limb spasticity, and uncontrolled blinking. This therapeutic usage has been enabled by botulinum toxin s ability to affect neuromuscular junctions, muscle activity or the release of neuropeptides, neurotransmitters and neuromediators in a controlled manner.

While botulinum toxin products have been very effective in the treatment of many conditions, there are limitations to the use of the currently approved products in their injectable form. For example, in the case of hyperhidrosis, injectable botulinum toxin products require up to 30 injections in the underarms, and the procedure is reimbursed to physicians at a low rate relative to the time required. As a result, the use of Botox®, the only injectable botulinum toxin product currently approved for hyperhidrosis, has been limited in this indication. In the case of chronic migraine headache, injectable botulinum toxin products require as many as 31 injections in different parts of the head and neck.

We believe this leads to a significant need for a painless, topically administered and highly effective botulinum toxin. We also believe that there is an opportunity to develop and seek approval for a botulinum toxin product in therapeutic indications, such as allergic rhinitis, where there are currently no approved botulinum toxin products.

Development of RT001 for Treatment of Hyperhidrosis

According to published medical articles, hyperhidrosis affects an estimated eight million people in the United States, one million of whom have severe hyperhidrosis. Prevalence in the United States is slightly higher among men than women, but women are more likely to take action to have the condition treated. Only 38% of

Table of Contents

those affected by hyperhidrosis seek treatment. We also believe that the appeal of RT001 may go beyond sufferers of hyperhidrosis and appeal to the one-third of all U.S. adults who believe they have too much underarm sweat. According to a 2008 survey by the International Hyperhidrosis Society, 60% of all U.S. adults reported that they would be embarrassed or very embarrassed by visible underarm sweat stains, and 70% of those U.S. adults who believe they have too much underarm sweat took steps to hide their condition.

Injectable botulinum toxin is among the currently available treatments for hyperhidrosis. Allergan s Botox® was approved in 2004 for underarm hyperhidrosis and remains the only botulinum toxin approved for the treatment of hyperhidrosis. However, the treatment requires up to 30 injections in the underarms. Having a topical solution could encourage more patients to seek treatment without having to suffer the pain of numerous injections. From the physicians standpoint, injections are very time-consuming and reimbursement for the procedure is low. RT001 could significantly decrease the physician time and effort necessary for the procedure and potentially make the procedure more profitable for a physician s practice.

Data from our initial dose escalation hyperhidrosis Phase 2 clinical trial suggest the feasibility of treating primary underarm hyperhidrosis with RT001.

Based on data generated from clinical trials to date, we plan to initiate additional clinical trials for the treatment of hyperhidrosis with RT001. These future trials will evaluate the efficacy of a higher dose compared to placebo and permit evaluation of the RT001 dose response to treatment of signs and symptoms of primary underarm hyperhidrosis. This data should help to establish whether this new botulinum toxin dose is adequate or whether further dose escalation in this clinical indication is needed prior to definitive safety and efficacy testing.

Development of RT001 for Prevention of Migraine Headache

Migraine headache is a central nervous system disorder characterized by moderate-to-severe headache and often includes additional symptoms such as nausea and vomiting. The global market for treatment of migraine headache was estimated to be $3.8 billion in 2009. Injected delivery of botulinum toxin has been validated as a therapeutically effective pharmaceutical agent for the preventive treatment of migraine headache. However, the treatment requires up to 31 injections in a patient s head and neck and may have significant side effects.

We have generated preliminary data that supports the feasibility of treating chronic migraine headache with topical application of RT001. In our initial Phase 2 clinical trial, RT001 was shown to be effective for the preventive treatment of chronic migraine headache, when applied topically to five areas on the head. This trial demonstrated statistically significant improvement of a composite endpoint.

For our next Phase 2 clinical trial, we plan to enroll and treat subjects with migraine headache using RT001 in a randomized double-blind placebo-controlled dose-ranging clinical trial design. This trial will provide new information on the treatment of subjects suffering migraine headache with RT001 and further characterize the dose-response relationship of RT001 in migraine headache to identify the optimal dose to be carried forward into later stage clinical trials.

RT001 for Treatment of Other Indications

Based on the results of our preclinical studies and clinical trials, we will determine further development of other indications for RT001, such as neuropathic pain and rhinitis.

Intellectual Property and Manufacturing

As of June 2, 2014, we held approximately 85 issued patents and approximately 144 pending patent applications in several countries and we expect to continue to expand this patent portfolio.

We have the ability to manufacture our own botulinum toxin type A product to support our clinical trials and eventually our commercial products. We manufacture and perform testing for both bulk drug substance and finished dose forms of drug product to support our topical RT001 product candidate and our injectable RT002

Table of Contents

product candidate. The additional components required for our topical RT001 dose form, the peptide, diluent and delivery apparatus, are all manufactured by third parties. We are licensed with the Centers for Disease Control and Prevention, or CDC, and with the California Department of Health Food and Drug Branch for use of botulinum toxin and to manufacture both the active pharmaceutical ingredient, or API, and the finished product in topical and injectable dose forms. We believe that having direct control over our manufacturing processes, from initial drug substance to finished product, will enable us to develop additional pharmaceutical product configurations effectively and with a competitive cost structure.

Our Strategy

Our objective is to be a leading provider of botulinum toxin products across multiple aesthetic and therapeutic indications in both topical and injectable dose forms and to expand the market for botulinum toxin products. To achieve this objective, we plan to develop and commercialize two proprietary, patent-protected product candidates: RT001, our topical botulinum toxin, and RT002, our injectable botulinum toxin.

Key elements of our strategy are:

- Complete development and seek regulatory approval for RT001 for crow s feet lines;
- Accelerate RT002 clinical development, including completing a Phase 2 active comparator study of RT002 for glabellar lines and initiating clinical development of RT002 for therapeutic indications;
- Advance the clinical development of RT001 for the treatment of hyperhidrosis;
- Assess and prioritize future therapeutic indications for RT001 and RT002;
- Build our own sales and marketing capabilities to commercialize RT001 and RT002 in North America to support commercial launches starting in 2017, assuming successful and timely completion of our clinical trials and approval of our Biologic License Applications;
- Expand the global market for botulinum toxin products;
- Establish selective strategic partnerships to maximize the commercial potential of our product candidates and TransMTS® delivery technology platform; and
- Maximize the value of our botulinum toxin cell line and manufacturing assets.

Risks That We Face

Our business is subject to numerous risks and uncertainties, including those highlighted in the section entitled Risk Factors immediately following this prospectus summary. These risks include, among others, the following:

- We are substantially dependent on the clinical and commercial success of our product candidates, primarily our lead product candidate RT001, which is in Phase 3 clinical development, and our second product candidate, RT002, which is expected to enter into Phase 2 clinical development;

We may be unable to obtain regulatory approval for RT001, RT002 or future product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business and our results of operations;

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts;

Even if our product candidates receive regulatory approval, they may fail to achieve the broad degree of physician adoption and use necessary for commercial success;

Table of Contents

Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration and expansion;

We currently make our clinical drug products exclusively in one manufacturing facility and plan to utilize this facility in the future to support commercial production if our product candidates are approved. If this or any future facility or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business would be materially harmed;

We have a limited operating history and have incurred significant losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future. We have only two product candidates in clinical trials and no commercial sales, which, together with our limited operating history, make it difficult to assess our future viability;

Even if RT001, RT002 or any future product candidates obtain regulatory approval, they may never achieve market acceptance or commercial success; and

If our efforts to protect our intellectual property related to RT001, RT002 or any future product candidates are not adequate, we may not be able to compete effectively in our market.

Our Corporate Information

We were incorporated in Delaware in August 1999 under the name Essentia Biosystems, Inc. We commenced operations in June 2002 and, in April 2005, changed our name to Revance Therapeutics, Inc. Our principal executive offices are located at 7555 Gateway Boulevard, Newark, California 94560, and our telephone number is (510) 742-3400. Our website address is http://www.revance.com. The information contained in, or that can be accessed through, our website is not part of this prospectus.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012. As an emerging growth company we are eligible for exemptions from various reporting requirements 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 and reduced disclosure obligations regarding executive compensation. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering in February 2014, (b) in which we have total annual gross revenue of at least $1.0 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We refer to the Jumpstart Our Business Startups Act of 2012 herein as the JOBS Act, and references herein to emerging growth company shall have the meaning associated with it in the JOBS Act.

Revance Therapeutics, the Revance logos and other trademarks or service marks of Revance appearing in this prospectus are the property of Revance. This prospectus contains additional trade names, trademarks and service marks of others, which are the property of their respective owners. We do not intend our use or display of other companies trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

Table of Contents

THE OFFERING

Common stock offered by us	3,000,000 shares
Common stock to be outstanding after this offering	21,653,301 shares
Option to purchase additional shares	The underwriters have an option to purchase up to 450,000 additional shares of our common stock.
Use of proceeds	We estimate the net proceeds from this offering will be approximately $84.1 million (or $96.8 million if the underwriters exercise their option to purchase additional shares in full), based on an assumed public offering price of $30.01 per share (which was the last reported sale price of our common stock as reported on the NASDAQ Global Market on June 13, 2014), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We currently expect to use the net proceeds from the offering as follows: Approximately $30.0 million to $40.0 million to complete two Phase 3 clinical pivotal trials in the United States and one pivotal clinical trial in Europe along with the continuation of our long term safety clinical trial and other associated programs relating to RT001 for the treatment of crow s feet lines, to initiate and complete a Phase 2 study in hyperhidrosis relating to RT001, to initiate and complete a Phase 2 active comparator clinical trial, to initiate associated nonclinical and clinical programs relating to RT002 for the treatment of glabellar lines, and to initiate clinical studies relating to RT002 for the treatment of blepharospasm and other therapeutic indications. Approximately $20.0 million to $30.0 million to fund research and development expenses associated with our RT001 and RT002 manufacturing, quality and regulatory efforts. We expect to use the balance of the proceeds, if any, for the development of RT001 and RT002 for the treatment of other indications, as well as for working capital and other general corporate purposes. Pending their use as described above, we plan to invest the net proceeds in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or guaranteed obligations of the U.S. government. See Use of Proceeds for additional information.

Risk factors	See the section titled Risk Factors beginning on page 13 and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
NASDAQ Global Market symbol	RVNC

Table of Contents

The number of shares of our common stock to be outstanding after this offering is based on 18,653,301 shares of common stock outstanding as of March 31, 2014, excluding the following shares:

- 1,243,750 shares of our common stock issuable upon the exercise of options to purchase our common stock outstanding as of March 31, 2014 under our 2002 Equity Incentive Plan, 2012 Equity Incentive Plan, and 2014 Equity Incentive Plan at a weighted-average exercise price of $8.05 per share;

- 173,975 shares of our common stock issuable upon the exercise of outstanding warrants at a weighted-average exercise price of $18.71 per share;

- 981,467 shares of our common stock reserved for future issuance under our 2014 Equity Incentive Plan; and

- 200,000 shares of our common stock reserved for future issuance under our 2014 Employee Stock Purchase Plan.

On May 19, 2014, we issued 162,000 shares of restricted common stock and granted options to purchase an aggregate of 479,300 shares of our common stock at an exercise price of $32.22 per share pursuant to equity awards made under our 2014 Equity Incentive Plan.

Unless otherwise indicated, all information in this prospectus assumes no exercise by the underwriters of their option to purchase up to 450,000 additional shares of our common stock from us in this offering.

Table of Contents

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables summarize our financial data. We derived the summary consolidated statements of operations data for the years ended December 31, 2013, 2012, and 2011 from our audited consolidated financial statements. The summary financial data for the three months ended March 31, 2014 and 2013 and the balance sheet data as of March 31, 2014 have been derived from our unaudited interim financial statements. The unaudited interim financial results have been prepared on the same basis as the audited financial statements and reflect all adjustments necessary to fairly reflect our financial position as of March 31, 2014 and results of operations for the three months ended March 31, 2014 and 2013. Our historical results are not necessarily indicative of the results to be expected in the future. You should read the following summary consolidated financial data in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements, related notes and other financial information in our Annual Report on Form 10-K filed with the SEC on March 28, 2014 and in our Quarterly Report on Form 10-Q filed with the SEC on May 14, 2014, each incorporated by reference in this prospectus. For more details on how you can obtain the documents incorporated by reference in this prospectus, see Where You Can Find More Information and Incorporation of Certain Information by Reference.

	Year Ended December 31,			Three Months Ended March 31,	
	2013	2012	2011	2014	2013
	(In thousands, except share and per share amounts)				
Consolidated Statements of Operations Data:					
Revenue	$ 617	$ 717	$ 557	$ 158	$ 75
Cost of Revenue			5		
Gross Profit	617	717	552	158	75
Operating expenses:					
Research and development(1)	27,831	32,708	22,735	7,551	7,527
Sales, general and administrative(1)	11,011	11,195	5,555	4,093	2,225
Total operating expenses	38,842	43,903	28,290	11,644	9,752
Loss from operations	(38,225)	(43,186)	(27,738)	(11,486)	(9,677)
Interest income	2	7	15	2	
Interest expense	(15,164)	(28,959)	(17,790)	(9,841)	(12,624)
Change in fair value of derivative liabilities associated with convertible notes	2,660	13,860	(356)	4,032	1,800
Change in fair value of derivative liabilities associated with the Medicis settlement	47			(416)	
Change in fair value of common stock warrant liability	(621)			(2,151)	
Change in fair value of convertible preferred stock warrant liability	(743)	125	836	(210)	(1,158)
Loss on settlement of preferred stock warrant liability				(1,356)	
Other income (expense), net	(404)	(106)	170		2
Net loss	$ (52,448)	$ (58,259)	$ (44,863)	$ (21,426)	$ (21,657)
Net income (loss) attributable to common stockholders(2):					
Basic	$ 258	$ (58,259)	$ (44,863)	$ (21,426)	$ 5,216
Diluted	$ 1,083	$ (58,259)	$ (44,863)	$ (21,426)	$ 13,349
Net income (loss) per share attributable to common stockholders(2):					
Basic	$ 1.17	$ (290.48)	$ (226.06)	$ (1.93)	$ 25.54
Diluted	$ 1.05	$ (290.48)	$ (226.06)	$ (1.93)	$ 21.00
Weighted-average number of shares used in computing net income (loss) per share attributable to common stockholders(2):					
Basic	220,220	200,560	198,456	11,092,471	204,220

Diluted	1,029,150	200,560	198,456	11,092,471	635,726

Table of Contents

(1) Results above include stock-based compensation as follows:

	Year Ended December 31,			Three Months Ended March 31,	
	2013	2012	2011	2014	2013
			(In thousands)		
Stock-Based Compensation:					
Research and development	$ 194	$ 48	$ 150	$ 495	$ 5
Sales, general and administrative	354	31	123	315	9
Total stock-based compensation	$ 548	$ 79	$ 273	$ 810	$ 14

(2) Please see Note 16 of our consolidated financial statements in our Annual Report on Form 10-K and Note 14 of our condensed consolidated financial statements in our Quarterly Report on Form 10-Q, each incorporated by reference in this prospectus, for an explanation of the calculations of our actual basic and diluted net income (loss) per share.

	As of March 31, 2014	
	Actual	As Adjusted(1)
	(In thousands)	
Balance Sheet Data:		
Cash and cash equivalents	$ 87,853	$ 171,915
Restricted cash current and non-current	510	510
Working capital	68,563	152,625
Total assets	106,912	190,974
Notes payable current and non-current	13,805	13,805
Derivative liabilities associated with Medicis settlement current and non-current	1,637	1,637
Total stockholders equity	78,687	162,749

(1) The as adjusted column gives effect to the sale of 3,000,000 shares of common stock in this offering at an assumed public offering price of $30.01 per share, which is the last reported sale price of our common stock as reported on The NASDAQ Global Market on June 13, 2014, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A $1.00 increase or decrease in the assumed public offering price of $30.01 per share would increase or decrease our as adjusted cash and cash equivalents, working capital, total assets and total stockholders equity by approximately $2.8 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of one million in the number of shares of common stock offered by us would increase or decrease our as adjusted cash and cash equivalents, working capital, total assets and total stockholders equity by approximately $28.2 million, assuming that the assumed public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

Table of Contents

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information included and incorporated by reference in this prospectus, before you decide to purchase shares of our common stock. We believe the risks and uncertainties described below are the most significant risks we face. If any of the following risks actually occurs, our business, prospects, financial condition and operating results could be materially harmed. As a result, the trading price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and stock price.

Risks Related to Our Business and Strategy

We are substantially dependent on the clinical and commercial success of our product candidates, primarily our lead product candidate RT001, which is in Phase 3 clinical development, and our second product candidate RT002, which is expected to enter into Phase 2 clinical development.

To date, we have invested most of our efforts and financial resources in the research and development of RT001, a topical formulation of botulinum toxin, which is currently our lead product candidate. In particular, we have conducted fourteen clinical trials and are in Phase 3 clinical development in the United States for RT001. We have also invested, to a lesser extent, in the research and development of an injectable form of botulinum toxin, RT002, which is expected to enter into Phase 2 clinical development with interim results expected in 2015. Our near-term prospects, including our ability to finance our company and generate revenue, will depend heavily on the successful development, regulatory approval and commercialization of RT001 and, to a lesser extent, RT002, as well as any future product candidates. The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- timely completion of, or need to conduct additional, clinical trials, including our U.S. Phase 3 clinical trials for RT001, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the accurate and satisfactory performance of third party contractors;
- our ability to demonstrate to the satisfaction of the United States Food and Drug Administration, or FDA, the safety and efficacy of RT001, RT002 or any future product candidates through clinical trials;
- whether we are required by the FDA or other similar foreign regulatory agencies to conduct additional clinical trials to support the approval of RT001, RT002 or any future product candidates;
- the acceptance of parameters for regulatory approval, including our proposed indication, primary endpoint assessment and primary endpoint measurement relating to our lead indications of RT001;
- our success in educating physicians and patients about the benefits, administration and use of RT001, RT002 or any future product candidates, if approved;
- the prevalence and severity of adverse events experienced with our product candidates or future approved products;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- the ability to raise additional capital on acceptable terms to achieve our goals;

achieving and maintaining compliance with all regulatory requirements applicable to RT001, RT002 or any future product candidates or approved products;

the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;

the effectiveness of our own or our future potential strategic collaborators marketing, sales and distribution strategy and operations;

Table of Contents

our ability to manufacture clinical trial supplies of RT001, RT002 or any future product candidates and to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practices, or cGMP;

our ability to successfully commercialize RT001, RT002 or any future product candidates, if approved for marketing and sale, whether alone or in collaboration with others;

our ability to enforce our intellectual property rights in and to RT001, RT002 or any future product candidates;

our ability to avoid third party patent interference or intellectual property infringement claims;

acceptance of RT001, RT002 or any future product candidates, if approved, as safe and effective by patients and the medical community; and

a continued acceptable safety profile of RT001, RT002 or any future product candidates following approval.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of RT001, RT002 or any future product candidate to continue our business.

We may be unable to obtain regulatory approval for RT001, RT002 or future product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business and our results of operations.

To gain approval to market a biologic product such as RT001 and RT002, we must provide the FDA and foreign regulatory authorities with clinical data that adequately demonstrate the safety, purity and potency of the product for the intended indication applied for in a Biologics License Application, or BLA, or other respective regulatory filing. The development of biologic products is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, including in Phase 3 development, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct. In particular, we have conducted three positive Phase 2b clinical trials of RT001, in which RT001 met the primary efficacy and all secondary endpoints. However, we have conducted one Phase 3 clinical efficacy trial using a modified diluent formulation, the results of which were inconsistent with our previous Phase 2b clinical trials and which did not show improvement from baseline in either the placebo or RT001 group. In the first quarter of 2014, we initiated an open label Phase 3 safety clinical trial designed to evaluate the long term safety and efficacy of RT001, including doses of botulinum toxin derived from our working cell bank, stored in frozen state and administered using our single-use administration apparatus. If this study, or any of our other clinical trials, do not demonstrate the safety and efficacy to our satisfaction, or to that of the FDA, the timing and our ability to obtain regulatory approval for RT001 could be materially and adversely affected.

Our lead product candidate, RT001, is currently in Phase 3 clinical development, and our business currently depends substantially on its successful development, regulatory approval and commercialization. We currently have no drug or biologic products approved for sale, and we may never obtain regulatory approval to commercialize RT001. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug and biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted

Table of Contents

to market RT001 in the United States until we receive approval of a BLA from the FDA. We are also not permitted to market RT001 in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our product candidates, including RT001, for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that RT001, RT002 or any future product candidates are safe and effective for the requested indication;
- the FDA s or the applicable foreign regulatory agency s disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that clinical and other benefits of RT001, RT002 or any future product candidates outweigh any safety or other perceived risks;
- the FDA s or the applicable foreign regulatory agency s requirement for additional preclinical or clinical studies;
- the FDA s or the applicable foreign regulatory agency s non-approval of the formulation, labeling or the specifications of RT001, RT002 or any future product candidates;
- the FDA s or the applicable foreign regulatory agency s failure to approve our manufacturing processes or facilities, or the manufacturing processes or facilities of third party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs, including biologics, in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. We are not conducting our U.S. Phase 3 clinical trials for RT001 under a Special Protocol Assessment, or SPA. In the absence of an agreed SPA, there can be no assurance that the FDA will agree with our Phase 3 clinical trial protocol.

Further, after our Phase 2 clinical trials, we used the FDA s Formal Dispute Resolution process to obtain confirmation from the FDA that our proposed indication, primary endpoint assessment and primary endpoint measurement were acceptable for continued clinical trials. While the FDA provided written confirmation that our proposed indication, primary endpoint assessment and primary endpoint measurement were acceptable for Phase 3 clinical trials, the FDA has not confirmed that our proposed indication, primary endpoint assessment and primary endpoint measurement are acceptable for regulatory approval. Further, while we did obtain written confirmation with respect to these aspects of our Phase 3 clinical trial designs, there is no assurance that the FDA will approve our BLA for RT001, will agree that the benefits of RT001 outweigh its risks or will not raise new concerns regarding our clinical trial designs.

Even if we eventually complete clinical testing and receive approval of any regulatory filing for RT001, RT002 or any future product candidates, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA or the applicable foreign regulatory agency also may approve RT001, RT002 or any future product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA or applicable foreign regulatory agency may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates and RT001, in particular, would delay or prevent commercialization of RT001 and would materially adversely impact our business, results of operations and prospects.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts.

Since our inception, most of our resources have been dedicated to the preclinical and clinical development of our lead product candidate, RT001. In particular, our U.S. Phase 3 clinical program for RT001 will require

Table of Contents

substantial funds to complete. We have recorded net losses of $52.4 million and $21.4 million for the year ended December 31, 2013 and the three months ended March 31, 2014, respectively, had an accumulated deficit during our development stage through March 31, 2014 of $217.3 million and had a working capital surplus of $68.6 million as of March 31, 2014, primarily as a result of our initial public offering. We have funded our operations primarily through the sale and issuance of common stock, convertible preferred stock, notes payable and convertible notes. As of March 31, 2014, we had capital resources consisting of cash and cash equivalents of $87.9 million. In February 2014, we sold 6,900,000 shares of common stock at $16 per share for aggregate net proceeds of $98.6 million, after underwriting discounts, commissions, and other offering expenses, in our initial public offering, or IPO. We believe that we will continue to expend substantial resources for the foreseeable future for the clinical development of RT001, RT002 and development of any other indications and product candidates we may choose to pursue. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, and manufacturing and supply as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of RT001, RT002 and any future product candidates.

We believe that our existing cash and cash equivalents, including the net proceeds from our IPO, together with our existing credit facility, will allow us to fund our operating plan through at least the next 12 months. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional capital sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financings may result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future capital requirements depend on many factors, including:

- the results of our clinical trials for RT001 and RT002;
- the timing of, and the costs involved in, obtaining regulatory approvals for RT001, RT002 or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the scope, progress, results and costs of researching and developing RT001, RT002 or any future product candidates, and conducting preclinical and clinical trials;
- the cost of commercialization activities if RT001, RT002 or any future product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing RT001, RT002 or any future product candidates and any products we successfully commercialize and maintaining our related facilities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the terms of and timing such arrangements;
- the degree and rate of market acceptance of any future approved products;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing products or treatments;

any product liability or other lawsuits related to our products;

the expenses needed to attract and retain skilled personnel;

the costs associated with being a public company;

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and

the timing, receipt and amount of sales of, or royalties on, future approved products, if any.

Table of Contents

Additional capital may not be available when we need them, on terms that are acceptable to us or at all. If adequate funds are not available to us on a timely basis, we may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for RT001, RT002 or any future product candidate;
- delay, limit, reduce or terminate our research and development activities; or
- delay, limit, reduce or terminate our establishment of manufacturing, sales and marketing or distribution capabilities or other activities that may be necessary to commercialize RT001, RT002 or any future product candidates.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted and the terms of any new equity securities may have a preference over our common stock. 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 or making capital expenditures or specified financial ratios, any of which could restrict our ability to commercialize our product candidates or operate as a business.

As of May 31, 2014, our existing cash balance was $75.3 million.

Even if our product candidates receive regulatory approval, they may fail to achieve the broad degree of physician adoption and use necessary for commercial success.

The commercial success of RT001, RT002 and any future product candidates, if approved, will depend significantly on the broad adoption and use of the resulting product by physicians for approved indications, including, in the case of RT001, the treatment of lateral canthal lines, or crow s feet lines, hyperhidrosis and other aesthetic and therapeutic indications that we may seek to pursue. The degree and rate of physician adoption of RT001, RT002 and any future product candidates, if approved, will depend on a number of factors, including:

- the effectiveness of our product as compared to existing therapies;
- physician willingness to adopt a new therapy to treat crow s feet lines, hyperhidrosis or other indications;
- overcoming any biases physicians or patients may have toward injectable procedures for the treatment of crow s feet lines, hyperhidrosis or other indications;
- patient satisfaction with the results and administration of our product and overall treatment experience;
- patient demand for the treatment of crow s feet lines, hyperhidrosis or other indications; and
- the revenue and profitability that our product will offer a physician as compared to alternative therapies.

If RT001, RT002 or any future product candidates are approved for use but fail to achieve the broad degree of physician adoption necessary for commercial success, our operating results and financial condition will be adversely affected.

Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration and expansion.

We expect to enter highly competitive pharmaceutical and medical device markets. Successful competitors in the pharmaceutical and medical device markets have the ability to effectively discover, obtain patents, develop, test and obtain regulatory approvals for products, as well as the ability to effectively commercialize, market and promote approved products, including communicating the effectiveness, safety and value of products to actual and prospective customers and medical staff. Numerous companies are engaged in the development, patenting, manufacture and marketing of health care products competitive with those that we are developing. Many of these potential competitors are large, experienced companies that enjoy significant competitive

Table of Contents

advantages, such as substantially greater financial, research and development, manufacturing, personnel and marketing resources, greater brand recognition and more experience and expertise in obtaining marketing approvals from the FDA and other regulatory authorities.

Upon marketing approval, the first expected use of our products will be in aesthetic medicine. The aesthetic product market, and the facial aesthetic market in particular, is highly competitive and dynamic, and is characterized by rapid and substantial technological development and product innovations. This market is also characterized by competitors obtaining patents to protect what they consider to be their intellectual property. We are seeking regulatory approval of RT001 for the treatment of crow s feet lines and RT002 for the treatment of glabellar lines.

We anticipate that RT001, if approved, will face significant competition from other facial aesthetic products, including injectable botulinum toxins and dermal fillers. If approved, RT001 may also compete with unapproved and off-label treatments. We anticipate that RT002, if approved, will also face significant competition from existing injectable botulinum toxins and dermal fillers, as well as unapproved and off-label treatments. Further, if approved, in the future we may face competition for both RT001 and RT002 from biosimilar products. To compete successfully in the aesthetic market, we will have to demonstrate that the reduction of crow s feet lines with RT001 or the treatment of glabellar lines with RT002 is a worthwhile aesthetic treatment and is a superior alternative to existing therapies. Competing in the aesthetic market could result in price-cutting, reduced profit margins and limited market share, any of which would harm our business, financial condition and results of operations.

Due to less stringent regulatory requirements, there are many more aesthetic products and procedures available for use in international markets than are approved for use in the United States. There are also fewer limitations on the claims that our competitors in international markets can make about the effectiveness of their products and the manner in which they can market them. As a result, we face more competition in these markets than in the United States.

We currently make our clinical drug products exclusively in one manufacturing facility and plan to utilize this facility in the future to support commercial production if our product candidates are approved. If this or any future facility or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business would be materially harmed.

We currently manufacture our own clinical drug products to support both RT001 and RT002 exclusively in a single manufacturing and laboratory facility and plan to utilize this facility in the future to support commercial production if our product candidates are approved. If this or any future facility were to be damaged, destroyed or otherwise unable to operate, whether due to earthquakes, fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages or otherwise, or if performance of our manufacturing facility is disrupted for any other reason, such an event could delay our clinical trials or, if our product candidates are approved, jeopardize our ability to manufacture our products as promptly as our customers expect or possibly at all. If we experience delays in achieving our development objectives, or if we are unable to manufacture an approved product within a timeframe that meets our customers expectations, our business, prospects, financial results and reputation could be materially harmed.

Currently, we maintain insurance coverage totaling $27.7 million against damage to our property and equipment, $2.0 million in general liability coverage, a $9.0 million umbrella policy, and an additional $30.0 million to cover business interruption and research and development restoration expenses, subject to deductibles and other limitations. If we have underestimated our insurance needs with respect to an interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses.

We have a limited operating history and have incurred significant losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future. We have only two product candidates in clinical trials and no commercial sales, which, together with our limited operating history, make it difficult to assess our future viability.

We are a clinical stage specialty biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of

Table of Contents

risk. We are not profitable and have incurred losses in each year since we commenced operations in 2002. We have only a limited operating history upon which you can evaluate our business and prospects. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. To date, we have not obtained any regulatory approvals for any of our product candidates or generated any revenue from product sales relating to RT001 or RT002. We continue to incur significant research and development and other expenses related to our ongoing clinical trials and operations. We have recorded net losses of $52.4 million and $21.4 million for the year ended December 31, 2013 and the three months ended March 31, 2014, respectively, had an accumulated deficit during our development stage through March 31, 2014 of $217.3 million and had a working capital surplus of $68.6 million as of March 31, 2014, primarily as a result of our initial public offering. In February 2014, we closed our IPO. The net proceeds from the sale of the shares in our IPO, after deducting the underwriters discount, commissions, and other offering expenses related to the IPO were approximately $98.6 million. Our capital requirements to implement our business strategy are substantial, including our capital requirements to develop and commercialize RT001 and RT002. We believe that our currently available capital is sufficient to fund our operations through at least the next 12 months. Given our desired clinical development plans for the next 12 months, our financial statements do not reflect an uncertainty about our ability to continue as a going concern. Accordingly, the financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should we be unable to continue as a going concern. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue our development of, and seek regulatory approvals for, RT001 and RT002, and begin to commercialize RT001. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals and successfully manufacture, market and commercialize our products. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

Even if RT001, RT002 or any future product candidates obtain regulatory approval, they may never achieve market acceptance or commercial success.

Even if we obtain FDA or other regulatory approvals, RT001, R