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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2016

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 001-36754

Neothetics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**20-8527075**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
9171 Towne Centre Drive, Suite 250 San Diego, CA	**92122**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: **(858) 750-1008**

Securities registered pursuant to Section 12(b) of the Act: Common Stock, Par Value $0.0001 Per Share; Common stock traded on the NASDAQ stock market

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

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

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

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

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

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

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	☐ (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 ☒

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $7,583,539 as of June 30, 2016 based upon the closing sale price on the NASDAQ Global Market reported for such date. Shares of common stock held by each executive officer and director and certain holders of more than 10% of the outstanding shares of the registrant's common stock have been excluded in that such persons may be deemed to be affiliates. Shares of common stock held by other persons, including certain other holders of more than 10% of the outstanding shares of common stock, have not been excluded in that such persons are not deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of Registrant's Common Stock outstanding as of March 1, 2017 was 13,829,716.

INCORPORATION BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission, or SEC, pursuant to Regulation 14A in connection with the registrant's 2017 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this annual report on Form 10-K. Such proxy statement will be filed with the SEC not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2016.

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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form, 10-K contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections entitled "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations." All statements, other than statements of historical facts, contained in this document, including statements regarding our business, operations and financial performance and conditions, as well as our plans, objectives and expectations for our business operations and financial performance and condition, are forward-looking statements. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "predict," "project," "potential," "should," "target," "will," "would," or the negative of those terms and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Form 10-K include, among other things, statements about:

- our ability to develop a modified formulation of LIPO-202;
- whether our modified formulation of LIPO-202 is able to achieve positive results;
- the initiation, timing, progress and results of ongoing and future Phase 2 and Phase 3 clinical trials and any preclinical studies;
- the results and success of our research and development programs;
- our expectations regarding timing of results in our clinical trials;
- our ability to raise additional funding for future clinical trials and operations;
- estimates of our expenses, future revenue, capital requirements and our needs for additional financing;
- implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology and our ability to operate our business without infringing on the intellectual property rights of others;
- our expectations regarding the timing of our submission of an NDA for approval of LIPO-202 with the FDA and the likelihood and timing of approval of such NDA;
- the potential for commercialization and market acceptance of LIPO-202;
- our expectations regarding the potential market size and opportunity for LIPO-202, if approved for commercial use;
- our plans to commercialize LIPO-202 and our ability to develop and maintain sales and marketing capabilities;
- regulatory developments in the United States and foreign countries;
- the success of competing procedures that are or become available;
- our ability to maintain and establish collaborations;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our ability to continue as a going concern;
- our financial performance; and
- developments and projections relating to our competitors and our industry.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Forward-looking statements should be regarded solely as our current plans, estimates and beliefs. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this document, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

Item 1. Business

Overview

We are a clinical-stage specialty pharmaceutical company developing therapeutics for the aesthetic market. Our initial focus is on localized fat reduction and body contouring. Our lead product candidate, LIPO-202, is a first-in-class injectable formulation of the long-acting ß2-adrenergic receptor agonist, salmeterol xinafoate, which is an active ingredient in the U.S. Food and Drug Administration, or FDA, approved inhaled products SEREVENT DISKUS®, ADVAIR HFA® and ADVAIR DISKUS®. In November 2016, we announced plans to prioritize our efforts and resources on the Phase 2 proof of concept trial for the reduction of localized fat deposits under the chin, or submental fat. We initiated this trial in December 2016 and expect top-line results in June of 2017. We also plan to continue development of LIPO-202 for the reduction of central abdominal bulging pending results from the submental Phase 2 proof of concept trial.

We previously completed our initial Phase 2 development of LIPO-202 in 2013, showing a statistically significant reduction in central abdominal bulging due to subcutaneous fat in non-obese patients. In 2015, we conducted two pivotal U.S. Phase 3 trials of LIPO-202 for this same indication, which failed to meet their co-primary composite or secondary endpoints as well as showing near identical results with no bias in sites or subgroups. In these trials, AbCONTOUR1 and AbCONTOUR2, LIPO-202 continued to show a safety profile similar to placebo. We, and expert consultants that we engaged, conducted a detailed review of these trial results and concluded that modifications intended to make LIPO-202 commercially ready may have affected the drug product. As part of continuing development efforts, we completed manufacturing of a modified formulation of LIPO-202 for use in our Phase 2 proof of concept trial for the reduction of localized fat deposits under the chin or submental fat, which is based on the drug product formulation used in the successful Phase 2 RESET trial. We initiated our Phase 2 proof of concept trial for the reduction of localized fat deposits under the chin or submental fat in December 2016 and expect top-line results in June of 2017. If this trial and any future Phase 2 and Phase 3 trials are successful, we would then expect to file a new drug application, or NDA, utilizing the 505(b)(2) regulatory pathway, which permits us to file an NDA where at least some of the information required for approval comes from studies that were not conducted by or for us, and to which we do not have a right of reference, and which allows us to rely to some degree on the FDA's finding of safety for, and approval of, another product containing salmeterol xinafoate, the active ingredient in LIPO-202. If approved by the FDA, we believe LIPO-202 will be a best-in-class non-surgical procedure for localized fat reduction and body contouring.

Current treatment options for localized fat reduction and body contouring are designed to remove, damage, or kill fat cells, and in many cases can cause discomfort, pain, swelling, and downtime for the patient. These current treatment options include surgical options, such as lipoplasty or liposuction for which the FDA has cleared relevant medical devices and non-surgical options, such as energy-based medical devices and an injectable drug, also cleared by the FDA. Lipoplasty and liposuction procedures remove fat and they require significant physician skill and resources, involve pain, and require recovery time. Existing non-surgical options are often painful, may produce limited or inconsistent results and may require multiple or ongoing maintenance treatments resulting in longer aggregate treatment time than is anticipated with LIPO-202. Unlike existing treatment options, LIPO-202, based upon our clinical trials for central abdominal bulging, would be a non-surgical, non-ablative, alternative that takes less than fifteen minutes to inject and is less painful with minimal risk or damage to nearby tissue, no downtime and results seen as early as four weeks. LIPO-202 is an injectable formulation of salmeterol xinafoate, a well-known long-acting ß2-adrenergic receptor agonist. Drugs containing the inhaled form of salmeterol xinafoate have been approved by the FDA and are marketed by GlaxoSmithKline (SEREVENT DISKUS®, ADVAIR HFA® and ADVAIR DISKUS®). Salmeterol xinafoate is used in these drugs to relax bronchial smooth muscle in the treatment of asthma and chronic obstructive pulmonary disease, or COPD. Our studies suggest that salmeterol xinafoate also activates ß2-adrenergic receptors on fat cells, triggering the metabolism of triglycerides stored in the fat cells and thereby shrinking them across the treatment area.

As of December 31, 2016, we had working capital of $11.6 million and capital resources consisting of cash and cash equivalents of $11.5 million available for operations. We believe that our existing cash and cash equivalents will be sufficient to fund our operations into the second quarter of 2018, including our on-going Phase 2 proof of concept trial for the reduction of submental fat. Should we receive positive results from this trial, we anticipate having to raise additional funds to support further development of LIPO-202, including completion of any future clinical trials related to the reduction of submental fat and any other trials we may want to conduct related to central abdominal bulging, however adequate funding may not be available to us on acceptable terms, or at all.

Our patent estate consists of nine U.S. issued/allowed method of treatment and/or formulation patents and four U.S. pending patent applications, as well as granted and/or pending foreign counterparts of the U.S. patents and pending applications. Seven of the nine issued/allowed U.S. patents are directed to both LIPO-202 and LIPO-102 product candidates. Our patent directed to methods of treatment and pharmaceutical formulations is expected to expire no earlier than 2026.

Our Strategy

Our objective is to build a leading aesthetics company grounded in innovation. We are focused on development and commercialization of high value medical aesthetic products. Our strategy is maximizing the value of LIPO-202, our injectable drug for subcutaneous fat reduction or body contouring and our current focus is on the submental region for double chin.

Key elements of our strategy are:

- *Complete Clinical Development and Seek Regulatory Approval*. In December 2016, we initiated LIPO-202-CL-31, a Phase 2 proof of concept trial of LIPO-202 for the reduction of submental subcutaneous fat. We expect top-line results from this trial in June of 2017. We also plan to continue development of LIPO-202 for the reduction of central abdominal bulging pending results from the submental Phase 2 proof of concept trial. If this trial and any future Phase 2 and Phase 3 trials are successful, we expect to file a new drug application, or NDA, utilizing the 505(b)(2) regulatory pathway.
- *Explore the Use of LIPO-202 in Additional Indications*. We have identified other areas of the body with high aesthetic value where LIPO-202 could potentially be effective for localized fat reduction, including fat deposits located on the back of arms, along bra lines, on the flanks, hips, side of knees, inner and outer thighs, calves or buttocks. We may develop LIPO-202 for the treatment of one or more of these areas.
- *Future Commercialization of LIPO-202 in the United States*. If LIPO-202 is approved by the FDA, our focus is to commercialize LIPO-202 in the United States by either building a focused, specialized sales force targeting plastic surgeons and cosmetic dermatologists operating in the aesthetics market on our own or with potential partners
- *Expand the Global Body Contouring Aesthetic Market Using Injectable Therapeutic Products*. Given the favorable efficacy and safety profile and ease of administration of LIPO-202, we believe it can expand the overall fat reduction and body contouring market by attracting new patients who would prefer a less painful, non-surgical and convenient approach to treatment.
- *Establish Selective Strategic Partnerships to Maximize the Commercial Potential of LIPO-202*. We plan to evaluate whether to further develop or commercialize LIPO-202 on our own or in collaboration with potential partners.

Our Market Opportunity

The American Society for Aesthetic Procedures, or ASAPS, reported that patients are pursuing aesthetic procedures in record numbers. ASAPS reported American's spent more than $15 billion on aesthetic procedures in 2016, an increase of 11% over the prior year. A consumer survey conducted by American Society for Dermatologic Surgery, or ASDS, reported that 60% of consumers are considering cosmetic procedures and 50% of these consumers are considering body contouring. In addition, this survey reported 83% of consumers are bothered by excess fat, with 73% specifically bothered by excess fat on their chin or neck. We expect that the aesthetic procedures market, particularly the body contouring market, to continue to experience significant growth due to a number of trends including:

- high patient demand for non-surgical aesthetic procedures;
- increasing interest by consumers in their twenties and thirties as well as male consumers;
- increasing direct to consumer advertising;
- increasing popularity of combination treatments; and
- more types of physicians performing aesthetic procedures.

Growth of Non-Surgical Body Contouring Market. The non-surgical body contouring market is the fastest growing category in the aesthetic market. The industry estimates there are roughly thirty million people eligible for non-surgical body contouring procedures. Current penetration into this market is in the low single digits. ASAPS estimated that in 2016 there were 169,695 nonsurgical fat reduction procedures performed, reflecting approximately 6% growth over the prior year. The 2016 ASDS Consumer Survey detailed the percentage of the population somewhat to extremely bothered by excess weight on any part of the body at 83% and excess fat under the chin/neck at 73%.

If approved, we believe LIPO-202 will be a novel non-surgical body contouring solution as the first approved non-ablative injectable treatment for localized fat reduction. Current treatment options for fat reduction and body contouring include surgical options, such as lipoplasty, or liposuction, and non-surgical options, such as energy-based medical devices and a single FDA approved injectable drug, specifically for submental fat contouring. These options are designed to remove, damage or kill fat cells and in many cases due to their mechanism of action, these options typically take weeks to months to demonstrate results in the desired fat reduction, and may cause pain and adverse consequences for the patient.

We believe that, continued growth of the fat reduction and body contouring market will be hampered by the limitations of the current surgical and non-surgical procedures. We highlight these limitations below:

Limitations of Surgical Liposuction Procedures

Liposuction is a surgical procedure that requires a physician to make an incision in the area to be treated and insert a suction cannula to dislodge and vacuum out the fat. The procedure may cause tissue trauma, involve pain and may have an extended recuperation period for patients. The surgery can be done under local or general anesthesia.

- *Complications of Liposuction Surgery*. The FDA indicates there are several risks and complications for liposuction, including infections, embolisms, puncture wounds in the organs, serum pooling in the treated area, nerve damage, swelling, skin death, toxicity from anesthesia and fatalities. In addition, ASAPS advises patients that this procedure has many risks and potential complications in addition to those indicated by the FDA such as uneven contours, rippling or loose skin, irregular pigmentation, unfavorable scarring, skin discoloration, bleeding or hematoma, deep vein thrombosis, cardiac and pulmonary complications, and possibility of corrective surgery.
- *Pain and Extended Recovery Time.* According to the Aesthetic Surgery Journal, a reported 90% of patients experience pain post-operatively and many require pain control medicines, even narcotic analgesics, for several days following a liposuction procedure. According to the FDA, patients should expect pain and swelling following a liposuction procedure for several weeks and even months. In addition, patients may be required to wear compression garments for several weeks to control the swelling and drainage. While following a limited volume liposuction, a patient usually can return to work within three days; larger volume surgeries require a longer recuperation period and extended recovery time. Over several weeks, a patient can resume normal activities but may still show the negative side effects of the procedure.
- *Potential for Undesirable Results.* Even following successful liposuction surgery, patients may suffer from skin irregularities as a result of the procedure. One of the most common types of skin irregularities post-liposuction is skin dimpling, in which the skin takes on the appearance of cellulite, causing patients to be dissatisfied with their result. In addition, according to ASAPS, liposuction patients who gain weight after their surgery may store fat in other body areas such as the arms, back or the breasts in greater concentrations. Finally, in one study of women who underwent liposuction versus a similar control population, fat had redistributed to both treated and non-treated areas of the treated women's bodies within one year.
- *Limited Repeatability*. The process of removing or destroying fat cells with liposuction triggers the body's wound healing response, which leads to the formation of scar tissue in the treated area. If a patient desires further fat reduction or is not satisfied with the aesthetic results from a procedure, the scar tissue in the treated area may prevent the patient from undergoing follow-up procedures to enhance or correct the original treatment results.

Limitations of Non-Surgical Options

In the last several years, more than 20 new medical devices and a single injectable drug have been introduced to the market to try to address the risks and complications associated with liposuction surgery. Most of these technologies are large footprint, energy-based medical devices which purportedly enable a physician to injure or kill a subcutaneous fat deposit without penetrating the patient's skin. The injectable drug is a synthetic deoxycholic acid designed to kill fat cells.

Non-Surgical Energy-Based Devices

- *Limited Clinical Evidence of Safety and Effectiveness.* Many of these devices have received marketing authorization through the FDA's 510(k) clearance pathway, which typically requires less clinical data than is required for FDA approval of a device subject to Premarket Approval, or PMA, or an NDA (and in many cases may not require clinical data at all). Further, the labeling and advertising of 510(k) cleared devices may not be subject to the same degree of regulatory scrutiny and ongoing oversight as the FDA applies to the labeling and advertising of devices or drugs subject to PMA. Today, the scientific support for many of these technologies is uncertain, with confusing and sometimes limited medical evidence demonstrating fat reduction effects. It appears that other devices are being actively promoted by manufacturers and physicians for fat reduction without having received FDA clearance or approval for that indication. We believe that the wide range of energy-based technologies with different FDA clearances and approvals, potentially insufficient limited clinical data, and potentially unsupported marketing claims has created confusion among both physicians and consumers as to the effectiveness and safety of these procedures.

- *Need for Capital Outlay and Exam Space.* According to our own market research, physicians are concerned about the significant capital outlay required to purchase an energy-based device, which can be well-over $100,000. In some cases, multiple devices may be required to address multiple treatment areas efficiently. These devices may require dedicated office space or exam rooms, reducing clinical practice room space.
- *Length of Time to Visible Result.* Many of the energy-based devices, based on their mechanism, cause the fat cell to be damaged or destroyed and rely on the body's own immune response mechanisms to clear the affected tissue from the body. As the tissue is cleared, results may slowly become noticeable and typically are apparent in two to four months.
- *Potential for Serious Side Effects.* FDA data indicates that fat reduction treatments such as cryolipolysis and ultrasound may lead to serious adverse events, such as umbilical hernia, nerve damage, extended and debilitating pain and burns.

Injectable Option

- *Pain and Swelling.* In clinical trials, 96% of patients experienced injection site reactions including, 87% edema and swelling, 72% hematoma/bruising, and 70% pain.
- *Warnings and Precautions.* Patients may have serious side effects including dysphagia or trouble swallowing , marginal mandibular nerve injury, manifested as an asymmetric smile or facial muscle weakness, and injection site hematoma/bruising.

Our Body Contouring Solution

LIPO-202 is a proprietary, first-in-class injectable formulation of the well-known long-acting ß2-adrenergic receptor agonist, salmeterol xinafoate, which is an active ingredient of FDA-approved inhaled products such as SEREVENT DISKUS®, ADVAIR HFA® and ADVAIR DISKUS®. Our studies suggest that salmeterol xinafoate activates ß2 -adrenergic receptors on fat cells, triggering the body's natural process of metabolizing stored triglycerides (fat) resulting in a reduction in size and volume of the fat cells in the treatment area without damage of nearby tissues. If approved, we believe LIPO-202 will offer physicians and patients a safe, non-surgical and effective means to achieve targeted localized fat reduction and will become the standard for body contouring treatment for the following reasons:

- *Level of Medical Evidence*. In our Phase 2 RESET trial, LIPO-202 produced a statistically significant reduction of central abdominal bulging due to subcutaneous fat in non-obese patients compared to placebo over the eight-week treatment period. The safety profile of salmeterol xinafoate as used in SEREVENT DISKUS®, ADVAIR HFA® and ADVAIR DISKUS® for the treatment of asthma and COPD is well-established.
- *Natural and Non-Traumatic Mechanism of Action*. Our studies suggest that LIPO-202 activates ß2-adrenergic receptors on fat cells, triggering the body's natural process of metabolizing stored triglycerides (fat) resulting in a reduction in size and volume of the fat cells in the treatment area without damage of nearby tissues. By activating this natural metabolic process, we have been able to demonstrate a reduction in central abdominal bulging due to subcutaneous fat without the risks and adverse events typically seen with current surgical and non-surgical options.
- *Widely Accepted Modality that Addresses an Established and Expandable Market.* Aesthetic physicians and patients are already familiar with and accept injectable products as a key modality for the treatment of cosmetic concerns. According to ASAPS, in 2016, cosmetic patients in the United States underwent approximately 7.3 million injectable procedures and spent close to $3.5 billion on those treatments. We believe these dynamics will drive adoption of LIPO-202 by patients seeking localized fat reduction and body contouring treatments.
- *Patient-Friendly Procedure with Rapid Onset of Effects.* Unlike surgical or energy-based device treatment, which can take over thirty minutes to an hour per area, the injection procedure for administering LIPO-202 takes less than fifteen minutes to perform. Furthermore, in our clinical trials for central abdominal bulging, the side effects of treatment observed were primarily mild and transient injection site reactions likely due to the needle sticks themselves. Unlike most other fat reduction procedures available today, LIPO-202 injections are simple and quick, and patients can be treated during their normal day and return to regular daily activities immediately, with measurable results in as soon as four weeks.
- *Low Barrier to Adoption.* If approved, we believe LIPO-202 will increase the rate of adoption by physicians due to (1) expanded use by physicians, including dermatologists and primary care physicians, by offering a localized fat reduction treatment without the need to acquire any capital equipment, (2) higher economics from a complementary therapy with cash-pay reimbursement, (3) increased efficiency by administration using a physician extender or nurse, (4) higher patient traffic to provide opportunities to upsell additional products and services and (5) simplicity of procurement through existing pharmaceutical channels for injectable aesthetic products.

Our Product Candidate: LIPO-202

Description of LIPO-202

LIPO-202 is a novel injectable form of salmeterol xinafoate designed to produce local, selective fat tissue reduction, or pharmaceutical lipoplasty. Our studies suggest that LIPO-202 targets and stimulates natural fat tissue metabolism to achieve non-ablative, non-surgical fat tissue reduction in specific locations using salmeterol xinafoate, which is an active ingredient of FDA-approved products such as SEREVENT DISKUS®, ADVAIR HFA® and ADVAIR DISKUS®. In November 2016, we announced plans to prioritize our efforts and resources on the Phase 2 proof of concept trial to evaluate the reduction of localized fat deposits under the chin, or submental fat. We initiated this trial in December 2016 and expect top-line results in June 2017. We also plan to continue development of LIPO-202 for the reduction of central abdominal bulging pending results from the submental Phase 2 proof of concept trial. LIPO-202 can be administered by a physician or clinician in less than fifteen minutes in a pre-defined number and placement of subcutaneous injections across the treatment area through a small 30-gauge needle.

Mechanism of Action

LIPO-202 is a novel injectable form of salmeterol xinafoate designed to produce local, selective fat tissue reduction, or pharmaceutical lipoplasty. Salmeterol xinafoate is a highly selective, long-acting ß2-adrenergic receptor agonist. Adrenergic receptors play a major role in the regulation of several processes in the body, including fat cell metabolism. As shown in Figure 1 below, salmeterol xinafoate activates ß2-adrenergic receptors located on human fat cells and triggers the natural process of metabolism of triglycerides in these cells to free fatty acids and glycerol. Unlike many other treatments which remove, damage or kill fat cells, LIPO-202 reduces local fat stores and the bulges they create without damage to the fat cells or nearby tissues.

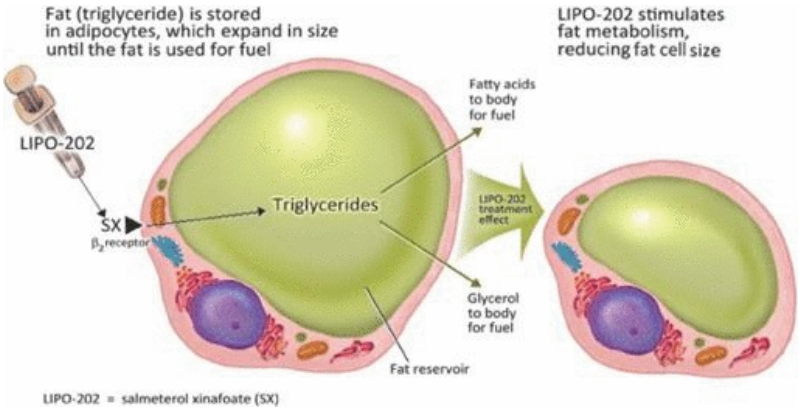


Figure 1. Graphic representation of the mechanism of action of LIPO-202

Clinical Program

We began the development of LIPO-202 with LIPO-102, an injectable combination of salmeterol xinafoate and the glucocorticoid fluticasone propionate, initially under the submission to the FDA on December 30, 2008, of an investigational new drug, or IND, application No. 102,514 for the treatment of symptomatic exophthalmos associated with thyroid-related eye disease. We additionally submitted IND No. 107,765 to the FDA on March 24, 2010, for the reduction of central abdominal bulging due to subcutaneous fat in non-obese subjects. Glucocorticoids like fluticasone propionate; have been shown in the literature and in our preclinical studies to potentially enhance the activity of the ß2-adrenergic receptor agonist salmeterol xinafoate. In our clinical trials, we learned that the efficacy of LIPO-102 was directly related to its contained dose of salmeterol xinafoate without a significant contribution from fluticasone propionate. Therefore, we determined to move forward with LIPO-202, our single-agent therapeutic containing only salmeterol xinafoate. We were granted allowance by the FDA to conduct a Phase 2 proof of concept trial to evaluate the treatment of localized fat under the chin, or submental fat, with LIPO-202 under IND No. 107,765.

The safety profile of LIPO-202, similar to LIPO-102, can be characterized as benign with mild, transient injection site reactions, such as erythema, hematoma and pain. These reactions were reported both infrequently and at the same rate as placebo injections, suggesting that these adverse events are related to the injection procedure itself and not the treatment.

Submental Area

Summary of Clinical Trials

- *Study LIPO-202-CL-31.* In December 2016, we initiated LIPO-202-CL-31, the Phase 2 proof of concept trial for LIPO202 for the reduction of submental subcutaneous fat. LIPO-202-CL-31 is a multi-center, randomized, double-blind, placebo-controlled trial to assess the safety and efficacy of two doses of LIPO-202 versus placebo. The trial is expected to enroll 150 patients at approximately ten sites across the United States.

  Subjects will be randomized 1:1:1 to one the following dose groups:

  - LIPO-202 (Salmeterol Xinafoate for Injection): 0.02 mcg SX/mL; total dose of up to 0.3 mcg SX
  - LIPO-202 (Salmeterol Xinafoate for Injection): 0.2 mcg SX/mL; total dose of up to 3.0 mcg SX
  - Placebo for LIPO-202 (Salmeterol Xinafoate for Injection)

  Subjects will receive up to 30 subcutaneous injections of LIPO-202 or placebo into the submental fat once a week for eight weeks. Upon the completion of the treatment visits, follow-up visits with the patients to assess safety and efficacy will occur one week and four weeks post the last treatment.

  The study endpoints include both safety and efficacy measurements. Efficacy measures will assess improvement in the patient's submental region as evaluated by the patient and clinician, overall patient satisfaction and evaluation of submental fat thickness by calipers. We have developed endpoint tools for the patient and clinician to assess the change in the submental area that are similar to other rating scales used for [a] recently approved FDA product[s].

Central Abdominal Area

Summary of Clinical Trials

Each of our clinical trials to date has provided important information on the safety and efficacy of LIPO-202, as well as on the tools with which to assess changes in central abdominal bulging due to subcutaneous fat. All of the clinical trials of LIPO-102 and LIPO-202 as well as several key endpoint evaluation studies are described below.

Endpoint Tools

There are currently no FDA-accepted endpoint tools for assessing change in central abdominal bulging due to subcutaneous fat for pharmaceutical products. Consequently, we developed methods of patient assessment and clinician rating of bulging, as well as physical measures of bulging and a questionnaire that measures the impact of bulging on patients. These assessment and rating tools are similar to other rating scales used for approved aesthetic drug products and medical devices, such as botulinum toxins, dermal fillers and injectable drug for fat reduction, and were validated using scientific principles and process recommendations consistent with the FDA's guidance document, "Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims," in an effort to ensure reliability, content validity, construct validity and sensitivity to change over time.

We developed the following patient and clinician scales to access the change in central abdominal bulging:

- *Patient-Reported Patient-Global Abdominal Perception Scale, or P-GAPS*. A patient self-assessment of the amount of bulging in the central abdomen on a five-point ordinal scale.
- *Clinician-Reported Clinician-Global Abdominal Perception Scale, or C-GAPS*. A clinician assessment of the amount of bulging in the patient's central abdomen on a five-point ordinal scale.
- *Patient-Reported Clinician Photonumeric Scale*. A patient's self-assessment of the amount of bulging in the central abdomen on a six-point photonumeric scale pursuant to which the patient performs a match-to-sample from a gender-specific scale of lateral profile torso pictures with progressively larger abdominal bulges.
- *Clinician-Reported Clinician Photonumeric Scale*. A clinician rating of the amount of bulging in the central abdomen on a six-point photonumeric scale pursuant to which the clinician performs a match-to-sample from two gender-specific scales of lateral profile torso pictures with progressively larger abdominal bulges.

Early Clinical Trials

- *Study LIPO-102-CL-01*. A single- and multiple-dose Phase 1 safety and pharmacokinetics study, which included 26 patients, identified the maximum potential dose of salmeterol xinafoate administered by subcutaneous injection to the abdomen that would qualify for consideration under FDA regulation 505(b)(2). The 505(b)(2) regulatory pathway will enable us to file an NDA using the FDA's approval of another product based on data generated by others, provided that we establish the necessary preclinical and clinical bridges to the previously approved product. We expect that we will be able to reference data on salmeterol xinafoate submitted to the FDA for ADVAIR®, such as that for reproductive toxicology, mutagenicity, carcinogenicity, long-term toxicology, clinical safety, QTc interval, and drug interactions, and will not need to repeat those studies. Study LIPO-102-CL-01 showed that approximately 50 µg of salmeterol xinafoate injected subcutaneously into the abdomen produces peak plasma levels of salmeterol comparable to those produced by 50 µg of salmeterol xinafoate administered twice daily by the oral inhalation of ADVAIR®. Thus, guidance was obtained for future trials on the limits of salmeterol xinafoate dosing when injected subcutaneously into the abdomen.
- *Study LIPO-102-CL-03*. This study, which included 54 patients, provided initial information on the safety and efficacy of a range of doses of LIPO-102 administered via subcutaneous injection once or twice per week for four weeks to non-obese patients with measureable abdominal bulging. This study demonstrated that the greatest reduction in abdominal circumference was produced by the lowest dose of LIPO-102 tested, 0.5 µg salmeterol xinafoate and 1.0 µg fluticasone propionate, that was administered once rather than twice weekly for four weeks. This study also demonstrated that 2-D ultrasound and skin-pinch calipers were highly variable as assessment tools relative to constant-tension tape measurement.
- *Study LIPO-102-CL-04*. This study, which included 58 patients, further defined the dose of LIPO-102 when injected as divided doses in a defined array across the abdomen. Two doses of LIPO-102 were compared to placebo when administered as 22 one mL central abdominal subcutaneous injections once a week for eight weeks. The use of 3-D digital photographic imaging to measure changes in abdominal circumference and volume, as well as patient and clinician rating scales were investigated in this trial as potential clinical endpoints. The lowest doses of salmeterol xinafoate in LIPO-102 produced superior efficacy compared to the higher doses. The pharmacokinetics of LIPO-102 at a total weekly salmeterol xinafoate plus fluticasone propionate dose of 11 µg+22 µg was also evaluated in Study LIPO-102-CL-04 after the first dose on Day 1 and after the last dose on Day 50. There was no significant difference between the plasma levels of either dose on Days 1 and 50. The peak plasma level of salmeterol xinafoate produced by LIPO-102 was approximately one fifth of that produced by the 505(b)(2) reference drug ADVAIR DISKUS 500/50®. Moreover, the peak plasma level of salmeterol xinafoate produced by the Phase 3 dose of LIPO-202, or 0.4 µg salmeterol xinafoate total weekly dose, is approximately over 100-fold less than that produced by the 505(b)(2) reference drug ADVAIR DISKUS 500/50®. The reductions in abdominal circumference and volume determined by 3-D digital imaging were also found to persist in responders to LIPO-102 for 12-weeks post-treatment.
- *Study LIPO-102-CL-09*. This study, which included 157 patients, was designed to:
  - define the optimal dose of LIPO-102 through an evaluation of the safety and efficacy of three doses of LIPO-102 compared to placebo delivered as 20 subcutaneous injections once a week for eight weeks;
  - test the Patient Photonumeric Scale, or PPnS, and CPnS, as potential clinical endpoints;
  - test the Abdominal Subcutaneous Adiposity Questionnaires, or ASAQ, now renamed the Abdominal Contour Questionnaire, or ACQ, as a clinical endpoint; and
  - evaluate the safety and efficacy of LIPO-102 for 12 weeks following the final dose.

Toward the stated objectives, a weekly dose of 0.4 µg salmeterol xinafoate and 20 µg fluticasone propionate LIPO-102 was identified as optimal based on significant reductions in treatment area volume and circumference as determined by 3-D digital imaging. LIPO-102-treated subjects in the 0.4 µg salmeterol xinafoate + 20 µg fluticasone propionate LIPO-102 and 1.0 µg salmeterol xinafoate + 20 µg fluticasone propionate LIPO-102 dose groups rated the change in abdominal flattening on the PPnS as significantly greater by End-of-Study compared with the placebo group (p-value = 0.044 and p-value = 0.006, respectively), with similar trends observed on the CPnS. The ASAQ was confirmed to be a valid patient-reported outcome instrument to measure the broader effects or impact of changes in central abdominal bulging due to subcutaneous fat. Importantly, the lowest dose of LIPO-102 tested, 0.1 µg salmeterol xinafoate + 20 µg fluticasone propionate, was inactive/no different than placebo across all outcome measures in this study. Similar to the prior study, in the non-drug observational follow-on to LIPO-102-CL-09, the reduction in abdominal circumference and volume produced by responders to 0.4 µg salmeterol xinafoate + 20 µg fluticasone propionate LIPO-102 remained significantly greater than that produced by placebo for at least six weeks post-treatment and remained above baseline and placebo for at least 12 weeks post-treatment.

- *Study VAL-CL-10.* This study enrolled 23 subjects who met the same inclusion/exclusion criteria as in Study LIPO-102-CL-09, but received only limited volume liposuction performed over the same treatment area in Study LIPO-102-CL-09. Acknowledging that these are cross-study comparisons, the VAL-CL-10 study showed that the reductions in abdominal circumference and volume measured ten weeks after liposuction were nearly identical to those produced by 0.4 µg salmeterol xinafoate + 20 µg fluticasone propionate LIPO-102 in Study LIPO-102-CL-09.
- *Study LIPO-102-CL-11.* In contrast to all previous studies with LIPO-102, this study, which included 228 patients, compared the safety and efficacy of three doses of LIPO-102 in which the dose of salmeterol xinafoate was fixed and dose of fluticasone propionate was varied. In addition, this clinical trial included a treatment arm of 0.4 µg salmeterol xinafoate alone, or LIPO-202. The LIPO-102 dose-response was relatively flat in terms of change from baseline to End-of-Study for most outcome measures, regardless of the contained dose of fluticasone propionate. In addition, the responses for salmeterol xinafoate alone, or LIPO-202, were similar to those of the combination of fluticasone propionate and salmeterol xinafoate, or LIPO-102. These results confirmed that salmeterol xinafoate alone is primarily responsible for the reduction of central abdominal bulging due to subcutaneous fat, prompting us to focus on LIPO-202 for future development.
- *Study VAL-CL-13.* This study was an exploratory study that compared MRI with external 3-D digital stereophotogrammetry and a laser-guided manual tape measure procedure as objective physical measures of abdominal circumference. One male and one female subject completed the study from each of the following BMI categories: BMI = 20 ± 2 kg/m^2, 25 ± 2 kg/m^2, 30 ± 2 kg/m^2 and 35 ± 2 kg/m^2. This study showed that MRI, 3-D digital imaging and the standardized laser-guided manual tape measure procedure were all effective tools for measuring abdominal circumferences in this single site, single visit study. However, variance was found to be the smallest for the laser-guided manual tape measure procedure warranting further evaluation of this technique in future clinical trials.
- *Studies VAL-CL-15 and VAL-CL-20.* These studies, which included 29 subjects and 30 subjects, respectively, and 10 clinicians and 11 clinicians, respectively, were non-drug studies that assessed the reliability of our clinical outcome assessment rating instruments, including the P-GAPS, Clinician-Global Abdominal Perception Scale, or C-GAPS, PPnS, CPnS. The ratings were performed by trained clinical raters of the studies, on two occasions 14 days apart to provide an estimate of test-retest reliability. In addition, the inter-rater reliability, or the degree of agreement among the raters, was determined for the clinician rating instruments, such as the C-GAPS and CPnS. An intra-class correlation coefficient, or ICC, is typically determined to estimate reliability when there are a number of different raters making an assessment. When the raters agree on an assessment, the ICC approaches a value of one. The ICC from all studies for all clinical outcome assessment or rating instruments approached or exceeded 0.9. These studies demonstrated a high degree of patient, clinician and test-retest reliability for our clinical outcome assessment instruments.
- *Study VAL-CL-24.* This non-drug study included 40 subjects and explored 2-D ultrasound as a tool to measure subcutaneous fat thickness in the anterior abdomen and determined the intra- and inter-rater reliability and retest reliability of 2-D ultrasound at two investigative clinical sites. The intra- and inter-rater reliability and retest reliability was also determined for our laser-guided tape measure procedure. This study achieved its intended purpose of establishing the protocol with which to assess 2-D ultrasound as a measure of change in up to four clinical sites in the two pivotal Phase 3 clinical trials.
- *Study RESET.* This study was a 513-patient, randomized, placebo-controlled, multi-center Phase 2 dose-ranging clinical trial with LIPO-202, known as the RESET study, utilizing key clinical endpoint tools and study design features. Non-obese male and female adult patients who had at least a slight abdominal bulge due to excess subcutaneous fat and who expressed dissatisfaction with their abdominal contour were enrolled in this study. Trial subjects received 20 one mL subcutaneous injections of LIPO-202 in 0.4, 1.0 or 4.0 µg total weekly doses or placebo once weekly for eight weeks. These injections were made into a standardized periumbilical treatment area defined by our treatment area grid with a pre-marked area of approximately 400 cm2 between axial planes at 35 mm above the umbilicus and at 70 mm below the umbilicus, and with each of the 20 injection sites spaced four cm apart. Central abdominal bulging due to subcutaneous fat was assessed on Day 1 as the baseline pre-treatment day, Day 29, which was one week after the fourth set of injections and on Day 57, which was one week after the eighth set of injections.

The RESET study showed statistically significant reductions in central abdominal bulging due to subcutaneous fat in non-obese patients from baseline at Day 1 and from placebo on the key clinical endpoint measures. The most significant reductions observed in the patients were those who received the 0.4 µg total weekly dose of LIPO-202. We also reviewed p-values, which is a conventional statistical method for measuring the statistical significance of clinical results. In clinical trials, the "p-value" is the probability that the result was obtained by chance. For example, a "p-value" of 0.10 would indicate that there is a 10% likelihood that the observed results could have happened at random. By convention, a "p-value" that is less than 0.05 is considered statistically significant.

- By both empirical and historical FDA definitions of a responder to treatment, there was a significantly greater percentage of responders to the 0.4 µg total weekly dose of LIPO-202 than to placebo. By the clinically-meaningful empirical definition of a responder, 16.4% of subjects treated with 0.4 µg of LIPO-202 weekly for eight weeks were defined as one-point P-GAPS and two-point CPnS responders compared to 6.8% of subjects receiving placebo injections. This was a statistically significant improvement (p-value = 0.043). By the FDA's historical definition of a responder, 6.4% of subjects treated with 0.4 µg of LIPO-202 weekly for eight weeks were defined as two-point P-GAPS and two-point CPnS responders compared to less than 1% of subjects receiving placebo injections. This was a statistically significant improvement (p-value = 0.024).
- Using the standardized laser-guided manual tape measure procedure, the 0.4 µg total weekly dose of LIPO-202 produced significant reductions in abdominal circumference at the umbilicus compared to placebo. The 0.4 µg total weekly dose of LIPO-202 reduced umbilical circumference, on average, by 1.6 cm compared to 0.7 cm for placebo. This was a statistically significant improvement (p-value = 0.001).
- As with umbilical circumference the 0.4 µg total weekly dose of LIPO-202 produced significant reductions in abdominal volume in the treatment area compared to placebo. The 0.4 µg total weekly dose of LIPO-202 reduced treatment area volume, on average, by 191.9 cubic centimeters, or cc, compared to 89.9 cc for placebo. This was a statistically significant improvement (p-value = 0.001).

It should be noted that in the RESET trial, change from baseline and change from placebo treatment effects with the 0.4 µg total weekly dose of LIPO-202 were enhanced on all outcome measures in subjects who remained weight neutral or lost weight. For example, this enhancement was observed on the P-GAPS/CPnS composites and on the laser-guided tape measure-determined circumference and volume endpoints, despite no differences in mean weight change between LIPO-202 and placebo treatment groups.

Also, the observed reduction in treatment area volume with LIPO-202 in the RESET study was similar to that observed in a non-drug, limited-volume VAL-CL-10 liposuction study conducted in a similar study population over a similar treatment area. A mean reduction in treatment area volume of approximately 200 cc was produced by both eight weeks of treatment with the 0.4 µg total weekly dose of LIPO-202 in the RESET study and by limited volume liposuction as assessed ten weeks after surgery.

There were no significant adverse events during the RESET study and no subject discontinued the study due to an adverse event; 92% of subjects completed the study per protocol. As shown in Table 1 below, the most commonly reported treatment-emergent adverse effects definitely or possibly related to study drug were mild and transient injection site events, including mild hematoma, erythema, contusion, and pain. The incidence of these adverse effects was low and they occurred with a similar frequency in subjects in both the placebo group and in the LIPO-202 treatment groups. Consequently, these injection site events were considered to be related to the typical mechanical trauma of an injection procedure rather than to the study drug itself. A similar safety profile has consistently been demonstrated and observed upon examination of all LIPO-102/LIPO-202 safety data.

Adverse Effect	Placebo	0.4 µg Salmeterol Xinafoate	1.0 µg Salmeterol Xinafoate	4.0 µg Salmeterol Xinafoate
Any Adverse Event Definitely or Possibly Related to Study Drug	10%	11%	12%	12%
Administration Site Conditions	5%	8%	10%	9%
Injection Site Hematoma	2%	5%	6%	6%
Injection Site Pain	2%	3%	2%	2%
Injection Site Erythema	2%	2%	<1%	0%
Injection Site Hemorrhage	2%	0%	0%	0%

Table 1. Adverse effects of LIPO-202 in RESET

Phase 3 Clinical Trials

- Studies AbCONTOUR1 and AbCONTOUR2. Our Phase 3 AbCONTOUR1 and AbCONTOUR2 clinical trials that enrolled 794 and 793 patients, respectively, were randomized, placebo-controlled, multi-center trials to study the safety and efficacy of LIPO-202. The design of these identical trials was similar to RESET and utilized key clinical endpoint tools. Non-obese male and female adult patients who had at least a slight abdominal bulge due to excess subcutaneous fat and who expressed dissatisfaction with their abdominal contour were enrolled in these studies. Trial subjects received 20 one mL subcutaneous injections of LIPO-202 in 0.4 g total weekly dose or placebo once weekly for eight weeks. As in the RESET study the injections were made into a standardized periumbilical treatment area defined by our treatment area grid with a pre-marked area of approximately 400 cm2 between axial planes at 35 mm above the umbilicus and at 70 mm below the umbilicus, and with each of the 20 injection sites spaced four cm apart. Central abdominal bulging due to subcutaneous fat was assessed on Day 1 as the baseline pre-treatment day, Day 29, which was one week after the fourth set of injections and on Day 57, which was one week after the eighth set of injections.

  The predefined clinical endpoint measures defined for these studies included a co-primary endpoint of the patient assessment and clinician rating of abdominal bulging and secondary endpoint measures that assessed the change in the abdominal circumference and volume. The co-primary endpoint includes both the "clinically-meaningful" and the "statistical" responders to treatment. The clinically-meaningful responders to treatment are those patients who show at least a one-point improvement in abdominal bulging, or achieve abdominal flattening, on the P-GAPS that is corroborated by the treating clinician as at least a two-point improvement in abdominal bulging, or achievement of abdominal flattening, on the CPnS. The statistical responders to treatment are those patients who show at least a two-point improvement in abdominal bulging, or achieve abdominal flattening, on the P-GAPS that is corroborated by the treating clinician as at least a two-point improvement in abdominal bulging, or achievement of abdominal flattening, on the CPnS. Secondary endpoints included an assessment of changes in abdominal circumference and volume as determined by the standardized laser-guided tape measure procedure.

  Neither the AbCONTOUR1 nor AbCONTOUR2 study showed a statistically significant reduction in central abdominal bulging due to subcutaneous fat in non-obese patients from baseline at Day 1 or from placebo with a 0.4 µg total weekly dose of LIPO-202 on the co-primary or the secondary clinical endpoint measures outlined above.

  - By both empirical and historical FDA definitions of a responder to treatment, there was not a statistical difference between the percentage of responders to the 0.4 µg total weekly dose of LIPO-202 than to placebo for either AbCONTOUR1 or AbCONTOUR2. By the clinically-meaningful empirical definition of a responder for AbCONTOUR1 and AbCONTOUR2, 12% and 10% respectively of subjects treated with 0.4 µg of LIPO-202 weekly for eight weeks were defined as one-point P-GAPS and two-point CPnS responders compared to 11% and 13% respectively of subjects receiving placebo injections.
  - Also by the FDA's historical definition of a responder for AbCONTOUR1 and AbCONTOUR2, 3% and 5% respectively, of subjects treated with 0.4 µg of LIPO-202 weekly for eight weeks were defined as two-point P-GAPS and two-point CPnS responders compared to 4% and 5% respectively of subjects receiving placebo injections.
  - Using the standardized laser-guided manual tape measure procedure, the 0.4 µg total weekly dose of LIPO-202 produced similar reductions in abdominal circumference at the umbilicus compared to placebo. The 0.4 µg total weekly dose of LIPO-202 reduced umbilical circumference, on average for AbCONTOUR1 and AbCONTOUR2, by 0.7 cm and 0.8 cm respectively compared to 0.9 cm and 0.9 cm for placebo.
  - As with umbilical circumference, the 0.4 µg total weekly dose of LIPO-202 produced similar reductions in abdominal volume in the treatment area compared to placebo. The 0.4 µg total weekly dose of LIPO-202 reduced treatment area volume, on average on average for AbCONTOUR1 and AbCONTOUR2, by 99.5 cubic centimeters (cc) and 105.6 cc, compared to 115.1 cc and 100.9 cc for placebo.

  It should be noted that both the AbCONTOUR1 and AbCONTOUR2 trials, the patient assessments and clinician ratings of abdominal bulge and the reductions observed in circumference at the umbilicus and treatment area volume of the 0.4 µg total weekly dose of LIPO-202 were the same as observed in the placebo group. Statistical improvement was not met for AbCONTOUR1 or AbCONTOUR2 in any of the endpoint clinical measures. The observed results of these studies are similar to the observed results in the placebo groups in the Phase 2 clinical program.

  There were no serious adverse events during either the AbCONTOUR1 or AbCONTOUR2 study and less than one percent of subjects discontinued the study due to an adverse event. As shown in Table 2 below, the most commonly reported treatment-emergent adverse effects definitely or possibly related to study drug were mild and transient injection site events, including mild bruising, pain, erythema, and hemorrhage. The incidence of these adverse effects was low and they occurred with a similar frequency in subjects in both the placebo group and in the LIPO-202 treatment groups. Consequently, these injection site events were considered to be related to the typical mechanical trauma of an injection procedure rather than to the study drug itself. A similar safety profile has consistently been demonstrated and observed upon examination of all LIPO-102/LIPO-202 safety data.

Adverse Effect	AbCONTOUR1 Placebo	AbCONTOUR1 0.4 µg Salmeterol Xinafoate	AbCONTOUR2 Placebo	AbCONTOUR2 4.0 µg Salmeterol Xinafoate
Any Adverse Event Definitely or Possibly Related to Study Drug	14%	13%	14%	12%
Administration Site Conditions	13%	12%	12%	12%
Injection Site Bruising	4%	4%	8%	9%
Injection Site Pain	7%	7%	3%	2%
Injection Site Erythema	0%	<1%	<1%	<1%
Injection Site Hemorrhage	<1%	<1%	<1%	1%

Table 2. Adverse effects of LIPO-202 in AbCONTOUR1 and AbCONTOUR2

Other Clinical Trials:

Special Population Trial

- *Study LIPO-202-CL-21.* The LIPO-202-CL-21trial was randomized, placebo-controlled, multi-center trial to study the safety and efficacy of LIPO-202 in obese patients. The design of this trial was similar to the Phase 3 trials. The study did not include the patient assessment or clinician rating tools to assess abdominal bulging as the instruments were not validated for this patient population. One hundred twenty nine obese male and female adult patients, defined as having a BMI at least 30 kg/m2 but less than 40 kg/m2, who had at least a slight abdominal bulge due to excess subcutaneous fat and who expressed dissatisfaction with their abdominal contour were enrolled in this study. As in the Phase 3 trials, subjects received 20 one mL subcutaneous injections of LIPO-202 in 0.4 µg total weekly dose or placebo once weekly for eight weeks. The injections were made into a standardized periumbilical treatment area defined by our treatment area grid with a pre-marked area of approximately 400 cm2 between axial planes at 35 mm above the umbilicus and at 70 mm below the umbilicus, and with each of the 20 injection sites spaced four cm apart. Central abdominal bulging due to subcutaneous fat was assessed on Day 1 as the baseline pre-treatment day, Day 29, which was one week after the fourth set of injections and on Day 57, which was one week after the eighth set of injections.

  LIPO-202 continued to show a benign safety profile in this study. There were no treatment-related serious adverse effects and one subject discontinued from the study due to an adverse event. As shown in Table 3 below, the most commonly reported treatment-emergent adverse effect definitely or possibly related to study drug was mild and transient injection site pain. The incidence of the adverse effects was low and they occurred with a similar frequency in subjects in both the placebo group and in the LIPO-202 treatment group.

Adverse Effect	Placebo	0.4 µg Salmeterol Xinafoate
Any Adverse Event Definitely or Possibly Related to Study Drug	7%	10%
Administration Site Conditions	7%	10%
Injection Site Pain	7%	10%

Table 3. Adverse effects of LIPO-202 in LIPO-202-CL-21

This study did not showed a statistically significant reduction in central abdominal bulging due to subcutaneous fat in obese patients from baseline at Day 1 or from placebo with a 0.4 µg total weekly dose of LIPO-202. Using the standardized laser-guided manual tape measure procedure, the 0.4 µg total weekly dose of LIPO-202 produced similar reductions in abdominal circumference at the umbilicus compared to placebo. The 0.4 µg total weekly dose of LIPO-202 reduced umbilical circumference, on average, 0.8 cm compared to 0.4 cm for placebo.

Retreatment Trial

- *Study LIPO-202-CL-22.* We initiated the LIPO-202-CL-22, an open-label, multi-center trial to evaluate the safety and efficacy of multiple treatment courses with LIPO-202. The design of this trial was similar to the Phase 3 trials that utilized all of the key clinical endpoint tools described above however it consisted of three courses of treatment with study drug with a three (3) month period between courses. Non-obese male and female adult patients who had at least a slight abdominal bulge due to excess subcutaneous fat and who expressed dissatisfaction with their abdominal contour were enrolled in these studies. Trial subjects received 20 one mL subcutaneous injections of LIPO-202 in 0.4 µg total weekly dose or placebo once weekly for eight weeks. As in the Phase 3 studies the injections were made into a standardized periumbilical treatment area defined by our treatment area grid with a pre-marked area of approximately 400 cm2 between axial planes at 35 mm above the umbilicus and at 70 mm below the umbilicus, and with each of the 20 injection sites spaced four cm apart. Central abdominal bulging due to subcutaneous fat was assessed during each of the three treatment courses on Day 1 as the baseline pre-treatment day, Day 29, which was one week after the fourth set of injections and on Day 57, which was one week after the eighth set of injections. We terminated the LIPO-202-CL-22 prior to completion based on the outcome of the AbCONTOUR1, AbCONTOUR2, and LIPO-202-CL-21 trials.

Observation Trial

- *Study LIPO-202-CL-23.* We initiated the LIPO-202-CL-23, a double-blind, multi-center study to evaluated the post-treatment safety and duration of clinical effect of LIPO-202 in subjects who completed either the AbCONTOUR1 or AbCONTOUR2 study. There was no study drug administered in this trial. The subjects were to be assessed for safety and efficacy measures every three months for up to a year. We terminated the LIPO-202-CL-23 based on the outcome of the AbCONTOUR1 and AbCONTOUR2 trials.

Bioavailability Trial

- *Study LIPO-202-CL-12.* An open-label, crossover study comparing the pharmacokinetics of LIPO-202 and ADVAIR DISKUS 500/50® (Fluticasone Propionate 500 mcg and Salmeterol Xinafoate 50 mcg Inhalation Powder) was completed in 24 in healthy volunteers. This study confirmed that the 0.4 µg total weekly dose of LIPO-202 administered by subcutaneous injection to the abdomen would qualify for consideration under FDA regulation 505(b)(2). The 505(b)(2) regulatory pathway will enable us to file an NDA using the FDA's approval of another product based on data generated by others, provided that we establish the necessary preclinical and clinical bridges to the previously approved product. We expect that we will be able to reference data on salmeterol xinafoate submitted to the FDA for ADVAIR®, such as that for reproductive toxicology, mutagenicity, carcinogenicity, long-term toxicology, clinical safety, QTc interval, and drug interactions, and will not need to repeat those studies. Study LIPO-102-CL-12 showed that 0.4 µg of LIPO-202 injected subcutaneously into the abdomen produces peak plasma levels of salmeterol significantly below to those produced by 100 µg of salmeterol xinafoate administered daily by the oral inhalation of ADVAIR®.

Nonclinical Program

Pharmacology

Salmeterol xinafoate is a highly selective, long-acting ß2-adrenergic receptor agonist. Consistent with the known role of ß-adrenergic receptors in the metabolism of stored triglycerides in fat cells, we have shown that salmeterol xinafoate stimulates the breakdown of triglycerides into free fatty acids and glycerol in cultured human fat cells in a manner similar to other ß-adrenergic receptor agonists, such as isoproterenol. We have also direct evidence that the injection of salmeterol xinafoate reduces subcutaneous fat in animal models as our pre-clinical studies demonstrated that the injection of salmeterol xinafoate into the inguinal fat pad of rats produced a dose-related reduction in fat pad weight. Similarly, our preclinical studies demonstrated that the injection of salmeterol xinafoate into the back fat of minipigs reduced subcutaneous fat thickness as determined by 2-D ultrasound.

Safety

Salmeterol xinafoate is approved by the FDA for use by oral inhalation for maintenance treatment of bronchial asthma and COPD either alone as the active ingredient of SEREVENT DISKUS® or in combination with another active ingredient, fluticasone propionate, as ADVAIR HFA® and ADVAIR DISKUS®. Consequently, the nonclinical safety profile of salmeterol xinafoate and fluticasone propionate alone and in combination has been extensively studied in mice, rats, rabbits, guinea pigs and/or dogs by several routes of administration, including by mouth, intravenous, intraperitoneal, subcutaneous, inhalation and/or dermal. The FDA's findings as to this information are available for us to reference in our NDA under the Section 505(b)(2) regulatory pathway provided that we establish the appropriate preclinical bridge to that data. Although salmeterol xinafoate and fluticasone propionate are established agents with well characterized nonclinical and clinical safety profiles, both systemically and locally, use of these drugs by the subcutaneous route and their potential properties to stimulate the breakdown of triglycerides into free fatty acids and glycerol are less well understood and have been the focus of our studies. Consequently, additional pharmacokinetics and toxicity studies were conducted in rats and minipigs by subcutaneous administration to assess local tolerability in support of early stage clinical trials. Local concentrations of salmeterol xinafoate 2500-fold greater than the anticipated clinical dose produced no untoward histopathological changes when injected into the back fat of minipigs. These findings have recently been extended; subcutaneous administration of salmeterol xinafoate into the back fat of minipigs 3 times per week for 13 weeks produced no untoward histopathological changes at local concentrations of salmeterol xinafoate 15,000-fold greater than the anticipated clinical dose. In addition, the preclinical bridge to the SEREVENT®/ADVAIR® preclinical safety data, under the Section 505(b)(2) regulatory pathway, was established in a 28-day study in rats comparing oral and subcutaneous administration of salmeterol xinafoate.

Government Regulation

Pharmaceutical products are subject to extensive regulation by government authorities in the United States, at the federal, state and local level, and in other countries. The Federal Food, Drug, and Cosmetic Act, or FDCA, and other federal, state and foreign statutes and regulations extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, reporting, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as LIPO-202. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

United States Regulation of Drugs. In the United States, the FDA regulates drugs such as our product candidates under the FDCA and implementing regulations. Failure to comply with the applicable FDA or other requirements at any time during the product development process, approval process, or after approval may subject an applicant or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice, or DOJ, or other governmental entities. We are pursuing a Section 505(b)(2) NDA regulatory strategy, explained further below, which we expect will allow us to rely in our new drug application, NDA, on certain nonclinical and clinical safety findings made by the FDA in its approval of salmeterol xinafoate, which is an active ingredient of FDA-approved products such as SEREVENT DISKUS®, ADVAIR HFA® and ADVAIR DISKUS®.

The U.S. Drug Approval Process. New drugs must be approved by the FDA before they can be marketed. There are three types of new drug applications: (1) an application that contains full reports of investigations of safety and effectiveness (a Section 505(b)(1) application); (2) an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference (a Section 505(b)(2) application); and (3) an application that contains information to show that the proposed product is, among other things, the same as a previously approved product in terms of its active ingredient, dosage form, strength, route of administration, labeling, and pharmacokinetics (a Section 505(j) application, referred to as an abbreviated new drug application or ANDA).

The steps required before a drug may be approved for marketing in the United States under Section 505(b) generally include:

- preclinical laboratory tests and animal tests conducted in accordance with Good Laboratory Practices or GLP;
- the submission to the FDA of an investigational new drug, or IND, application for human clinical testing, which must become effective before human clinical trials commence in the United States (the sponsor may also elect to conduct foreign clinical trials under an IND, and if it does elect to do so, all FDA requirements must be followed);
- the 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 conducted in accordance with Good Clinical Practice, or GCP, to establish the safety and efficacy of the proposed drug for each indication (the FDA will accept non-IND foreign studies as support for an FDA application provided the study was conducted in accordance with GCP and the FDA is able to validate the data through an onsite inspection if necessary);

- the submission to the FDA of an NDA;
- FDA acceptance of the NDA for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made to assess compliance with current Good Manufacturing Practice, or cGMP, and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- responding to questions raised by the FDA regarding the application ("complete response" letters), if any; and
- the FDA's approval of the NDA.

As noted above, we plan to pursue the 505(b)(2) approval pathway, which is an option for modifications to drug products previously approved by the FDA. Section 505(b)(2) permits the filing of an NDA where at least some of the information demonstrating safety or effectiveness comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. This can include allowing the applicant to rely indirectly upon the FDA's findings with regard to the adequacy of certain preclinical or clinical data in demonstrating the safety or effectiveness of an approved product to which the proposed product is similar. Such an application may be appropriate if an applicant is seeking approval of a product that contains the same active ingredient as an already-approved product, but in a different strength or dosage form, or for a different indication. The FDA typically requires a 505(b)(2) NDA applicant to perform additional testing, which can be extensive and include clinical trials, to support the change from the approved product.

Regardless of the path taken, the U.S. drug testing and approval process requires substantial time, effort and financial resources, and the receipt and timing of any approval are uncertain and may vary substantially based upon the type, complexity and novelty of the product or disease. The FDA, the IRB, or the sponsor may suspend clinical trials or impose other conditions at any time on various grounds, including that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with regulatory or IRB requirements.

Preclinical Studies. Preclinical studies include laboratory evaluations of the chemistry, formulation and toxicity, as well as animal studies to assess the potential safety and efficacy of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLP. The results of the preclinical studies, together with manufacturing information, analytical data and a proposed clinical trial protocol, are submitted to the FDA as part of the IND, which must become effective before clinical trials may be commenced. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. The IND will become effective automatically 30 days after receipt by the FDA, unless prior to that time the FDA raises concerns or questions about the conduct of the proposed clinical trials as outlined in the IND. In that case, the FDA may place the clinical trial on a clinical hold, and the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. A separate submission to an existing IND application must also be made for each successive clinical trial conducted during product development.

Clinical Trials. Clinical trials involve the administration of an 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 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. Each clinical trial must be reviewed and approved by an IRB covering each site proposing to conduct the clinical trial before the trial may commence. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution. The IRB must also monitor the trial until completed.

Clinical trials are typically conducted in three sequential phases prior to approval, but the phases may overlap. These phases generally include the following:

- *Phase 1.* Phase 1 clinical trials represent the initial introduction of a product candidate into human subjects, frequently healthy volunteers. In Phase 1, the product candidate is usually tested for safety, including adverse effects and dosage tolerance, and/or absorption, distribution, metabolism, excretion and pharmacodynamics. If possible, Phase 1 clinical trials may also test for early evidence of effectiveness.
- *Phase 2.* Phase 2 clinical trials usually involve studies in a limited patient population to (1) evaluate the efficacy of the product candidate for specific indications, (2) determine dosage tolerance and optimal dosage and (3) identify possible adverse effects and safety risks.
- *Phase 3.* If a product candidate is found to be potentially effective and to have an acceptable safety profile in Phase 2 clinical trials, the clinical trial program will progress to Phase 3 clinical trials, in which the product candidate will be administered to an expanded patient population with the target condition, 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. In most cases, the

FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances, including where the study is a large multicenter trial demonstrating internal consistency and a statistically persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome, and confirmation of the result in a second trial would be practically or ethically impossible.

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.

In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and effectiveness after NDA approval. Such post-approval trials are typically referred to as Phase 4 clinical trials.

Marketing Application. Assuming successful completion of the required clinical testing, the results of preclinical studies and clinical trials, together with detailed information on the manufacture, composition and quality of the product and the proposed labeling, are submitted to the FDA in the form of an NDA, requesting approval to market the product. The application generally must be accompanied by a significant user fee payment.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on a threshold determination that it is sufficiently complete to permit substantive review. The FDA has substantial discretion in the approval process and may refuse to accept any application or decide that the data is insufficient for approval and require additional preclinical, clinical or other studies. If the FDA requests additional information rather than accept an NDA for filing, the NDA must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is again subject to filing review before the FDA accepts it for filing.

Also, under the Pediatric Research Equity Act of 2003, an NDA or supplement to an NDA must generally contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers from the pediatric data requirements. Based on early indications from the FDA, we do not anticipate that the FDA would grant a full waiver for LIPO-202 and may have to conduct some pediatric studies, perhaps on a deferred or partial waiver basis.

Review of Application. Once the NDA has been accepted for filing, the FDA begins an in-depth substantive review and sets a Prescription Drug User Fee Act date that informs the applicant of the specific date by which the FDA intends to complete its review. The FDA has agreed to certain performance goals in the review of NDAs through a two-tiered classification system, Standard Review and Priority Review. Priority Review designation is given to drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. The FDA endeavors to review applications subject to Standard Review within ten months of the application's receipt (except where the application includes a new molecular entity, i.e., an active moiety not previously approved, in which case the review goal is ten months from the 60 day filing date). The FDA's goal is to review Priority Review applications within six months of receipt (except where the application includes a new molecular entity, in which case the review goal is six months from the 60 day filing date). The review process is often extended by FDA requests for additional information or clarification. The FDA reviews NDAs to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA may inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facility complies with cGMP. The FDA may also inspect one or more clinical trial sites to assure compliance with cGCP requirements.

During the approval process, the FDA also will determine whether a risk evaluation and mitigation strategy, or REMS, is necessary to assure the safe use of the product. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other elements to assure safe use, such as special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. In addition, the REMS must include a timetable to periodically assess the strategy. If the FDA concludes that a REMS is needed, the sponsor of the application must submit a proposed REMS; the FDA will not approve the application without an approved REMS, if required. A REMS can substantially increase the costs of obtaining approval, and can materially affect the potential market and profitability of a drug. The FDA may also refer the application to an advisory committee of external experts to provide input on certain review issues relating to risk, benefit and interpretation of clinical trial data.

After the FDA evaluates the NDA and the manufacturing facilities, the agency issues either an approval letter or, if the review cycle is complete and the application is not ready for approval, a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. Even if the sponsor submits this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval. If, or when, the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Post-Approval Requirements. Once an NDA is approved, the product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to manufacturing, drug listing and establishment registration, recordkeeping, periodic reporting, product sampling and distribution, advertising, marketing 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, as well as some manufacturing and supplier changes are subject to prior FDA review and approval of a new NDA or an NDA supplement. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the similar procedures in reviewing NDA supplements as it does in reviewing NDAs. The manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees, as well as new application fees for certain supplemental applications.

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 or effectiveness, 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.

In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to conform to cGMP after approval. 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 and announced inspections by the FDA and these state agencies for compliance with cGMP and other requirements. 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 time, money, and effort in the area of production and quality control to maintain cGMP compliance. Further, the Drug Supply Chain Security Act of 2013 imposes new obligations that require prescription drugs distributed in the United States to be traced throughout the supply chain. A number of states also require the licensing of pharmaceutical manufacturers and wholesalers, and as a result pharmaceutical companies are subject to additional oversight at the state level.

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 study or clinical trial requirements 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 applications or supplements to approved applications, 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.

Advertising and Promotion. 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. 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. The FDA considers off-label promotion to "misbrand" a drug. Pharmaceutical companies have paid millions and even billions of dollars to resolve government allegations of off-label promotion, including allegations that such off-label promotion led to violations of the False Claims Act.

The Hatch-Waxman Amendments. As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on the FDA's previous findings of safety and effectiveness is scientifically appropriate, including by providing data or information that "bridge" the differences between the proposed product and the already-approved product, it may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the branded reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant. We are pursuing a Section 505(b)(2) NDA regulatory strategy, which we expect will allow us to rely on our NDA filing on certain nonclinical and clinical safety findings made by the FDA in its approval of salmeterol xinafoate, which is an active ingredient of FDA-approved products such as SEREVENT DISKUS®, ADVAIR HFA® and ADVAIR DISKUS®.

By pursuing the Section 505(b)(2) regulatory pathway for LIPO-202, our reliance on the FDA's prior findings of safety from salmeterol xinafoate may require any approved labeling for LIPO-202 to include, in addition to safety information from our clinical trials, certain safety information that is included in the label for approved salmeterol xinafoate products, including warnings and other safety information. Similarly, using the 505(b)(2) pathway may require us to include certifications with our NDA submission for any patents that are listed with the reference drug product in the Orange Book.

Orange Book Listing. In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, an applicant is required to list with the FDA patents that claim the drug substance, drug product, or the proposed method of using the drug. Upon approval of an NDA, each of the patents listed in the application is published in the Orange Book. Any applicant who files a 505(b)(2) NDA or ANDA referencing a drug listed in the Orange Book must certify to the FDA that: (1) no patent information on the reference drug product has been submitted to the FDA, referred to as a Paragraph I Certification; (2) such patent has expired, referred to as a Paragraph II Certification; (3) the date on which such patent expires, referred to as a Paragraph III Certification; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted, referred to as a Paragraph IV Certification. With regard to a method of use patent, the applicant may submit a "section viii" statement stating that the proposed product's label does not contain, or carves out, any language regarding the method of use claimed in the patent. By submitting a Paragraph III Certification, an applicant is stating that it is not seeking approval before expiration of the patent. An applicant submitting a Paragraph IV Certification must provide notice to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the 505(b)(2) application or ANDA refers. If within 45 days of receiving the Paragraph IV Certification notice, the reference NDA holder or patent owner responds by filing a lawsuit asserting patent infringement, the FDA is prohibited from approving the application until the earlier of thirty months from the receipt of the Paragraph IV Certification, expiration of the patent, a judgment in the lawsuit that the patent is invalid or not infringed, or a settlement of the lawsuit that includes a finding that the patent was invalid or not infringed.

Non-Patent Exclusivity and Approval of Competing Products. A 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the reference drug, described below, has expired. Regulatory exclusivity provisions under the FDCA can delay the submission or the approval of certain applications for competing products. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon approval of an NDA for a new chemical entity, or NCE, which is a drug that contains an active moiety that has not previously been approved by the FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any ANDA or 505(b)(2) NDA for the same active moiety, except that the FDA may accept an ANDA or 505(b)(2) application for filing after four years if the application contains a Paragraph IV Certification. In instances of a four year filing, if the reference product sponsor timely sues on the patent, approval of the proposed product cannot occur until expiration of seven and a half years from the approval date of the reference product, unless the patent expires, there is a judgment in the lawsuit that the patent is invalid or not infringed, or a settlement of the lawsuit that includes a finding that the patent was invalid or not infringed.

A drug that is not an NCE, including one approved via a 505(b)(2) NDA, may obtain a three-year period of exclusivity for a particular condition of approval (often a change from a marketed product, such as a new formulation, dosage form, or indication), if one or more new clinical trials, other than bioavailability or bioequivalence studies, was essential to the approval of the application and was conducted or sponsored by the applicant. During this three-year period of exclusivity, the FDA may not approve an ANDA or 505(b)(2) application for a product with the same condition of approval, but the agency is not precluded from accepting the application and reviewing it.

Orphan Drug Designation and Exclusivity. 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 affects 200,000 or more individuals in the United States and for which there is no reasonable expectation that sales of a product to treat the disease or condition will allow recovery of the cost of developing the drug and making it available in the United States. A request for orphan designation must be submitted before the NDA for the product is submitted. If a sponsor demonstrates that a drug is intended to treat a rare disease or condition and has a medically plausible basis for expecting the drug to be effective in the prevention, diagnosis, or treatment of that disease or condition, the FDA will grant orphan designation for that product for the orphan indication. After granting orphan drug designation, the FDA publicly discloses the identity of the therapeutic agent and its potential orphan use. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process, but the product is eligible for research grants and tax credits and, if approved, orphan drug exclusivity. If a product that has orphan drug designation subsequently receives the first FDA approval of the active moiety for the orphan designated disease or condition, the product is entitled to seven years of orphan drug exclusivity, which generally prohibits the FDA from approving another product with the same active moiety for the same indication. Orphan exclusivity will not bar approval of another product with the same moiety for the same use if the subsequent product is clinically superior to the approved product, as demonstrated by better effectiveness or safety, or by making a major contribution to patient care. Orphan exclusivity also does not bar approval of a different drug for the same orphan indication, or approval of the same drug for a different indication, nor does it prevent approval of the same drug for the same use if the manufacturer of the approved product cannot meet market demand. As a result, even if one of our product candidates receives orphan exclusivity, we may still be subject to competition. Also, if a competitor obtains orphan exclusivity for a product that has the same active moiety and is approved for the same orphan designated use as one of our product candidates before we do, our product could be blocked from approval.

Foreign Regulation. In order to market any product outside of the United States, we will need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding development, approval, commercial sales and distribution of our products, and governing, among other things, clinical trials, marketing authorization, and if approved, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies 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.

Federal and State Fraud and Abuse, Data Privacy and Security and Physician Payment Transparency Laws. In addition to FDA restrictions on marketing and promotion of drugs and devices, other federal and state laws and regulations could restrict our business practices. These laws and regulations include, without limitation, anti-kickback and false claims laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers. These laws typically relate to a service or item that is paid for in whole or in part by a government healthcare program or private third-party payor. Although we anticipate it would be extremely rare, if ever, that third-party payors would pay in whole or in part for our product candidates currently in development or related procedures, the government is known to look broadly for any connection to government dollars when enforcing healthcare fraud and abuse laws. Further, many states have adopted similar state laws and regulations, some of which broadly apply to healthcare items and services regardless of whether the payor is a government entity, commercial payor, or the individual patient. In addition, patient privacy and security laws have been imposed at the federal and state level.

The federal Anti-Kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations of the federal Anti-Kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Further, 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 federal civil False Claims Act.

The federal civil False Claims Act imposes civil penalties, and provides for whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The civil False Claims Act also applies to false submissions that cause the government to be paid less than the amount to which it is entitled, such as a rebate. Intent to deceive is not required to establish liability under the civil False Claims Act. Under the civil False Claims Act, no specific intent to defraud is required. The civil False Claims Act defines "knowing" to include not only actual knowledge but also instances in which the person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information. Several pharmaceutical, device and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-covered, uses (i.e., "off-label promotion).

The government may further prosecute conduct constituting a false claim under the federal criminal Health Care False Statements Statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact, making any materially false, fictitious, or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Unlike the civil False Claims Act, this law requires proof of intent to submit a false claim.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback statute a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The Civil Monetary Penalties Law authorizes, among other things, the imposition of substantial monetary penalties and exclusion from participation in federal healthcare programs against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offers any "remuneration" to beneficiaries of government healthcare programs where the person making the payment knows or should know that it is likely to influence the beneficiaries' selection of items or services reimbursable by government healthcare programs.

The federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires applicable pharmaceutical manufacturers of covered drugs (prescription drugs for which government healthcare program payment is available either separately or as part of a bundled payment) to track payments and other transfers of value made by them to physicians and teaching hospitals, maintain a payments database, and publicly report the payment data. Applicable pharmaceutical manufacturers are also required to track and report physician investment and ownership interests that are within the scope of the law. Pharmaceutical manufacturers with products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program were required to begin such tracking on August 1, 2013, and were required to make their first report containing aggregate data to the Centers for Medicare & Medicaid Services, or CMS, by March 31, 2014 and the second report containing detailed payment and transfers of value data and submit legal attestation to the completeness and accuracy of such data by June 30, 2014. Thereafter, covered manufacturers must submit reports by the 90th day of each subsequent calendar year. CMS will post manufacturer disclosures on a searchable public website on or before September 30, 2014. Failure to comply with the reporting obligations may result in civil monetary penalties of up to an aggregate of $150,000 per year, and up to an aggregate of $1 million per year for "knowing failures."

Similar state laws and regulations, such as state anti-kickback and false claims laws, and state laws governing professional licensing and licensee conduct, may apply to sales, marketing, or referral arrangements and claims involving healthcare items or services. Such state laws vary in scope; some are limited to state funded healthcare such as Medicaid, while others broadly apply to providers of healthcare items and services regardless of whether the payor is a government entity, commercial payor, or the individual patient. Several state laws require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual healthcare providers in those states, prohibit certain marketing related activities including the provision of gifts, meals or other items to certain healthcare providers and/or require pharmaceutical companies to implement compliance programs or marketing codes.

Under HIPAA and its implementing regulations, the Department of Health and Human Services has issued regulations to protect the privacy and security of patients' protected health information used or disclosed by "covered entities," with certain requirements for "business associates" of covered entities. In the context of clinical trials, healthcare providers and facilities that serve as investigators and study sites are frequently HIPAA covered entities and must adhere to applicable requirements. Although we do not generally anticipate that we will be directly subject to HIPAA it is possible that some of our activities may trigger HIPAA compliance concerns. In addition, state privacy laws may be more broadly applicable to a variety of entities.

The shifting commercial compliance environment and the need to build and maintain robust systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including certain sales and marketing practices and the provision of certain items and services to our customers in the future, could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal and civil and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products, if approved, are sold in a foreign country, we may be subject to similar foreign laws, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Payment for Aesthetic Products. In general, in the U.S. health system, much of the financial success of a product typically relies on the government or commercial payors paying for a patient's use of a product. Typically coverage of a product will depend on whether it is deemed medically necessary by government and commercial payors. Given the cosmetic nature and intent of LIPO-202, we do not anticipate that any government or commercial payors will cover and reimburse for this product or procedures using this product. Accordingly, a patient would have to pay for the cost of LIPO-202 out-of-pocket, making our expected reimbursement for our products and procedures using our products different from that of many pharmaceutical companies offering non-aesthetic products in the United States. Nevertheless, given our planned operation in the aesthetic market and the reimbursement framework for other aesthetic products currently on the market, we do not expect that the inability to receive reimbursement from a government or other third party payor for the use of the product will significantly impact a patient's decision to use or a physician's decision to prescribe or recommend our products.

Healthcare Reform. The recent implementation of the Affordable Care Act is an example that has the potential to substantially change healthcare financing and delivery by both governmental and private insurers, and significantly impact the pharmaceutical and medical device industries.

The Affordable Care Act is designed to expand access to affordable health insurance, control healthcare spending, and improve healthcare quality. The law includes provisions to tie Medicare provider reimbursement to healthcare quality and incentives, require the implementation of healthcare compliance programs, enhance physician payment transparency disclosure requirements, increase funding and initiatives to address fraud and abuse, and include incentives to state Medicaid programs to expand their coverage and services. It also imposes an annual tax on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to certain federal healthcare programs.

We expect that additional state and federal healthcare reform measures as well as cost containment initiatives by third-party payors will be adopted in the future, any of which could limit the amounts that governmental and other third-party payors will pay for healthcare products and services, which could result in reduced demand for certain products or additional pricing pressure. Although as noted above, we anticipate that our lead product candidate, if approved, will be paid for out-of-pocket by the patient, it is nevertheless possible that federal or state healthcare reform could impact our business, particularly if we resume development of LIPO-102.

Sales and Marketing

We have retained all commercial rights to LIPO-202 in all areas of the world except Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan. Our plan is to create a focused commercial capability in the United States to market and sell LIPO-202 and to consider strategic partners in other areas of the world to complete development and commercialization of the product candidate. Specifically, we plan to build a focused, specialized sales force targeting plastic surgeons and cosmetic dermatologists operating in the aesthetics market.

Manufacturing

We contract with third parties for the manufacture of LIPO-202 and LIPO-102 and intend to do so in the future. We do not own or operate and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, and which govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. Our systems and our contractors are required to be in compliance with these regulations, and this is assessed regularly through monitoring of performance and a formal audit program.

Competition

The aesthetic market, and in particular the market for fat reduction and body contouring, is highly competitive and is rapidly evolving due to new technology introductions. The FDA has recently approved several modalities for the reduction of fat, most of which are energy-based medical devices. In April 2015, the FDA approved Kybella as the first and only injectable submental fat contouring drug. Kybella is an injectable deoxycholic acid owned by Allergan in the United States. We anticipate that LIPO-202, if approved, will also face significant competition from surgical alternatives and other medical device technologies designed for the reduction of fat.

Surgical Fat Reduction. Liposuction remains the primary treatment option for subcutaneous fat reduction. We expect that LIPO-202 may compete indirectly with limited-volume liposuction for physician preference and resources.

Non-Surgical Technologies for Fat Reduction. The FDA has approved several medical devices for fat reduction as well as one injectable drug, Kybella, specifically for submental fat contouring. For example, ZELTIQ Aesthetics, Inc. received clearance for their body contouring system, CoolSculpting®, which utilizes controlled cooling to reduce the temperature of fat cells in the treated area for the selective reduction of fat around the abdomen and flanks. SculpSure® is the first FDA-cleared laser treatment for on-invasive lipolysis of the flanks and abdomen, using controlled light-based technology. Zerona, a laser energy-based product marketed by Erchonia Corporation, and Liposonix, an ultrasound energy-based product marketed by Valeant Pharmaceuticals International, Inc., have also received FDA marketing clearance. TruSculpt, a radiofrequency energy-based product introduced by Cutera, Inc., is used to heat fat to kill fat cells. However, unlike the devices provided by Erchonia, Valeant or ZELTIQ, the Cutera device is not cleared by the FDA for fat reduction; rather, it has a clearance for topical heating and for temporary reduction in the appearance of cellulite. In addition, we may in the future face competition from new and emerging technologies.

Aesthetic Therapeutics Market Competition. Injectable botulinum toxins and dermal fillers dominate the injectable aesthetic therapeutics market, specifically for facial rejuvenation. . In April 2015, the FDA approved Kybella as the first and only injectable submental fat contouring drug. While we believe LIPO-202 will be a complementary procedure to these existing injectables, for some patients we may compete for a share of their discretionary budget and share of mind within the physician's office for improving body aesthetics.

We expect to also generally compete against medical technology and aesthetic companies, including those offering products and technologies unrelated to fat reduction, for physician resources and mind share. Many of our potential competitors are large, experienced companies that have substantially greater resources and brand recognition than we do. For a description of the risks we face related to competition, please see "Risk Factors — Risks Related to Our Business — *LIPO-202, if approved, will face significant competition, and the failure by us to compete effectively may prevent us from achieving significant market acceptance*."

Intellectual Property

Our success depends in large part on our ability to obtain and maintain patent and other proprietary protection for our product candidates, novel biological and chemical discoveries, and drug development technology and other know-how, to operate without infringing on the proprietary or intellectual property rights of others and to prevent others from infringing our proprietary and intellectual property rights. We seek to protect and enhance our proprietary position by, among other methods, filing U.S. and foreign patent applications related to any patentable aspects of our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on know-how, copyright, trademarks and trade secrets and continuing technological innovation, and we continue to evaluate potential in-licensing opportunities, in order to develop and maintain our proprietary position.

The patent positions of pharmaceutical/biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual issues. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. After issuance, if challenged, the courts can redefine the scope of the patent. Consequently, we do not know with certainty whether issued patents in each country will cover our product candidates, or if issued, whether the patent will remain in force after challenge. It is possible that our current patents, or patents which we may later acquire, may be successfully challenged or invalidated in whole or in part. We cannot predict with certainty whether the patent applications we are currently pursuing will issue as patents in a particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from potential competitors. Any of our patents could potentially be challenged, narrowed, circumvented or invalidated by third parties. It is also possible that we may not obtain issued patents from our pending patent applications or other inventions we seek to protect. Due to uncertainties inherent in prosecuting patent applications, sometimes patent applications are rejected and we subsequently abandon them. It is also possible that we may develop proprietary products or technologies in the future that are not patentable or that the patents of others will limit or altogether preclude our ability to do business. In addition, any patent issued to us may provide us with little or no competitive advantage, in which case we may abandon such patent or license it to another entity. For more information, please see "Risk Factors — Risks Related to Our Intellectual Property."

Since patent applications in the United States and certain other jurisdictions are maintained in secrecy for a minimum of eighteen months, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of our inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention, which for most of our patent applications are based on the first party to invent (patents filed after March 16, 2013 are given priority based on first to file). The date of an invention is not publically disclosed. It may be necessary for us to participate in post-grant challenge proceedings, such as patent oppositions or *inter partes* reviews that seek to invalidate the patentability of third party patents before they issue. Such proceedings could result in substantial cost, even if the eventual outcome is favorable to us.

As of December 31, 2016, we are the sole owner of a patent portfolio that includes nine issued/allowed patents and four pending patent applications in the United States, as well as granted and pending foreign counterparts of such U.S. patents and pending applications directed to LIPO-202 and/or LIPO-102. Our foreign counterparts include issued or granted patents and pending applications in Australia, Canada, various countries in Europe, Israel, Japan, South Korea, Mexico, China, Brazil, Hong Kong, Singapore, India, and Taiwan. The earliest expiration of any of our issued or granted patents is presently expected to occur in 2026. Seven of our eight issued U.S. patents, specifically U.S. Pat. Nos. 8,404,750, 8,420,625, 9,132,084, 9,198,885, 9,452,147, 9,370,498, and 9,452,132 cover both of our LIPO-202 and LIPO-102 product candidates, and will be listable in the Orange Book for each of these product candidates upon product approval.

The '625, '885, '147, and the '498 patents are directed to methods of treatment for reduction of adiposity and/or pharmaceutical formulations using a long-acting substantially selective ß2-adrenergic receptor agonist and are expected to expire no earlier than 2026.

The ’750, ’084, and the ’132 patents are directed to methods of treatment for reducing adipose tissue and pharmaceutical formulations using low doses of long-acting selective ß2-adrenergic receptor agonist active ingredient, e.g. salmeterol xinafoate, and are expected to expire no earlier than 2030. We expect that the breadth of coverage provided by our issued patents relating to our product candidates will create a significant barrier to third party competition with our LIPO-202 and LIPO-102 products, and will help to render any challenge to our patent position by a third party in relation to our core product candidates difficult. We expect to continue pursuing in the United States and foreign jurisdictions additional patent protection of our product candidates and any future pipeline products or technologies where appropriate, as well as continuing to take appropriate measures to maintain non-patent proprietary protection for our innovative technologies.

Trademarks. We have a pending U.S. trademark application for the word mark “NEOTHETICS” and for our logo. We intend to pursue additional registrations in markets outside the United States for appropriate marks where we plan to sell our product candidates. This Annual Report on Form 10-K contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other company.

Other Proprietary Rights and Processes. We also rely on trade secret protection for some of our confidential and proprietary information. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and disclose our technology. If these events happen, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business, scientific, development or financial affairs that are either developed or made known to the individual during the course of the individual’s relationship with us are to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or based on the employee’s use of our confidential information are our exclusive property or that we have an exclusive royalty-free license to use such technology.

Material Agreements

Technology Transfer Agreement. In connection with our Series C convertible preferred stock financing, in December 2012, we entered into a Technology Transfer Agreement with Domain Russia Investments Limited, or DRI, an affiliate of Domain Partners VII, L.P. and DP VII, L.P., a significant stockholder of our company**.** Concurrently with the signing of the Technology Transfer Agreement, we, together with DRI and NovaMedica, LLC, or NovaMedica, executed an Assignment and Assumption Agreement, pursuant to which all of DRI’s rights and obligations under the Technology Transfer Agreement were transferred to NovaMedica. The following description of the Technology Transfer Agreement gives effect to the transfer of DRI’s rights and obligations under the Technology Transfer Agreement to NovaMedica. The Technology Transfer Agreement obligated us to assign and license certain of our intellectual property to NovaMedica and to enter into the Clinical Development and Collaboration Agreement, Clinical Supply Agreement and the Commercial Supply Agreement with NovaMedica as further described below.

Pursuant to the Technology Transfer Agreement, in exchange for a nominal payment, we assigned to NovaMedica certain patents and patents applications in Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan, or the Covered Territory, owned by us and necessary or useful for the development and commercialization of LIPO-102, LIPO-202 and/or certain future products we may develop, or the LIPO Products. We also granted to NovaMedica an exclusive, fully paid-up, royalty-free and irrevocable license under certain of our patented and non-patented intellectual property to develop and commercialize LIPO Products, solely in the Covered Territory. The license is not sublicensable or assignable, other than to an affiliate of NovaMedica or a successor to substantially all of the business of NovaMedica to which the Technology Transfer Agreement relates. We further agreed not to directly or indirectly develop, manufacture, sell or commercialize any product that (A) contains salmeterol xinafoate (alone or in combination) or (B) is designed or intended for use in the field of localized reduction of fat in the human body, including without limitation body contouring, or the Field, and is approved in the Covered Territory for the same indication for which a LIPO Product is approved during the term of the Technology Transfer Agreement.

To assist in NovaMedica's development, commercialization, and manufacturing of LIPO Products, we agreed to transfer our know-how which is necessary or useful for development or commercialization of LIPO Products in the Covered Territory. Further, we agreed to provide certain development and manufacturing support to NovaMedica, including making our manufacturing personnel and other personnel knowledgeable of LIPO Products available to provide scientific and technical explanations, advice and on-site support that may be reasonably requested by NovaMedica and, upon request, to use commercially reasonable efforts to assist NovaMedica to establish a manufacturing relationship with our clinical manufacturing organizations. In addition, prior to the first commercial sale of a LIPO Product in the Covered Territory, we have agreed to sell to NovaMedica supplies of the applicable LIPO Product and related compounds solely for the purpose of conducting clinical trials of such LIPO Product and related compounds in the Covered Territory at our cost plus a mark-up in the low double digits, so long as any sale does not reasonably interfere with our own development and commercialization activities. Furthermore, within 120 days of NovaMedica's request, we are obligated to negotiate in good faith and enter into a Commercial Supply Agreement with NovaMedica for the supply of the LIPO Product required for commercialization of an approved LIPO Product in the Covered Territory, on commercially fair and reasonable terms at our cost plus a mark-up in the low double digits.

Under the Technology Transfer Agreement, NovaMedica will be responsible for filing and maintaining regulatory approvals for the LIPO Products in the Covered Territory and has the right to use the data from our regulatory filings to support its regulatory filings for LIPO Products. NovaMedica also has the sole right to import LIPO Products into the Covered Territory for purposes of development and commercialization of LIPO Products and the right to import and export LIPO Products outside the Covered Territory in connection with noncommercial research, clinical trials, or obtaining a supply of LIPO Product to exercise its other rights under the Technology Transfer Agreement.

We may terminate the Technology Transfer Agreement in the event NovaMedica (1) knowingly exports out of the Covered Territory for commercial purposes a material and substantial quantity of salmeterol xinafoate or a LIPO Product or (2) challenges or contests the validity or enforceability of any of our patents assigned or licensed to NovaMedica, and fails to cure such breach during the applicable cure period. NovaMedica has the right to terminate the Technology Transfer Agreement at any time at its convenience upon 90 days prior written notice. Upon termination by NovaMedica, the licenses granted to NovaMedica would also terminate, but the assigned patents and patent applications would not return to our control.

In connection with the signing of the Technology Transfer Agreement, we also concurrently entered into a letter agreement with NovaMedica pursuant to which we are obligated to pay NovaMedica a make-whole payment up to a maximum amount of $1.2 million upon the occurrence any of the following events:

- any granted patent within the assigned patents is held to be invalid or unenforceable by a court or other governmental body in the Covered Territory;
- it is determined that we do not (or did not at the time of assignment) hold exclusive title and ownership to any assigned patent or patent application or licensed intellectual property (free and clear of all liens or encumbrances); or
- the licenses or other rights granted by us to NovaMedica pursuant to the Technology Transfer Agreement terminate prior to the expiration date of the Technology Transfer Agreement (other than as contemplated by the Technology Transfer Agreement), and as a result, NovaMedica is required under Russian law to make a compensatory contribution to NovaMedica.

Clinical Development and Collaboration Agreement. As required by the Technology Transfer Agreement, we entered into a Clinical Development and Collaboration Agreement, or Collaboration Agreement, with NovaMedica in July 2013 to further specify the terms on which NovaMedica develops LIPO Products. Under the terms of the Collaboration Agreement, a joint committee consisting of equal numbers of our representatives and NovaMedica representatives will prepare an initial development plan to obtain regulatory approval for LIPO Products. Pursuant to the Technology Transfer Agreement, we have also agreed to enter into a pharmacovigilance agreement within 180 days of the first regulatory approval of a LIPO Product in the Covered Territory. NovaMedica may sell LIPO Products approved for sale in the Covered Territory under either NovaMedica's trademarks or our trademarks, in its sole discretion.

The Collaboration Agreement expires on the earlier of (1) the termination of the Technology Transfer Agreement or (2) ten years following the first commercial sale of a LIPO Product in the Covered Territory, provided that if the first commercial sale of a LIPO Product in the Covered Territory has not occurred within three years of the approval of the first LIPO Product by the FDA, then the Collaboration Agreement will terminate on the thirteenth anniversary of such FDA approval. NovaMedica may terminate the Technology Transfer Agreement for convenience upon 90 days prior written notice.

Clinical Supply Agreement. As required by the Technology Transfer Agreement, we entered into a Clinical Supply Agreement with NovaMedica in July 2013 to further specify the terms on which we supply LIPO-202 to NovaMedica. In addition to the supply terms set forth above, under the Clinical Supply Agreement, we are not required to supply any LIPO-202 until we have retained a clinical manufacturing organization to manufacture such product. We are only required to supply LIPO-202 up to a specified maximum amount of 1,000 doses. The Clinical Supply Agreement has an initial term of four years, which can be extended by mutual agreement between us and NovaMedica. NovaMedica may terminate the agreement for convenience upon 90 days' notice.

Facilities

Our corporate headquarters are located in San Diego, California, where we lease approximately 14,687 square feet of office space. We occupy approximately 3,580 square feet of this space and sublease approximately 11,107 square feet of this space. On January 20, 2015, we entered into an operating lease through March 2020. We have a renewal option for an additional five years. We believe that our existing facilities are adequate for our current needs.

Legal Proceedings

We are subject from time to time to various claims and legal actions during the ordinary course of our business. We believe that there are currently no claims or legal actions that would reasonably be expected to have a material adverse effect on our results of operations or financial condition.

General Information

We were originally incorporated in Delaware in February 2007 as Lipothera, Inc. In September 2008, we changed our name to Lithera, Inc. and in August 2014, we changed our name to Neothetics, Inc. Our principal corporate offices are located at 9171 Towne Centre Drive, Suite 270, San Diego, CA 92122 and our telephone number is (858) 750-1008. Our website is located at www.neothetics.com. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, will be made available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The contents of our website are not incorporated into this Annual Report and our reference to the URL for our website is intended to be an inactive textual reference only. The information contained on, or that can be accessed through, our website is not a part of this document.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of our initial public offering, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.0 billion, (3) the day 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 measured as of each June 30th, and (4) 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 Startup 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.

Unless the context requires otherwise, references in this Annual Report on Form 10-K to "NEOT," "we," "us" and "our" refer to Neothetics, Inc.

Item 1A. Risk Factors.

Except for the historical information contained herein or incorporated by reference, this Annual Report and the information incorporated by reference contains forward-looking statements that involve risks and uncertainties. These statements include projections about our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. These statements are not guarantees of future performance or events. Our actual results may differ materially from those discussed here. Factors that could cause or contribute to differences in our actual results include those discussed in the following section, as well as those discussed in Part II, Item 7 entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this Annual Report and in any other documents incorporated by reference into this Annual Report. You should consider carefully the following risk factors, together with all of the other information included or incorporated in this Annual Report. Each of these risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock. There may be additional risks that we do not presently know of or that we currently believe are immaterial which could also impair our business and financial position.

Risks Related to Our Business

Our lead product candidate, LIPO-202, failed to meet its co-primary composite and secondary endpoints from our AbCONTOUR1 and AbCONTOUR2 U.S.-based pivotal Phase 3 trials.

On December 14, 2015, we announced that top-line results from our AbCONTOUR1 and AbCONTOUR2 U.S.-based pivotal Phase 3 trials to evaluate the safety and efficacy of our lead product candidate, LIPO-202, for the reduction of central abdominal bulging due to subcutaneous fat, showed that in both studies that LIPO-202 did not meet its co-primary composite and secondary endpoints resulting in a significant set-back to our company. We, and expert consultants that we engaged, conducted a detailed review of these unexpected trial results. Based on the results of the review by us and our expert consultants, we concluded that modifications intended to make LIPO-202 commercially ready may have affected the drug product. We have completed manufacturing of a modified formulation of LIPO-202, which is primarily based on the drug product formulation used in the Phase 2 RESET trial. We are continuing our LIPO-202 development program focused on localized fat reduction and body contouring using this modified formulation of LIPO-202. In November 2016 we announced plans to prioritize our efforts and resources on the Phase 2 proof of concept trial for the reduction of localized fat deposits under the chin, or submental fat. We initiated this trial in December 2016 and expect top-line results in June of 2017. We also plan to continue development of LIPO-202 for the reduction of central abdominal bulging, pending results from the submental Phase 2 proof of concept trial and capital resources. If the Phase 2 proof of concept trial for the reduction of submental fat and any future Phase 2 and Phase 3 trials are successful, we would then expect to file a new drug application, or NDA, utilizing the 505(b)(2) regulatory pathway. We have experienced a significant delay in any future development and commercialization of LIPO-202 and while we anticipate having enough cash on hand to finance our planned Phase 2 proof of concept trial, we will require substantial funding to further develop and commercialize LIPO-202 in the event that we obtain positive results from this trial.

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, substantially all of our resources have been dedicated to the preclinical and clinical development of our lead product candidate, LIPO-202. As of December 31, 2016, we had working capital of $11.6 million and capital resources consisting of cash and cash equivalents of $11.5 million. We suffered a significant set-back based on the negative results from our Phase 3 trials and, therefore, we expect to need substantial additional funding to pursue the further clinical development of LIPO-202. Based on the results of any further clinical trials, we expect to continue to expend additional and substantial resources on the completion of clinical development and regulatory preparedness of LIPO-202, preparing and filing any NDA filing, preparations for the commercial launch of LIPO-202, if approved, and development of any other current or future product candidates we may choose to pursue. These expenditures will include costs associated with research and development, conducting additional preclinical studies and clinical trials, obtaining regulatory approvals, 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 drug development process is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of LIPO-202 or any other current or future product candidates.

We believe that our existing cash and cash equivalents will be sufficient to fund our operations into the second quarter 2018, including our on-going Phase 2 proof of concept trial for the reduction of submental fat. Should we receive positive results from this trial, we anticipate having to raise additional funds to support further development of LIPO-202, including completion of any future clinical trials related to the reduction of submental fat and any other trials we may want to conduct related to the reduction of central abdominal bulging. However, our operating plan may change as a result of factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, or other restrictions that may adversely 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:

- results from our new Phase 2 proof of concept trial and any future Phase 2 and Phase 3 trials;
- the scope, progress, results and costs of researching and developing LIPO-202 or any of our other current and future product candidates, and conducting preclinical and clinical trials;
- the cost of commercialization activities if LIPO-202 or any of our other current and future product candidates are approved for sale, including marketing, sales and distribution costs and preparedness of our corporate infrastructure;
- the cost of manufacturing LIPO-202 or any of our other current and future product candidates that we obtain approval for and successfully commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- whether NovaMedica continues to pursue or terminate our technology transfer agreement with NovaMedica for the development and commercialization of LIPO-202 in certain jurisdictions outside of the United States;
- the number and characteristics of any additional product candidates we may develop or acquire;
- any product liability or other lawsuits related to our products or commenced against us;
- the expenses needed to attract and retain a CEO and other 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, any future approved products, if any. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to:
- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for LIPO-202 or any of our other current or future product candidates;
- delay, limit, reduce or terminate our research and development activities;
- delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize LIPO-202 or any of our other current or future product candidates; or
- identify and evaluate a potential strategic transaction, such as a merger or sale of the company.

If we are unable to secure additional capital when needed, we may be required to reduce activities and personnel, sell assets such as our intellectual property, and/or declare bankruptcy, and we may not be able to remain in business.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We will need to seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidate, or grant licenses on terms unfavorable to us.

Our ability to use our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be subject to certain limitations.

As of December 31, 2016, we had U.S. federal and California net operating loss carryforwards, or NOLs, of approximately $119.4 million and state NOLs of approximately $64.0 million, which expire in various years beginning in 2017 if not utilized. Under Sections 382 and 383 of Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOLs and other pre-change tax attributes, such as research tax credits, to offset its future post-change income and taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We believe we have experienced certain ownership changes in the past and have reduced our deferred tax assets related to NOLs accordingly. In the event that it is determined that we have in the past experienced additional ownership changes, or if we experience one or more ownership changes as a result of future transactions in our stock, then we may be further limited in our ability to use our NOLs and other tax assets to reduce taxes owed on the net taxable income that we earn in the event that we attain profitability. Any such limitations on the ability to use our NOLs and other tax assets could adversely impact our business, financial condition and operating results in the event that we attain profitability.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

At December 31, 2016, we had approximately $11.5 million of cash and cash equivalents. While we are not aware of any material losses or other significant deterioration in the fair value of our cash equivalents since December 31, 2016, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

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 one lead product candidate and no commercial sales, which, together with our limited operating history, makes it difficult to assess our future viability.

We are a clinical-stage specialty pharmaceutical company with a limited operating history. Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have focused principally on developing our lead product candidate, LIPO-202, an injectable formulation of salmeterol xinafoate. We are not profitable and have incurred losses in each year since our inception in 2007. 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 specialty pharmaceutical industry. We have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. Our net loss for the years ended December 31, 2016 and December 31, 2015 was approximately $13.0 million and $43.2 million, respectively. As of December 31, 2016, we had an accumulated deficit of $125.9 million. We expect to continue to incur losses for the foreseeable future, as we continue our development of, and seek regulatory approvals for, LIPO-202, which may include funding additional clinical trials, and assuming we obtain regulatory approval, begin to commercialize LIPO-202. 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, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We are substantially dependent on the success of our lead product candidate LIPO-202.

To date, we have invested substantially all of our efforts and financial resources in the research and development and commercial planning for LIPO-202. Additionally, in December 2015, we announced that top-line results from both Phase 3 trials did not meet its co-primary composite and secondary endpoints. Our near-term prospects, including our ability to finance our company and generate revenue, as well as our future growth, will depend heavily on our ability to conduct successful Phase 2 and Phase 3 studies and obtain positive results from either one of these studies, obtaining regulatory approval and successful commercialization of LIPO-202. The clinical and commercial success of LIPO-202 will depend on a number of factors, including the following:

- conducting substantial clinical development, including initiating new clinical trials based on a modified formulation;
- there can be no assurance that further trials will produce different results and, even if any such trials were successful, that the FDA will agree that we have satisfactorily addressed these concerns or that the FDA will not raise new issues regarding the design of our clinical trials;
- our ability to demonstrate efficacy of LIPO-202 to the satisfaction of the FDA and other applicable foreign regulatory bodies, including our ability to utilize FDA-acceptable endpoint tools for measuring efficacy of LIPO-202 in our clinical trials;
- our ability to demonstrate the safety of LIPO-202 to the satisfaction of the FDA and other applicable foreign regulatory bodies;
- our ability to conduct and raise additional funds for further clinical trials to support the approval of LIPO-202;
- whether the FDA or other applicable foreign regulatory bodies ultimately grant a deferral or waiver with regard to submission of some or all pediatric data, despite the acceptance by the FDA to our initial Pediatric Study Plan, which includes a waiver of pediatric study requirements with regard to patients through age 12, and deferral of submission of data in adolescents ages 13-17 until after the approval of LIPO-202, if LIPO-202 is approved;
- whether the institutional review boards, or IRBs, approve and allow us to include adolescent patients in our clinical trials or to gather pharmacokinetic data in that population, if a need to do so arises;
- whether we are able to secure a partner or partner(s) for the development and commercialization of LIPO-202 outside of the United States and if so, whether such partners will be required to conduct additional studies for the approval of LIPO-202 in such markets in a timely manner;
- the acceptance by the FDA of our proposed parameters for regulatory approval, including our proposed indication, endpoints and endpoint measurement tools relating to LIPO-202;
- the approval by the FDA of a product label that will permit commercially desirable promotional claims for LIPO-202;
- our success in educating physicians and patients about the benefits, administration and use of LIPO-202;
- the incidence, duration and severity of adverse side effects;
- the timely receipt of necessary marketing approvals from the FDA and similar regulatory bodies around the world;
- achieving and maintaining compliance with all regulatory requirements applicable to LIPO-202;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- the effectiveness of our and our potential partners' marketing, sales and distribution strategy and operations in the United States and other markets around the world;
- the ability of our third-party manufacturers and potential partners to manufacture clinical trial and commercial supplies of LIPO-202 to remain in good standing with regulatory bodies, and to develop, validate and maintain commercially viable manufacturing processes that are compliant with Current Good Manufacturing Practice, or cGMP, regulations;
- our ability to successfully commercialize LIPO-202 in the United States, if approved, for marketing;
- our potential partners' ability to successfully commercialize LIPO-202 in other markets outside of the United States;
- our ability to enforce our intellectual property rights in and to LIPO-202;
- our ability to avoid third-party patent interference, patent infringement claims, and challenges by third parties to our intellectual property rights;
- acceptance of LIPO-202 as safe and effective by patients and the medical community; and
- a continued acceptable safety profile of LIPO-202 following approval.

Many of these factors are beyond our control. Accordingly, we cannot assure you that our clinical trials will be successful, that we can obtain regulatory approval or that we will be able to generate revenue through the sale of LIPO-202, if approved. Any one of these factors or other factors discussed in this document could affect our ability to successfully commercialize LIPO-202, which could impact our ability to earn sufficient revenues to transition from a developmental stage company and continue our business. If we are not successful in obtaining regulatory approval of and commercialization of LIPO-202, or are significantly delayed in doing so, our business will be materially harmed.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive, and can take many years to complete, and its outcome is inherently uncertain. Based on the negative results from our U.S.-based pivotal Phase 3 trials, we suffered a significant setback and will be required to conduct further trials to evaluate the safety and efficacy of LIPO-202. Furthermore, we rely on clinical research organizations, or CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. The costs of clinical trials may vary significantly over the life of a project owing to factors that include but are not limited to the following:

- per patient trial costs;
- salaries and related overhead expenses, including share-based compensation and benefits for personnel in research and development functions;
- fees paid to third-party professional consultants and service providers;
- costs to develop and manufacture preclinical study and clinical trial materials;
- costs for laboratory supplies;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the number of trials required for approval;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the phase of development of the product candidate;
- requests by regulatory agencies for pediatric data;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidate.

Failure can occur at any time during the clinical trial process. For example, we have in the past terminated early-stage development and clinical programs for other potential product candidates due to a lack of sufficient efficacy or the potential for unacceptable adverse reactions to a particular product candidate, as well as our desire to concentrate our efforts on the development of LIPO-202. The results of preclinical and clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. It is not uncommon for a number of companies in the specialty pharmaceutical industry in advanced clinical trials to suffer significant setbacks due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. On December 14, 2015, we announced that LIPO-202 failed to meet its co-primary composite and secondary endpoints of the Phase 3 clinical trial resulting in us suffering a significant setback. We are continuing our LIPO-202 development program focused on localized fat reduction and body contouring using this modified formulation of LIPO-202. In November 2016, we announced plans to prioritize our efforts and resources on the Phase 2 proof of concept trial for the reduction of localized fat deposits under the chin, or submental fat. We initiated this trial in December 2016 and expect top-line results in June of 2017. We also plan to continue development of LIPO-202 for the reduction of central abdominal bulging, pending results from the submental Phase 2 proof of concept trial. We cannot be certain that any new trials will produce results showing safety and efficacy and that additional setbacks will not occur. Even if our ongoing or future clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

We may experience delays in our future clinical trials and we do not know whether these clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed or aborted for a variety of reasons, including:

- delay or failure in obtaining regulatory approval to commence a trial;
- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- regulatory objections to commencing a clinical trial or proceeding to the next phase of investigation, including inability to reach agreement with the FDA or non-U.S. regulators regarding the scope, design or implementation of our clinical trials or for other reasons such as safety concerns identified during preclinical development or early stage clinical trials;
- inability to qualify for exemptions from infringement of intellectual property rights for clinical trial testing of products in countries where we want to conduct clinical trials outside the United States;
- inability to identify, add and maintain a sufficient number of trial sites;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- difficulty identifying and engaging qualified clinical investigators;
- failure to obtain IRB approval at each site;
- difficulty recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including failure to meet the enrollment criteria for our study and competition from other clinical trial programs;
- inability to retain patients in clinical trials due to the treatment protocol, personal issues, side effects from the therapy or lack of efficacy;
- failure to have clinical sites observe trial protocol or continue to participate in a trial;
- failure to address any patient safety concerns that arise during the course of a trial;
- failure to address any conflicts with new or existing laws or regulations;
- failure to manufacture sufficient quantities of product candidates or placebos for use in clinical trials; or
- inability to obtain sufficient funding to commence or finish a clinical trial.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with the requirements of the relevant regulatory filing (including clinical protocol and manufacturing), inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial due to unforeseen costs resulting from enrollment delays, requirements to conduct additional trials and studies, increased expenses associated with the services of our CROs and other third parties or other reasons.

If we experience delays in the completion of, or terminate, any clinical trial of our current or future product candidates, if any, the commercial prospects of these product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of a clinical trial may also ultimately lead to the denial of regulatory approval of a product candidate.

Changes in regulatory requirements and guidance may occur and we or any of our partners may be required by appropriate regulatory authorities to amend clinical trial protocols to reflect these changes. Amendments may require us or any of our partners to resubmit clinical trial protocols to independent review boards for re-examination, which may impact the costs, timing or successful completion of a clinical trial. If we or any of our partners experience delays in the completion of, or if we or our partners terminate, clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate revenue from sales of our products will be prevented or delayed. In addition, many of the factors that may cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

Clinical failure can occur at any stage of clinical development. Because the results of earlier clinical trials are not necessarily predictive of future results, any product candidate we or our current or potential future partners advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and based on the negative results from our pivotal Phase 3 trials, we have determined to proceed with additional clinical testing with a modified formulation of LIPO-202. Even if we obtain positive results from our new clinical trials, we, or our partners, may decide, or regulators may require us to conduct additional clinical or preclinical testing. In addition, data obtained from tests are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Frequently, product candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials, as evidenced by the failure of LIPO-202 to meet its co-primary composite and secondary endpoints in the AbCONTOUR1 and AbCONTOUR2 U.S.-based pivotal Phase 3 trials. In addition, the design of a clinical trial can determine whether its results will support approval of a product, or approval of a product for desired indications, and flaws or shortcomings in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval for our desired indications, and we have never previously submitted an NDA. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. If LIPO-202 is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business would be harmed. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in Phase 2 and Phase 3 clinical trials, even after seeing promising results in earlier clinical trials.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including differences in trial protocols and design, the size and type of the patient populations, adherence to the dosing regimen and the rate of dropout among clinical trial participants. We do not know whether any Phase 2, Phase 3 or other clinical trials we or any partners may conduct will demonstrate consistent and/or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

We cannot be certain that LIPO-202 or any of our other current and future product candidates will receive regulatory approval, and even with regulatory approval they may never achieve market acceptance or commercial success.

We are not permitted to market LIPO-202 or any of our other current and future product candidates in the United States until we receive approval of an NDA from the FDA. Similar regulatory approvals are required in other countries. To gain approval to market a drug product like LIPO-202, we must provide the FDA and any applicable foreign regulatory authorities with, among other things, data from well controlled clinical trials that adequately demonstrate the safety and efficacy of the product candidate for the intended indication applied for in the NDA or other respective regulatory filing, as well as information demonstrating manufacturing that meets regulatory requirements. We have not submitted an application or obtained marketing approval for LIPO-202 anywhere in the world. Obtaining regulatory approval of an NDA can be a lengthy, expensive and uncertain process. In addition, the regulatory process is ongoing, and we will be subject to continued regulatory review if LIPO-202 is approved.

We have invested a significant portion of our efforts and financial resources in the development of LIPO-202, and our ability to generate significant revenue related to product sales will depend on the successful development and regulatory approval of LIPO-202. LIPO-202 did not meet its co-primary composite and secondary endpoints in our recent Phase 3 trials, which could impact future regulatory approval. Even if we conduct additional trials which prove the efficacy of LIPO-202, we may not be able to obtain regulatory approval for LIPO-202.

Even if we obtain FDA or other foreign regulatory approvals, LIPO-202 or any of our other current and future product candidates may not achieve market acceptance among physicians and patients, and may not be commercially successful. Market acceptance of LIPO-202 or any of our other current and future product candidates for which we receive regulatory approval depends on a number of factors, including:

- the safety and efficacy of LIPO-202 or any of our other current and future product candidates as demonstrated in clinical trials;
- acceptance by physicians and patients of LIPO-202 or any of our other current and future product candidates as safe and effective treatments;
- the clinical indications for which LIPO-202 or any of our other current and future product candidates are approved and whether our desired labeling is approved;
- proper training and administration of LIPO-202 or any of our other current and future product candidates by physicians;
- the potential and perceived advantages of LIPO-202 or any of our other current and future product candidates over alternative treatments;

- acceptance by physicians and patients that the duration of effect of LIPO-202 or any of our other current and future product candidates are significant and have advantages over alternative treatments;
- the cost of treatment in relation to alternative treatments and willingness to pay for LIPO-202 or any of our other current and future product candidates, if approved, on the part of physicians and patients;
- the willingness of patients to pay for LIPO-202 or any of our other current and future product candidates and other aesthetic treatments in general, relative to other discretionary items, especially during economically challenging times;
- relative convenience and ease of administration and the ability of patients to commit to an eight-week treatment period;
- the incidence, duration and severity of adverse side effects;
- the effectiveness of our sales and marketing efforts; and
- the degree to which the approved labeling supports promotional initiatives for commercial success.

Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would adversely affect our results of operations.

We may be unable to successfully pursue the 505(b)(2) pathway as planned, which would materially impact our likelihood of obtaining FDA approval.

A 505(b)(2) application that relies for approval on the FDA's finding of safety and/or effectiveness for one or more listed drugs must establish that such reliance is scientifically appropriate, and must submit data necessary to support any aspects of the proposed drug product that represent modifications to the listed drug(s). We must establish a bridge between our proposed drug product and each listed drug upon which we propose to rely, to demonstrate that such reliance is scientifically justified. Determining and reaching agreement with the FDA regarding exactly what additional or "bridging" data will be needed to support the proposed modification to the listed drug can present challenges and is a fact-specific determination that must be made on a case-by-case basis.

If we are unable to establish to the FDA's satisfaction that our reliance on the listed drug is scientifically appropriate, and that we have sufficiently addressed the safety and effectiveness implications of our proposed modifications (including, importantly, the different indication), we may be unable to utilize this regulatory pathway.

We rely on third parties to conduct all our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize LIPO-202.

We do not have the ability to conduct preclinical studies or clinical trials independently. We rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as CROs, to conduct clinical trials on our product candidates. The third parties with whom we contract for execution of our clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we have limited ability to control the amount, quality or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our preclinical studies and clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA requires us to comply with regulations and standards referred to as current Good Laboratory Practice, or GLP, for conducting preclinical studies, and Good Clinical Practice, or GCP, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials.

In addition, the execution of preclinical studies and clinical trials, and the subsequent compilation and analysis of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. These third parties may terminate their agreements with us upon as little as 30 days prior written notice of a material breach by us that is not cured within 30 days. Many of these agreements may also be terminated by such third parties under certain other circumstances, including our insolvency or our failure to comply with applicable laws. In general, these agreements require such third parties to reasonably cooperate with us at our expense for an orderly winding down of services of such third parties under the agreements. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, become insolvent or undergo restructuring, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated. If any of the foregoing were to occur, we may not be able to obtain regulatory approval for or commercialize the product candidate being tested in such trials in a timely fashion, or at all.

We currently rely on the services of a few testing organizations. Failure of these vendors to perform adequately can materially and adversely affect our business.

There are a limited number of providers for testing of LIPO-202, and we do not have direct control over our testing labs. Nor do we have direct control over the processes or timing for the acquisition of the raw materials and components necessary to test our product candidate. If these raw materials and/or components are not available at the volumes and quantity levels required, it could have a material and adverse impact on the supply of drug substance and finished drug product. We work closely with our testing labs to enable timely delivery of required drug substance and drug product, but these efforts may be insufficient which may lead to delays in testing of drug product. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a drug product to complete the study, a delay in the supply of sufficient drug product could delay completion of clinical trials and the clinical program, regulatory approval, and generation of revenue.

Testing and stability services for LIPO-202 are currently provided by PPD. We have not yet entered into long-term agreements with PPD.

As a result of our Phase 3 clinical trial data, we were required to reduce our headcount in order to control expenses, which may have an adverse impact on our internal programs, our ability to hire and retain key personnel and may be distracting to management.

As of December 31, 2016, we had seven full-time employees. In January 2016, we implemented a reduction in force, which resulted in reducing our headcount to twelve full-time employees from sixteen, or an approximate reduction of 25%. Throughout 2016, we had further cost-saving measures and employee departures resulting in reduced headcount to seven full-time employees. Depending on our need for additional funding and expense control, we may be required to further implement workforce and expense reductions in the future. Further workforce and expense reductions could result in reduced progress on our internal programs. In addition, employees, whether or not directly affected by a reduction, may seek future employment with our business partners or competitors. Although our employees are required to sign a confidentiality agreement at the time of hire, the confidential nature of certain proprietary information may not be maintained in the course of any such future employment.

Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reductions in workforce and reduced employee morale which may cause our remaining employees to seek alternate employment. Competition among biotechnology companies for qualified employees is intense, and the ability to retain our key employees is critical to our ability to effectively manage our resources following the Phase 3 data and our path forward. Although we have implemented severance arrangement for certain key employees, these retention protections may not be successful in incentivizing these employees to stay employed with us. Additional attrition could have a material adverse effect on our business.

If we are able to conduct further trials which demonstrate the efficacy of LIPO-202, we may need to expand our managerial, operational, commercial, medical affairs, finance and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize LIPO-202 or any of our current and future product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future development and commercialization efforts. Our need to effectively execute our growth strategy requires that we:

- manage our clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees;
- build effective business processes to launch LIPO-202 and other products;
- manage our internal development efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

If we fail to attract and keep senior management and key scientific and commercial personnel, we may be unable to successfully develop LIPO-202 or any of our other current and future product candidates, conduct our clinical trials and commercialize LIPO-202 or any of our other current and future product candidates.

Based on the results of our Phase 3 clinical trials, we were required to implement workforce reductions, which have reduced our headcount.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific, and commercial personnel. We have not entered into any employment agreements with our key personnel other than our senior management team, nor do we maintain key man life insurance on the lives of any of the members of our senior management. Although we have an equity incentive plan pursuant to which we provide our executive officers with various economic incentives to remain employed with us, these incentives may not be sufficient to retain them. None of our senior management has any arrangement with us for a fixed term of service. The ability to retain our key employees is critical to our ability to effectively manage our resources following the LIPO-202 data and the loss of services of any of these individuals or our inability to hire, retain and motivate additional qualified personnel in the future could delay or prevent the completion of our planned clinical trials or the commercialization of LIPO-202 or any of our other current and future product candidates.

Our chief executive officer, or CEO, tendered his resignation in February 2016. While we have established an Operating Committee to assist with many of the responsibilities arising in the day-to-day operations of the company, we currently do not have a Chief Executive Officer or President. Pending results of our Phase 2 proof of concept trial, we expect to conduct a search for a new CEO and while we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future, especially considering the negative results from our Phase 3 clinical studies and our current cash position. Competition for qualified personnel in the biotechnology and specialty pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. While we have established a Development Committee responsible for general oversight and overall strategy for the LIPO-202 development plan activities including CMC, clinical and regulatory, we currently do not have a Chief Medical Officer or Chief Scientific Officer, and we may need to hire additional personnel in the event that we receive positive results from our on-going Phase 2 proof of concept trial, and we are able to proceed with additional clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

LIPO-202, if approved, will face significant competition, and the failure by us to compete effectively may prevent us from achieving significant market acceptance.

The aesthetic procedure market is highly competitive and dynamic, and is characterized by rapid and substantial technological development and product innovations. A substantial portion of our target physician market is comprised of dermatologists, primary care physicians, OB/GYNs, and members of other specialties, some of whom perform liposuction, non-invasive fat reduction and other procedures for fat reduction. Such physicians may find it more advantageous to utilize these surgical and non-surgical procedures to remove localized fat deposits rather than a cosmetic injectable therapy such as LIPO-202. In addition, we expect that LIPO-202, if approved, will compete for the attention and discretionary income of patients with new and existing therapies for the treatment of localized fat, including liposuction and other procedures, as well as other technologies aimed at fat reduction, including injectable therapies, laser energy-based, cryolipolysis-based, and ultrasound energy-based products.

If approved, LIPO-202 may also compete with unregulated, unapproved and off-label fat reduction and body contouring treatments. For example, we are aware that there are entities such as compounding pharmacies that have manufactured quantities of phosphatidylcholine and deoxycholic acid-based formulations, which are being sold as fat reduction treatments without drug approval from the FDA. In order to compete successfully in the aesthetics market, we will have to demonstrate that LIPO-202 is a worthwhile aesthetic treatment and is a superior alternative to existing therapies. There may be other drug or device products or injectable therapies currently under development or being considered for similar indications of which we are not currently aware, but which upon approval would compete directly with LIPO-202.

LIPO-202, if approved, will also compete for patient and physician resources and mindshare with products and technologies that are not primarily related to fat reduction and body contouring, such as skin tightening, anti-aging, dispigmentation and other aesthetic technologies. The medical technology and aesthetic companies that offer these products tend to have a broad range of other product offerings, large direct sales forces, and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts.

In addition, a large portion of our target physician market is comprised of plastic surgeons who utilize surgical methods for fat reduction. Such physicians may find it more advantageous to utilize surgical techniques to remove localized fat deposits rather than a cosmetic injectable therapy such as LIPO-202. Additionally, some non-invasive technologies for the reduction of fat or "body contouring" have received marketing clearance from the FDA. For example, , Zeltiq Aesthetics, Inc. received multiple clearances for various anatomical regions of the body for their body contouring system, CoolSculpting®, which utilizes controlled cooling to reduce the temperature of fat cells in the treated area for the selective reduction of fat. Additional products such as SculpSure®, a laser energy based product marketed by Cynosure, Vanquish Fat Removal System , a radio frequency energy-based product marketed by BTL Aesthetics, Zerona®, a laser energy-based product marketed by Erchonia Corporation, and Liposonix®, an ultrasound energy-based product marketed by Valeant Pharmaceuticals, Inc., have also received FDA marketing clearance. In April 2015, Kythera, Inc., which was acquired by Allergan plc, received FDA approval for KYBELLA®, for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat, or chin fat, in adults. CoolSculpting®, KYBELLA® and Vanquish Fat Removal System have approval in expected treatment indications for LIPO-202. Moreover, these methods and technologies may be used off-label by physicians in the expected treatment indications for LIPO-202, which may decrease the market available for LIPO-202, if approved.

Many of these potential competitors are large and/or experienced companies that have substantially greater resources and brand recognition than we do. By way of example, Kythera was acquired by Allergan. 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.

The commercial success of LIPO-202, if approved, will depend significantly on broad physician adoption and use of LIPO-202.

The commercial success of LIPO-202, if approved, will depend significantly on the broad adoption and use of LIPO-202 by physicians for fat reduction and body contouring. Physician adoption of LIPO-202, if approved, will depend on a number of factors, including:

- the safety and effectiveness of LIPO-202 for fat reduction and body contouring as compared to alternative treatments or procedures;
- physician willingness to adopt a new therapy for fat reduction and body contouring;
- patient compliance with the treatment regimen;
- overcoming any biases surgeons may have in favor of other surgical procedures for similar indications;
- patient satisfaction with administration, results and duration of the effects of LIPO-202;
- patient demand for fat reduction and body contouring;
- the revenue and profitability that LIPO-202 will offer a physician as compared to alternative treatments or procedures; and
- the difficulty of administering LIPO-202 and any potential side effects of the administration and/or use of LIPO-202.

If LIPO-202 is approved for use and physicians do not broadly adopt it for fat reduction and body contouring, our financial performance will be adversely affected.

We currently have no sales or marketing organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell LIPO-202 effectively in the United States or any other current and future product candidates, if approved, or generate product revenue.

We currently do not have a commercial organization. If LIPO-202 receives regulatory approval, we intend to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive, require substantial additional capital and be time consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize LIPO-202. If we are not successful in commercializing LIPO-202 or any of our current or future product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

We rely completely on third-party suppliers to manufacture and distribute our clinical drug supplies for LIPO-202, we intend to rely on third parties for commercial manufacturing and distribution of LIPO-202 and we expect to rely on third parties for manufacturing and distribution of preclinical, clinical, and commercial supplies of any of our other current and future product candidates.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to manufacture or distribute preclinical, clinical, or commercial quantities of drug substance or drug product, including LIPO-202. Facilities used by our contract manufacturers to manufacture drug substance and drug product for commercial sale must be approved by the FDA or other relevant foreign regulatory bodies pursuant to inspections that will be conducted after we submit our NDA or any relevant foreign regulatory submission to the applicable regulatory agency.

We do not have direct control over the ability of our contract manufacturers to maintain adequate manufacturing capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. We are dependent on our contract manufacturers for compliance with cGMP requirements, for manufacture of drug substance and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and/or the strict regulatory requirements of the FDA or foreign regulatory bodies, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. Furthermore, these contract manufacturers are engaged with other companies to supply and/or manufacture materials or products for such companies, which also exposes our manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract manufacturers' facility. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the manufacture of LIPO-202 or any of our other current and future product candidates, or if it withdraws its approval in the future, we may need to find alternative manufacturing facilities, which would negatively impact our ability to develop, and obtain regulatory approval for or market LIPO-202 or any of our other current and future product candidates, if approved. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of our product candidates, entail higher costs or impair our reputation.

We and our contract manufacturers continue to characterize and improve manufacturing processes and quality systems. As development and commercialization progresses, we may encounter difficulties with new or existing processes. Depending upon the extent of the challenges encountered, there may be an interruption in clinical and/or commercial supply.

In addition, a failure to provide drug substance supply could have an adverse effect on supply of finished drug product for clinical trials and/or finished drug product in our commercial territories, and, as a result, may have an adverse effect on our operating results.

We expect to continue to depend on third-party contract manufacturers and suppliers for the foreseeable future. We currently source salmeterol xinafoate, the active drug ingredient of LIPO-202, from Natco Pharma Limited. Lyophilization Services of New England, Inc. manufactures LIPO-202. Testing and stability services for LIPO-202 are currently provided by Pharmaceutical Product Development, LLC, or PPD. We have not yet entered into long-term agreements with any of the aforementioned third-party providers. We currently do not have alternative drug substance and drug product manufacturers; although through extensive diligence several providers have been identified. To manufacture and distribute LIPO-202 in the quantities that we believe will be required to meet anticipated market demand, our third-party manufacturers may need to increase capacity, which could involve significant challenges and will require additional regulatory approvals. In addition, the development of commercial-scale manufacturing capabilities may require us and our third-party manufacturers to invest substantial additional funds and hire and retain the technical personnel who have the necessary manufacturing and quality experience. Neither we nor our third-party manufacturers may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all.

When completed, our supply agreements cannot guarantee that a contract manufacturer or supplier will provide services adequate for our needs. If a contract manufacturer/supplier becomes financially distressed or insolvent, or discontinues manufacturing supply for us beyond the term of the existing agreement, if any, or for any other reason, this could result in substantial management time and expense to identify and qualify alternative manufacturers or suppliers, and could lead to an interruption in clinical or commercial supply.

If there is a disruption to our or our third-party manufacturers' or suppliers' relevant operations, we will have no other means of producing LIPO-202 until the affected facilities are restored or we or they procure and qualify alternative facilities. Additionally, any damage to or destruction of our or our third-party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to manufacture LIPO-202 on a timely basis.

Our reliance on contract manufacturers further exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate our trade secrets or other proprietary information.

Manufacturing and supply of drug substance and finished drug product is a complex and technically challenging undertaking, and there is potential for failure at many points in the manufacturing, testing, quality assurance and distribution supply chain, as well as the potential for latent defects after product has been manufactured and distributed.

Manufacturing and supply of drug substance and finished drug product is technically challenging. Changes that may be made outside the purview of our direct control can have an impact on the success of our processes, on quality, and successful delivery of product to physicians. Mistakes and mishandling are not uncommon and can affect successful production and supply. Some of these risks include:

- failure of our manufacturers to follow cGMP requirements, equipment failures or mishandling of our product while in production or in preparation for transit;
- transportation and import/export risk;
- delays in analytical results or failure of sensitive analytical techniques that we will depend upon for quality control, release of product, and shelf life determination;
- natural disasters, labor disputes, financial distress, lack of raw material and component supply, issues with facilities and equipment or other forms of disruption to business operations at our contract manufacturers/suppliers; and
- latent defects that may become apparent after product has been released and that may result in recall and destruction of drug.

Our existing collaboration with NovaMedica is important to our business, and future collaborations may also be important to us. If we are unable to maintain any of these collaborations, or if these collaborations are not successful, our business could be adversely affected.

We have entered into a collaboration with NovaMedica for the development and commercialization of our product candidates in Russia, Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, Ukraine and Uzbekistan. Our existing collaboration, and any future collaborations we enter into, may pose a number of risks, including:

- collaborators have significant discretion in determining the efforts and resources that they will apply to the development and commercialization of product candidates under these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval, or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with the products or product candidates that are the subject of our collaboration agreements with them, which may cause collaborators to cease to devote resources to the commercialization of the product candidates that are covered under our collaboration with them;
- a collaborator with marketing and distribution rights to one or more product candidates that are subject to a collaboration agreement with us and achieves regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, lead to additional responsibilities for us with respect to product candidates, or result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to result in litigation that could jeopardize or invalidate our intellectual property rights or proprietary information;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborations may be terminated and, if terminated, in certain instances, we would potentially lose the right to pursue further development or commercialization of the applicable product candidates;
- collaborators may learn about our technology and use this knowledge to compete with us;
- negative results in preclinical or clinical trials conducted by our collaborators could produce results that harm or impair other products using our technology;
- there may be conflicts between collaborators that could negatively affect those collaborations or others; and
- the number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers.

All of the risks relating to product development, regulatory approval and commercialization described in this document also apply to the activities of our collaborators and there can be no assurance that our collaborations will produce positive results or successful products on a timely basis or at all. Additionally, subject to its contractual obligations to us, if a collaborator of ours is involved in a business combination or otherwise changes its business priorities, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one or more of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities, as well as our stock price, could be adversely affected.

Even if LIPO-202 is approved for commercialization, if there is not sufficient patient demand for procedures using LIPO-202, our financial results and future prospects will be harmed.

Any procedure using LIPO-202 will likely be an elective procedure, the cost of which must be borne by the patient, and we do not expect it to be reimbursable through government or private health insurance. The decision by a patient to elect to undergo treatment with LIPO-202 may be influenced by a number of factors, such as:

- the success of any sales and marketing programs that we, our collaborators, or any third parties we or they engage, undertake, and as to which we have limited experience;
- the extent to which physicians adopt and recommend LIPO-202 to their patients;
- the extent to which LIPO-202 satisfies patient expectations;
- the ability of physicians and clinicians to properly follow instructions in administering the subcutaneous injections across the treatment area such that their patients do not experience excessive discomfort during treatment or adverse side effects;
- the cost, safety and effectiveness of LIPO-202 versus other aesthetic treatments;
- consumer sentiment about the benefits and risks of aesthetic procedures generally and LIPO-202 in particular;
- the success of any direct-to-consumer marketing efforts we may initiate; and
- general consumer confidence, which may be impacted by economic and political conditions.

Our financial performance will be materially harmed if we cannot generate significant patient demand for LIPO-202.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of LIPO-202 or any of our other current and future product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties, among others. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for LIPO-202 or any of our other current and future product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize LIPO-202 or any our other current or future product candidates.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of LIPO-202 or any of our other products we develop. We currently carry product liability insurance covering our clinical trials in the amount of $10.0 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing LIPO-202, we intend to expand our insurance coverage to include the sale of LIPO-202; however, we may be unable to obtain this liability insurance on commercially reasonable terms.

Requirements associated with being a public company increase our costs significantly, as well as divert significant company resources and management attention.

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act, and regulations regarding corporate governance practices. The listing requirements of The NASDAQ Global Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

After the completion of our IPO in November 2014, we became subject to Section 404 of The Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the Securities and Exchange Commission, or the SEC, which generally require our management and an independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of our IPO, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.0 billion, (3) the day 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 measured as of each June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by these rules. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall.

In addition, as a public company we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act, as amended. In order to report our results of operations and financial statements on an accurate and timely basis, we will depend on CROs to provide timely and accurate notice of their costs to us and, if LIPO- 202 is approved by relevant foreign regulatory authorities and sold by NovaMedica, we would depend on NovaMedica to provide timely and accurate reports on royalties payable to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The NASDAQ Global Market or other adverse consequences that would materially harm our business. In addition, being a public company could make it more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Furthermore, the market for aesthetic medical procedures may be particularly vulnerable to unfavorable economic conditions. In particular, we do not expect LIPO-202 to be reimbursed by any government or third-party payor and, as a result, demand for this product will be tied to discretionary spending levels of our targeted patient population. A severe or prolonged economic downturn, such as the most recent global financial crisis, could result in a variety of risks to our business, including, weakened demand for LIPO-202, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

We or the third parties upon whom we depend may be adversely affected by earthquakes, wildfires or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters and other facilities are located in the San Diego area, which in the past has experienced both severe earthquakes and wildfires. We do not carry earthquake insurance. Earthquakes, wildfires or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are geographically concentrated and operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our current and any future 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 material 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 development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture LIPO-202 and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. 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 and commercialization of our product candidate could be delayed.

Risks Related to Our Intellectual Property

If our efforts to protect the intellectual property related to our product candidates are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and technology.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and any future licensors and licensees may not be able to prepare, file, prosecute, and maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner. Moreover, if we are unable to raise sufficient capital to continue to prosecute and maintain our existing patent portfolio in all countries that we determine to be necessary or desirable, we may elect to forego or abandon patent protection in certain jurisdictions if we determine such election to be in the best interest of the Company.

It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, etc., although we are unaware of any such defects that we believe are of material import. If we or any future licensors or licensees, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current licensors, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The strength of patents in the specialty pharmaceutical field involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law in ways affecting the scope or validity of issued patents. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or foreign countries. Even if patents do successfully issue from the patent applications that we own or in-license, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. For example, third party challenges, including for example *ex parte* reexamination and *inter partes* review proceedings to United States patents in the specialty pharmaceutical field are not uncommon. These processes are provided for by law and require the USPTO to consider the scope and validity of issued patents if requested. In addition, patents granted by the European Patent Office may be challenged, also known as opposed, by any person within nine months from the publication of their grant. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our product candidates. Furthermore, even if they are unchallenged, our patents may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize our product candidates.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after the first non-provisional filing in the patent family, subject to any applicable terminal disclaimer, patent term adjustment and/or patent term extension. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic or follow-on versions of our product candidates. Further, if we encounter delays in our development efforts, including our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

The majority of our patents and patent applications are entitled to effective filing dates prior to March 16, 2013. For U.S. patent applications in which patent claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party, for example a competitor, or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by those patent claims. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our participation in an interference proceeding may fail and, even if successful, may result in substantial costs and distract our management and other employees.

In addition to the protection afforded by patents, we also rely on trade secret protection to protect proprietary know-how that may not be patentable or that we elect not to patent, processes for which patents may be difficult to obtain or enforce, and any other elements of our product candidates, and our product development processes (such as a manufacturing and formulation technologies) that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, trade secrets can be difficult to protect if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have a material adverse effect on our business. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent information and techniques and we cannot guarantee that our competitors will not independently develop substantially equivalent information and techniques. The FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Further, if we were to enforce a claim that a third-party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

Moreover, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

In an effort to protect our trade secrets and other confidential information, we require our employees, consultants, advisors, and any other third parties that have access to our proprietary know-how, information or technology, for example, third parties involved in the formulation and manufacture of our product candidates, and third parties involved in our clinical trials to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. However, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed despite having such confidentiality agreements. Adequate remedies may not exist in the event of unauthorized use or disclosure of our trade secrets. In addition, in some situations, these confidentiality agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, or advisors have previous employment or consulting relationships. To the extent that our employees, consultants or contractors use any intellectual property owned by third parties in their work for us, disputes may arise as to the rights in any related or resulting know-how and inventions. If we are unable to prevent unauthorized material disclosure of our trade secrets to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other specialty pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the specialty pharmaceutical industry involves both technological and legal complexity, and therefore, is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, several recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

For our U.S. patent applications containing one or more claim that is not entitled to priority before March 16, 2013, there is a potential for a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, or the American Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted, reviewed after issuance, and may also affect patent litigation. The USPTO has developed regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA. It still remains unclear what other, if any, impact the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-inventor-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (a) file any patent application related to our product candidates or (b) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit for certain types of cases and providing opportunities for third parties to challenge any issued patent in the USPTO for certain grounds of unpatentability. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid as unpatentable even though the same evidence may be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent prosecution process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patent and/or pending patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent or patent application. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are many 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. If we fail to maintain the patents and patent applications directed to our product candidates, our competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business.

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Various countries limit the subject matter that can be patented and limit the ability of a patent owner to enforce patents in the medical and other related fields. This may limit our ability to obtain or utilize those patents internationally. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we 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 enforcement on infringing activities is inadequate. These products may compete with our products, if approved, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from 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 pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

Third-party claims alleging intellectual property infringement may adversely affect our business.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties, for example, the intellectual property rights of competitors. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, reexaminations, oppositions, *inter partes* review, and post-grant review proceedings before the USPTO and corresponding foreign patent offices. Our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents owned or controlled by third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to our product candidates may give rise to claims of infringement of the patent rights of others. Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, formulations or methods of manufacture related to the use or manufacture of LIPO-202, LIPO-102 and other future product candidates. We cannot assure you that our product candidates will not infringe existing or future patents. We may not be aware of patents that have already issued that a third party, for example a competitor in the cosmetic market, might assert are infringed by our product candidates. It is also possible that patents of which we are aware, but which we do not believe are relevant to our product candidates, could nevertheless be found to be infringed by our product candidates. Nevertheless, we are not aware of any issued patents that we believe would prevent us from marketing our product candidates, if approved. Because patent applications can take many years to issue and may be confidential for eighteen months or more after filing, there may be currently pending third-party patent applications that have been filed but not published that result in issued patents that LIPO-202, LIPO-102, our future product candidates or our technologies may infringe, or which such third parties claim are infringed by the use of our technologies. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages, or the holders of any such patents may be able to block our ability to develop, manufacture or commercialize the applicable product candidate unless we obtained a license under the applicable patents, or until such patents expire.

Third parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would cause us to incur substantial expenses and, and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us by a third party, we may have to (a) pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed the third party's patents; (b) obtain one or more licenses from the third party; (c) pay royalties to the third party; and/or (d) redesign any infringing products or acquire or in-license third-party intellectual property rights. Redesigning any infringing products may be impossible or require substantial time and monetary expenditure. Further, we cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms. In the event that we could not obtain a license, we may be unable to further develop and commercialize our product candidates, which could harm our business significantly, or we may be required to expend significant time and resources to develop or license replacement technology. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

The licensing and acquisition of third-party proprietary rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party proprietary rights that we may consider necessary or attractive in order to commercialize LIPO-202, LIPO-102 and future product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Further, companies that perceive us to be a competitor may be unwilling to assign or license rights to us, either on reasonable terms, or at all. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. Ultimately, we could be prevented from commercializing LIPO-202 and our other current and future product candidates, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

Defending ourselves or our licensors in litigation is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time consuming, and may not ultimately be successful.

Third parties may infringe misappropriate or otherwise violate our intellectual property rights, including our existing patents, patents that may issue to us in the future, or the patents of our licensors to which we have a license. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. Further, we may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Generic drug manufacturers may develop, seek approval for, and launch generic versions of our products, if approved. If we file an infringement action against such a generic drug manufacturer, that company may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us and/or our licensors to engage in complex, lengthy and costly litigation or other proceedings.

For example, if we or one of our future licensors initiated legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidates is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post grant review, and equivalent proceedings in foreign jurisdictions, such as opposition proceedings.

In addition, within and outside of the United States, there has been a substantial amount of litigation and administrative proceedings, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in various foreign jurisdictions, regarding patent and other intellectual property rights in the pharmaceutical industry. Recently, the AIA introduced new procedures including *inter partes* review and post grant review. The implementation of these procedures brings uncertainty to the possibility of challenges to our patents in the future, including those that patents perceived by our competitors as blocking entry into the market for their products, and the outcome of such challenges.

Such litigation and administrative proceedings could result in revocation of our patents or amendment of our patents such that they do not cover our product candidates. They may also put our pending patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. Additionally, it is also possible that prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, may, nonetheless, ultimately be found by a court of law or an administration panel to affect the validity or enforceability of a claim. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Enforcing our or any of future licensor's intellectual property rights through litigation is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, during the course of litigation or administrative proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our patents or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above the initial purchase price.

The market price of shares of our common stock could be subject to wide fluctuations as a result of many risks listed in this section, and others beyond our control, including:

- adverse results or delays in clinical trials;
- inability to obtain additional funding;
- failure to successfully develop and commercialize our product candidates;
- changes in laws or regulations applicable to our products, if approved;
- inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- failure to meet or exceed product development or financial projections we provide to the public;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

In addition, the stock markets in general, and the markets for pharmaceutical, specialty pharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business.

If securities or industry analysts issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

An active trading market for our common stock may not be sustained

We completed our IPO in November 2014. Following completion of our IPO, an active trading market may not be sustained. The lack of an active trading market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, applications, or technologies using our shares of common stock as consideration.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this document. In particular, in this document we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we 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 be more volatile.

In addition, the JOBS Act also provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Should we fail to comply with the NASDAQ Listing Qualification, we could be delisted from The NASDAQ Global Market, which could seriously harm the liquidity of our stock and our ability to raise capital

On March 21, 2016, we received a letter from the Listing Qualifications staff of The NASDAQ Stock Market LLC ("NASDAQ Listing Qualification") indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we no longer meet the requirement of the NASDAQ Global Market to maintain a minimum bid price of $1 per share, as set forth in Nasdaq Listing Rule 5450(a)(1). On June 3, 2016, we received written notification from the NASDAQ Listing Qualification that we had regained compliance with NASDAQ Listing Rule 5450(a)(1) and we are now in compliance with the bid price requirement for continued listing on The NASDAQ Global Market. If in the future we are unable to comply with the Listing Qualifications as set forth in Nasdaq Listing Rule 5450(a)(1), we would have to regain compliance within the 180 day time period prescribed by The NASDAQ Global Market, and if it appears that we would not be able to cure the deficiency in a timely manner, or if we are then otherwise not eligible, then we may be subject to delisting, or forced to transfer to a less desirable trading market within Nasdaq.

If our shares of common stock have a Market Value of Listed Securities, or MVLS, for 30 consecutive business days of less than $50,000,000, we would no longer meet the requirement to maintain a MVLS of $50,000,000, as set forth in Nasdaq Listing Rule 5450(b)(2)(a). If this occurs and we are unable to regain compliance within the 180 day time period prescribed by The NASDAQ Global Market, or if we were to fall out of compliance with this rule once again, and if it appears that we would not be able to cure the deficiency in a timely manner, or if we are then otherwise not eligible, then we may be subject to delisting, or forced to transfer to a less desirable trading market within Nasdaq.

There can be no assurance that we will be able to maintain compliance with the minimum bid price requirement or the MVLS requirement, or maintain compliance with the other listing requirements, or that we will be eligible for listing on any comparable trading market. The effects of losing the NASDAQ listing could materially harm our ability to raise additional capital.

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

As of December 31, 2016, our principle stockholders, executive officers, directors and their respective affiliates beneficially owned approximately 57% of our outstanding voting stock. Therefore, these stockholders have the ability to influence us through this ownership position and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to LIPO-202, including further clinical trials based on the negative results from our AbCONTOUR1 and AbCONTOUR2 U.S.-based pivotal Phase 3 trials;
- variations in the level of expenses related to any of our other current and future product candidates;
- if LIPO-202 receives regulatory approval, the level of underlying demand for this product candidate and wholesalers' buying patterns;
- addition or termination of clinical trials or funding support;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.
- any intellectual property infringement lawsuit in which we may become involved; and
- regulatory developments affecting our LIPO-202 or any of our other current and future product candidates or those of our competitors.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate

substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. On December 14, 2015, we announced that top-line results from our AbCONTOUR1 and AbCONTOUR2 U.S.-based pivotal Phase 3 trials to evaluate the safety and efficacy of our lead product candidate, LIPO-202, showed that in both studies that LIPO-202 did not meet its co-primary composite and secondary endpoints. Based on this announcement, we incurred a significant reduction in the value of shares of our common stock in the public market. We are unable to predict the effect that future sales may have on the prevailing market price of our common stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2014 Equity Incentive Plan, or the 2014 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. In addition, we have a number of outstanding awards under our 2007 Stock Plan, or 2007 Plan. The number of shares available for future grant under the 2014 plan will automatically increase on January 1 of each year by 4% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. In addition, we may grant or provide for the grant of rights to purchase shares of our common stock pursuant to our 2014 Employee Stock Purchase Plan, or ESPP. The number of shares of our common stock reserved for issuance under the 2014 ESPP will automatically increase on January 1 of each calendar year by 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. We have filed a registration statement permitting shares of common stock issued or issuable in the future pursuant to the 2007 Plan, 2014 Plan and 2014 ESPP to be freely resold by plan participants in the public market, subject to the lock-up agreements, applicable vesting schedules and, for shares held by directors, executive officers and other affiliates, volume limitations under Rule 144 under the Securities Act. Currently, we plan to register the increased number of shares available for issuance under the 2014 plan and 2014 ESPP each year. Increases in the number of shares available for future grant or purchase may result in additional dilution, which could cause our stock price to decline.

We have broad discretion to determine how to use our cash, and may use them in ways that may not enhance our operating results or the price of our common stock.

Our management will have broad discretion over the use of our cash, and we could spend our cash in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We currently expect to use substantially all of the remaining net proceeds from our IPO to fund our Phase 2 clinical trial of LIPO-202, and any excess funds to be used for general corporate purposes, including our planned research, clinical trial and product development activities. However, our use of cash, including the remaining net proceeds from our IPO may differ substantially from our current plans. If we do not invest or apply our cash in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult, limit attempts by our stockholders to replace or remove our current directors and management team, and limit the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws became effective immediately prior to the completion of our IPO contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- prohibiting our stockholders from calling a special meeting of stockholders or acting by written consent;
- permitting our board to issue additional shares of our preferred stock, with such rights, preferences and privileges as they may designate, including the right to approve an acquisition or other changes in control;
- establishing an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- providing that our directors may be removed only for cause;
- providing that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- requiring the approval of our board of directors or the holders of a supermajority of our outstanding shares of capital stock to amend our bylaws and certain provisions of our certificate of incorporation.

Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management team by making it more difficult for stockholders to replace members of our board, which is responsible for appointing the members of our management.

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. The restrictions contained in Section 203 are not applicable to any of our existing stockholders prior to IPO that own 15% or more of our outstanding voting stock upon the completion of our IPO.

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

Our amended and restated certificate of incorporation and amended and restated bylaws that became effective immediately prior to the completion of our IPO provides that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

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

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.

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

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Additionally, the terms of our credit facility restrict our ability to pay dividends. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

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 will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. 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.

Item 1B. Unresolved Staff Comments

None

Item 2. Properties.

We lease approximately 14,687 square feet of office space pursuant to which we occupy approximately 3,580 square feet of space for our headquarters in San Diego, California and sublease approximately 11,107 square feet under agreements that expire in March 2020 with a renewal option for an additional five years.

Item 3. Legal Proceedings.

From time to time the Company may be involved in various disputes and litigation matters that arise in the ordinary course of business.

We are currently not a party to any material legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable

PART II

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

Market Information

Our common stock began trading on the NASDAQ Global Market on November 20, 2014 and trades under the symbol "NEOT". Prior to November 20, 2014, there was no public market for our common stock. The table below provides the high and low intra-day sales prices of our common stock for the periods indicated, as reported by The NASDAQ Global Market.

	High	Low
Year ended December 31, 2016		
Fourth Quarter	$ 1.35	$ 0.96
Third Quarter	$ 1.25	$ 0.79
Second Quarter	$ 1.44	$ 0.57
First Quarter	$ 1.42	$ 0.58
Year ended December 31, 2015		
Fourth Quarter	$ 10.78	$ 1.24
Third Quarter	$ 15.05	$ 7.77
Second Quarter	$ 9.05	$ 5.92
First Quarter	$ 8.88	$ 6.42

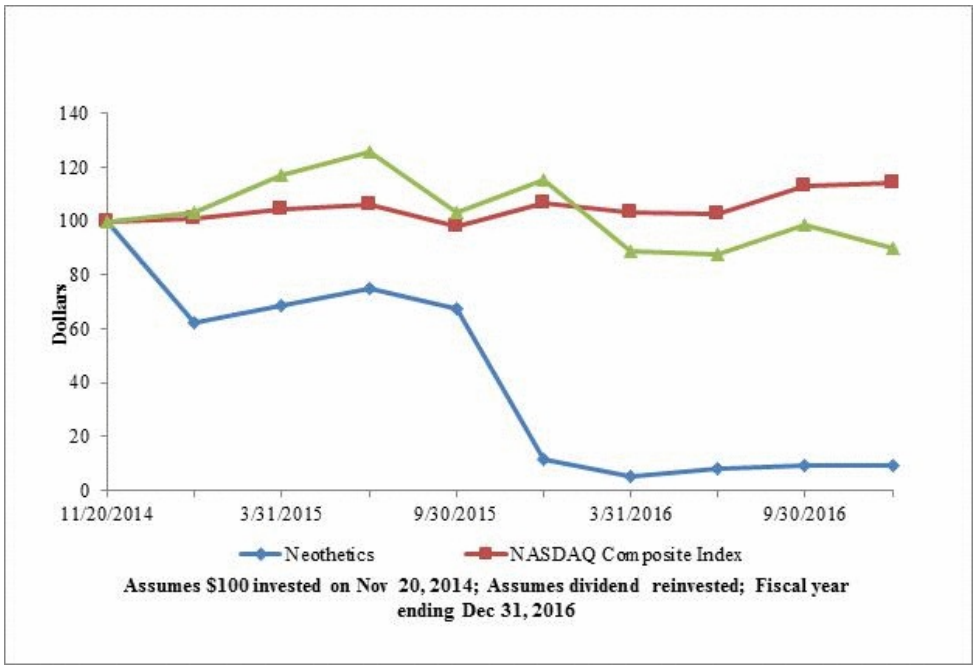
The last sale price for our common stock as reported by the NASDAQ Global Market on March 1, 2017 was $1.49 per share.

Holders of Common Stock

As of March 1, 2017, there were 13,829,716 shares of our common stock outstanding and 5 holders of record of our common stock. This number was derived from our shareholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

Performance Graph

Set forth below is a graph comparing the cumulative total return on an indexed basis of a $100 investment in the Company's common stock, the NASDAQ Composite® (US) Index and the NASDAQ Biotechnology Index commencing on November 20, 2014 (the date our common stock began trading on the NASDAQ Global Market) and continuing through December 31, 2016. The stock price performance on the following graph is not necessarily indicative of future stock price performance.



Recent Sales of Unregistered Securities

During the year ended December 31, 2016, we did not issue any securities that were not registered under the Securities Act.

Dividend Policy

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

Equity Compensation Plan Information

Information about our equity compensation plans is incorporated herein by reference to Part III, Item 12 of this Annual Report.

Issuer Repurchases of Equity Securities

None.

Item 6. Selected Financial Data.

The following table shows selected financial data as of, and for the periods ended on, the dates indicated. Our historical results are not necessarily indicative of the results to be expected in the future and results of interim periods are not necessarily indicative of the results for the entire year. You should read the following selected financial data in conjunction with our financial statements, the notes to the financial statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this report. The selected financial data included in this section are not intended to replace the financial statements and the related notes included elsewhere in this report.

	Year Ended December 31,		
	2016	2015	2014
	(in thousands, except share and per share data)		
Statement of Operations Data:			
Operating expenses:			
Research and development	$ 6,579	$ 34,410	$ 5,175
General and administrative	5,463	7,639	4,416
Total operating expenses	12,042	42,049	9,591
Loss from operations	(12,042)	(42,049)	(9,591)
Interest income	59	26	8
Interest expense	(1,036)	(1,134)	(375)
(Loss) gain on change in fair value of preferred stock warrants	—	—	(861)
Net loss	$ (13,019)	$ (43,157)	$ (10,819)
Net loss per share, basic and diluted(1)	$ (0.94)	$ (3.15)	$ (5.36)
Weighted average shares used to compute basic and diluted net loss per share(1)	13,801,003	13,696,033	2,017,601

(1) Please see Note 2 of our financial statements included elsewhere in this document for an explanation of the calculations of our actual basic and diluted net loss per share.

	As of December 31,		
	2016	2015	2014
	(in thousands)		
Balance sheet data:			
Cash and cash equivalents	$ 11,478	$ 37,749	$ 75,948
Working capital	$ 11,605	$ 30,626	$ 74,964
Total assets	$ 12,817	$ 40,112	$ 76,898
Long-term debt, less current portion	$ -	$ 7,205	$ 9,741
Accumulated deficit	$ (125,850)	$ (112,832)	$ (69,675)
Total stockholders' equity	$ 11,915	$ 23,807	$ 65,247

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this report. Some of the information contained in this discussion and analysis or set forth elsewhere in this reports, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this document, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage specialty pharmaceutical company developing therapeutics for the aesthetic market. Our initial focus is on localized fat reduction and body contouring. Our lead product candidate, LIPO-202, is a first-in-class injectable formulation of the long-acting ß2-adrenergic receptor agonist, salmeterol xinafoate, which is an active ingredient in the U.S. Food and Drug Administration, or FDA, approved inhaled products SEREVENT DISKUS®, ADVAIR HFA® and ADVAIR DISKUS®. We previously completed development of LIPO-202 in our Phase 2 RESET trial in 2013, showing a statistically significant reduction in central abdominal bulging due to subcutaneous fat in non-obese patients. In 2015, we conducted two pivotal U.S. Phase 3 trials of LIPO-202, which failed to meet their co-primary composite or secondary endpoints as well as showing near identical results with no bias in sites or subgroups. In these trials, AbCONTOUR1 and AbCONTOUR2, LIPO-202 continued to show a safety profile similar to placebo. We, and expert consultants that we engaged, conducted a detailed review of these unexpected trial results. Based on the results of the review by us and our expert consultants, we concluded that modifications intended to make LIPO-202 commercially ready may have affected the drug product. We have completed manufacturing of a modified formulation of LIPO-202, which is primarily based on the drug product formulation used in the Phase 2 RESET trial. We are continuing our LIPO-202 development program focused on localized fat reduction and body contouring using this modified formulation of LIPO-202. In November 2016 we announced plans to prioritize our efforts and resources on the Phase 2 proof of concept trial for the reduction of localized fat deposits under the chin, or submental fat. We initiated this trial with the modified formulation of LIPO-202 in December 2016 and expect top-line results in June of 2017. We also plan to continue development of LIPO-202 for the reduction of central abdominal bulging, pending results from the submental Phase 2 proof of concept trial and capital resources. Since commencing operations in February 2007, we have invested substantially all of our efforts and financial resources in the research and development and commercial planning for LIPO-202, which is currently our lead product candidate. Through December 31, 2016, we have funded substantially all of our operations through the sale and issuance of our preferred stock, venture debt, convertible debt and the sale of shares in our initial public offering.

We have never been profitable and, as of December 31, 2016, we had an accumulated deficit of $125.9 million. We incurred net losses of $13.0 million and $43.2 million for the years ended December 31, 2016 and 2015, respectively. We expect to continue to incur net operating losses for at least the next several years as we advance LIPO-202 through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization. We have no manufacturing facilities and all of our manufacturing activities are contracted out to third parties. Additionally, we currently utilize third-party CROs to carry out our clinical development. We will need substantial additional funding to support our operating activities including further development of LIPO-202. Adequate funding may not be available to us on acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations, and financial condition.

Basis of Presentation

Revenue

Our ability to generate revenues from product sales, which we do not expect will occur before 2020, at the earliest, will depend heavily on our obtaining marketing approval from the FDA for, and, subsequent to that, our successful commercialization of, LIPO-202. If we fail to complete the development of LIPO-202 in a timely manner or to obtain regulatory approval, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Research and Development Expenses

Our research and development expenses consist primarily of:

- fees paid to clinical consultants, clinical trial sites and vendors, including CROs in conjunction with implementing and monitoring our preclinical and clinical trials and acquiring and evaluating preclinical and clinical trial data, including all related fees, such as for investigator grants, patient screening fees, laboratory work and statistical compilation and analysis;
- expenses related to preclinical studies, clinical trials and related clinical manufacturing, materials and supplies;

- expenses related to compliance with drug development regulatory requirements in the United States and other foreign jurisdictions; and
- personnel costs, including cash compensation, benefits and share-based compensation expense.

We expense both internal and external research and development costs in the periods in which they are incurred. To date, substantially all our research and development expenses have related to the development of LIPO-202. For the years ended December 31, 2016, 2015 and 2014, we incurred costs of $6.6 million, $34.4 million and $5.2 million respectively, on research and development expenses.

We do not allocate compensation expense to individual product candidates, as we are organized and record expense by functional department and our employees may allocate time to more than one development project. We do not utilize a formal time allocation system to capture expenses on a project-by-project basis.

Conducting significant research and development is central to our business and strategy. 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 greater duration of late stage clinical trials as compared to earlier clinical and preclinical development. Our research and development expenses decreased temporarily and we expect that these expenses will increase with the initiation of our Phase 2 proof of concept trial in December 2016. The costs of clinical trials may vary significantly over the life of a project owing to a number of factors. See "Risk Factors — Risks Related to Our Business — *Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.*"

General and Administrative Expenses

Our general and administrative expenses primarily consist of personnel costs, including cash compensation, benefits and share-based compensation expense, associated with our executive, accounting and finance departments. Other general and administrative expenses include costs in connection with patent filings, director and officer insurance premiums to support our operations as a public facility, facilities expenses, information technology costs and professional fees for legal, consulting, marketing, audit and tax services.

Interest Income

Our interest income consists primarily of interest received or earned on our cash and cash equivalents. We expect interest income to vary each reporting period depending on our average cash and cash equivalents and marketable securities balances during the period and applicable interest rates. To date, our interest income has not been significant in any individual period.

Interest Expense

Our interest expense consists of cash and non-cash interest costs related to our borrowings. The non-cash interest costs consist of the amortization of the fair value of warrants that were issued in connection with our borrowings, with the initial fair value of the warrants being amortized to interest expense over the term of the governing agreements, and the amortization of other debt issuance costs, primarily legal and banker fees, over the period the related convertible notes were outstanding.

We expect interest expense to decrease due to the prepayment in full of the Hercules debt facility in September 2016.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements as well as the reported revenues and expenses during the reported periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and share-based compensation. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ materially from these estimates. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected.

While our significant accounting policies are described in the notes to our financial statements appearing elsewhere in this document we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Accrued Research and Development Expenses

As part of the process of preparing our 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 vendor 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 balance sheet date in our financial statements based on facts and circumstances known to us at that time.

Examples of estimated accrued research and development expenses include:

- fees paid to CROs in connection with clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to vendors in connection with preclinical development activities; and
- fees paid to vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials 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. Through December 31, 2016, there have been no material adjustments to our prior period estimates of accrued expenses for clinical trials. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Share-Based Compensation

We account for all share-based compensation payments using an option pricing model for estimating fair value. Accordingly, share-based compensation expense for employees and directors is measured based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. Compensation expense is recognized for the portion that is ultimately expected to vest over the period during which the recipient renders the required services to us using the straight-line single option method. In accordance with authoritative guidance, the fair value of non-employee share-based awards is remeasured as the awards vest, and the resulting change in value, if any, is recognized as expense during the period the related services are rendered.

We estimate the fair value of our share-based awards using the Black-Scholes option pricing model. The Black-Scholes model requires the use of subjective and complex assumptions, including (a) the expected stock price volatility, (b) the calculation of the expected term of the award, (c) the risk free interest rate and (d) the expected dividend yield, which determine the fair value of share-based awards.

We will continue to use judgment in evaluating the fair value of the underlying common stock and expected term and expected volatility, related to our share-based compensation on a prospective basis. As we continue to accumulate additional data related to our common stock, we may make refinements to the estimates of our expected term and expected volatility, which could materially impact our future share-based compensation expense.

Results of Operations

Comparison of the Years Ended December 31, 2016 and 2015

	Year Ended December 31,		Change
	2016	2015	$
	(in thousands, except percentage)		
Operating expenses:			
Research and development	$ 6,579	$ 34,410	$ (27,831)
General and administrative	5,463	7,639	(2,176)
Total operating expenses	12,042	42,049	(30,007)
Loss from operations	(12,042)	(42,049)	30,007
Interest income	59	26	33
Interest expense	(1,036)	(1,134)	98
Net loss	$ (13,019)	$ (43,157)	$ 30,138

Research and Development Expenses. Research and development expenses decreased by $27.8 million to $6.6 million for the year ended December 31, 2016 from $34.4 million for the year ended December 31, 2015. Approximately $19.1 million of the decrease was due to the completion of our AbCONTOUR1 and AbCONTOUR2 U.S. Phase 3 clinical trials and $4.7 million of the decrease was due to the termination of the supplemental clinical trials. Approximately $1.1 million of the decrease was due to the reduction of consulting and other outside services, the elimination of the Corporate Advisory Board, as well as a decrease of $1.4 million due to a reduction in headcount in research and development. The remaining decrease of approximately $1.5 million was due to a reduction of regulatory, preclinical and CMC activities.

General and Administrative Expenses. General and administrative expenses decreased by $2.1 million to $5.5 million for the year ended December 31, 2016, from $7.6 million for the year ended December 31, 2015. The decrease of approximately $2.0 million was due to reduction in general legal fees, public and investor relation expenses, accounting fees and outside services expenses. The remaining decrease of $0.1 million was related to a reduction of headcount for the year ended December 31, 2016.

Interest Income. Interest income increased by $33,000 to $59,000 for the year ended December 31, 2016 from $26,000 for the year ended December 31, 2015. The increase resulted from higher rates of return during the year ended December 31, 2016.

Interest Expense. Interest expense decreased by $0.1 million to $1.0 million for the year ended December 31, 2016 from $1.1 million for the year ended December 31, 2015. The decrease in interest expense was due to the prepayment in full of the Hercules debt facility in September 2016.

Comparison of Years Ended December 31, 2015 and 2014.

	Year Ended December 31,		Change
	2015	2014	$
	(in thousands, except percentage)		
Operating expenses:			
Research and development	$ 34,410	$ 5,175	$ 29,235
General and administrative	7,639	4,416	3,223
Total operating expenses	42,049	9,591	32,458
Loss from operations	(42,049)	(9,591)	(32,458)
Interest income	26	8	18
Interest expense	(1,134)	(375)	(759)
Loss on change in fair value of preferred stock warrants	—	(861)	861
Net loss	$ (43,157)	$ (10,819)	$ (32,338)

Research and Development Expenses. Research and development expenses increased by $29.2 million, $19.0 million of the increase was due to operating costs of our AbCONTOUR1 and AbCONTOUR2 U.S. Phase 3 clinical trials, which evaluate the safety and efficacy of LIPO-202. Approximately $5.7 million of the increase was due to operating costs of LIPO-202-CL-21 safety study in a special population of obese patients, LIPO-202-CL-22 open label trial and LIPO-202-CL-23 extension study in support of the registration of LIPO-202. Additionally, there was an increase of $1.2 million in activities related to drug manufacturing to support our clinical trial programs. The remainder of the increase is due to the expansion of headcount in our clinical and regulatory departments and consulting services to support our trials, as well as the formation of a Corporate Advisory Board, or CAB, comprised of plastic surgeons, dermatologists and other physicians, that provided expertise regarding research, product development and regulatory affairs.

General and Administrative Expenses. General and administrative expenses increased by $3.2 million to $7.6 million for the year ended December 31, 2015, from $4.4 million for the year ended December 31, 2014. Substantially all of the increase was due to an increase in costs associated with being a publicly traded company, such as, public and investor relations, board of director expenses, general legal fees, Directors' and Officers' liability insurance and addition of personnel to assist with the Securities and Exchange reporting requirements. Our consulting and outside services costs increased by approximately $557,000 due to use of consultants to assist with our human resources activities compensation strategy, and PR/IR activities. Our general legal fees increased by approximately $697,000 due to an increase in general business activities and publicly traded company requirements. In addition, share-based compensation increased by approximately $598,000 as a result of options granted and Directors' and Officers' insurance increased by $428,000.

Interest Expense. Interest expense increased by $759,000 to $1.1 million for the year ended December 31, 2015, from $375,000 for the year ended December 31, 2014. The increase resulted from an increase in our average debt outstanding during the year ended December 31, 2015, as compared to the same period in the prior year, due to the total $10.0 million drawn in 2014 under the loan agreement we entered into in June 2014.

Loss on Change in Fair Value of Convertible Preferred Stock Warrants. There was no loss on the change in fair value of convertible preferred stock warrants for the twelve months ended December 31, 2015. Upon completion of the IPO in November 2014, all convertible preferred stock warrants were converted to common stock warrants and are no longer subject to remeasurement. The loss of approximately $861,000 for the twelve months ended December 31, 2014, was as a result of an increase in the fair value of the warrants through the date of the IPO.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operating activities for the years ended December 31, 2016 and 2015. As of December 31, 2016, we had an accumulated deficit of $125.9 million. We anticipate that we will continue to incur net losses for the foreseeable future as we continue the development and potential commercialization of LIPO-202 and incur additional costs associated with being a public company. We believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements for at least the next fifteen months. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

Prior to our IPO in November 2014, we funded our operations primarily through private placements of our convertible preferred stock, warrants, venture debt and convertible debt. In November 2014, we completed our IPO of 4,650,000 shares of common stock at an offering price of $14.00 per share. We received net proceeds of approximately $57.7 million, after deducting underwriting discounts, commissions and offering-related transaction costs. At December 31, 2016, we had cash and cash equivalents of approximately $11.5 million.

On December 1, 2015, the Company entered into a Controlled Equity Offering Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as a sales agent ("Cantor Fitzgerald") pursuant to which the Company may offer and sell from time to time, through Cantor Fitzgerald shares of Neothetics common stock, par value $0.0001 per share, having an aggregate offering price of up to $20.0 million. As of December 31, 2016, no shares were issued pursuant to the Sales Agreement.

We believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements for at least the next fifteen months. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

To fund further operations, we will need to raise additional capital. If we are unable to obtain additional financing on commercially reasonable terms, or at all, our business, financial condition and results of operations will be materially adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements. We may obtain additional financing in the future through the issuance of our common stock from other equity or debt financings or through collaborations or partnerships with other companies.

Summary Statement of Cash Flows

The following table sets forth a summary of the net cash flow activity for each of the periods set forth below (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Net cash used in operating activities	$ (16,255)	$ (37,911)	$ (9,572)
Net cash provided by (used in) investing activities	3	(426)	(18)
Net cash provided by (used in) financing activities	(10,019)	139	81,174
Net increase (decrease) in cash and cash equivalents	$ (26,271)	$ (38,198)	$ 71,584

Cash Flows from Operating Activities.

Net cash used in operating activities was $16.3 million, $37.9 million and $9.6 million for the years ended December 31, 2016, 2015 and 2014, respectively. The primary use of cash was to fund our operations related to the development of our product candidates in each of these periods.

Cash Flows from Investing Activities.

Net cash provided by investing activities was $3,000 during the year ended December 31, 2016. Net cash used in investing activities was $426,000 and $18,000 during the years ended December 31, 2015 and December 31, 2014, respectively. Cash provided by investing activities consisted of proceeds from the sale of equipment for the year ended December 31, 2016. Cash used for investing activities consisted primarily of the purchase of property and equipment and a $200,000 letter of credit for the year ended December 31, 2015. Cash used for investing activities consisted of the purchase of property and equipment for the year ended December 31, 2014.

Cash Flows from Financing Activities.

Net cash used in financing activities was $10.0 million for the year ended December 31, 2016, primarily from the prepayment of debt of $9.5 million and principal payments on debt of $0.5 million.

Financing activities provided cash of $139,000 for the year ended December 31, 2015, primarily from the issuance of common stock from the exercise of stock options and employee stock purchase plan.

Financing activities provided cash of $81.2 million for the year ended December 31, 2014, consisting of approximately $57.7 million of net proceeds from our IPO, $13.6 million of proceeds from the issuance of preferred stock for cash net of offering costs and $10.0 million of proceeds from the advance under our loan and security agreement, offset by the pay-down of $0.2 million of principal under our loan and security agreement.

Operating and Capital Expenditure Requirements

Our future capital requirements are difficult to forecast and will depend on many factors, including:

- the progress, costs and results of our planned Phase 2 proof of concept clinical trial of LIPO-202, any additional Phase 2 clinical trials and potential future Phase 3 clinical trials and any preclinical studies;
- the outcome, timing and cost of regulatory approvals;
- the costs and timing of establishing sales, marketing and distribution capabilities, if LIPO-202 is approved;
- delays that may be caused by changing regulatory requirements;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims; and
- the extent to which we acquire or invest in businesses, products or technologies.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic partnerships and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic partnerships or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, our other technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market LIPO-202 even if we would otherwise prefer to develop and market LIPO-202 ourselves.

Contractual obligations and commitments

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

	Payments Due by Period						
	Total	2017	2018	2019	2020	2021	More than 5 Years
Operating lease	$ 1,347,171	$ 395,520	$ 410,850	$ 431,508	$ 109,293	$ —	$ —
Total	$ 1,347,171	$ 395,520	$ 410,850	$ 431,508	$ 109,293	$ —	$ —

See Note 9 of the Notes to the Condensed Financial Statements for additional subsequent event information related to operating leases.

We believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements for at least the next fifteen months.

Off-balance sheet arrangements

We do not have any off-balance sheet arrangements (as defined by applicable regulations of the SEC) that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

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

Interest Rate Risk. Our cash, cash equivalents and short-term investments as of December 31, 2016 consisted of cash and money market funds. We are exposed to market risk related to fluctuations in interest rates and market prices. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. We currently do not hedge interest rate exposure. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation.

Effects of Inflation. Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

Item 8. Financial Statements and Supplementary Data.

The financial statements and the reports of our independent registered public accounting firm required pursuant to this item are included in this report beginning on page F-1.

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

None.

Item 9A. Controls and Procedures. Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of the end of the period covered by this annual report on Form 10-K, or December 31, 2016, our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, as of the December 31, 2016. Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of such date, our disclosure controls and procedures were effective.

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

Management's Annual Report on Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Management conducted an assessment of the effectiveness of the Company's internal control over financial reporting based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework (2013 Framework). Based on this assessment, our management concluded that, as of December 31, 2016, our internal control over financial reporting was effective based on those criteria.

Attestation Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to the deferral allowed under the JOBS Act for emerging growth companies

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the year ended December 31, 2015, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item will be contained in our definitive proxy statement to be filed with the SEC in connection with our 2017 Annual Meeting of Stockholders, or the Definitive Proxy Statement, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2016, under the headings "Board of Directors Information," "Corporate Governance," "Executive Officers," and "Section 16(a) Beneficial Ownership Reporting Compliance," and is incorporated herein by reference.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees, which is available on our website at www.neothetics.com. The Code of Business Conduct and Ethics contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics and is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Item 11. Executive Compensation

Information required by this item will be contained in our Definitive Proxy Statement under the heading "Executive Compensation and Other Information," and is incorporated herein by reference.

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

Information required by this item will be contained in our Definitive Proxy Statement under the heading "Security Ownership of Certain Beneficial Owners and Management," and is incorporated herein by reference.

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

Information required by this item will be contained in our Definitive Proxy Statement under the headings "Certain Relationships and Related Transactions," "Director Independence" and "Committees of the Board of Directors" and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

Information required by this item will be contained in our Definitive Proxy Statement under the heading "Principal Accountants' Fees and Services," and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed as part of this Annual Report

1. Financial Statements.

The following financial statements of Neothetics, Inc., together with the report thereon of Ernst & Young LLP, an independent registered public accounting firm, are included in this annual report on Form 10-K: All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto. A list of exhibits is set forth on the Exhibit Index immediately following the signature page of this annual report on Form 10-K and is incorporated herein by reference.

2 List of financial statement schedules. All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. List of Exhibits required by Item 601 of Regulation S-K. See Item 15(b) below.

(b). Exhibits

A list of exhibits is set forth on the Exhibit Index immediately following the signature page of this annual report on Form 10-K and is incorporated herein by reference.

NEOTHETICS, INC.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Neothetics, Inc.

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

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

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

/s/ Ernst & Young LLP

San Diego, California
March 23, 2017

NEOTHETICS, INC.

BALANCE SHEETS

	December 31,	
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	$ 11,477,852	$ 37,748,603
Prepaid expenses and other current assets	1,029,546	1,976,997
Total current assets	$ 12,507,398	$ 39,725,600
Restricted cash	200,000	200,000
Property and equipment, net	109,320	186,372
Total assets	$ 12,816,718	$ 40,111,972
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 503,739	$ 4,017,192
Accrued clinical trial expenses	359,067	1,422,810
Other accrued expenses	39,386	903,148
Long-term debt, current portion	—	2,756,351
Total current liabilities	902,192	9,099,501
Long-term debt, net of current portion	—	7,205,176
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock - $0.0001 par value; 300,000,000 shares authorized; 13,828,496 and 13,750,016 shares issued and outstanding at December 31, 2016 and 2015 respectively	1,382	1,374
Additional paid-in capital	137,763,499	136,637,678
Accumulated deficit	(125,850,355)	(112,831,757)
Total stockholders' equity	11,914,526	23,807,295
Total liabilities and stockholders' equity	$ 12,816,718	$ 40,111,972

See accompanying notes.

NEOTHETICS, INC.

STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2016	2015	2014
Expenses:			
Research and development	$ 6,578,678	$ 34,409,664	$ 5,174,876
General and administrative	5,463,622	7,639,427	4,416,181
Total operating expenses	12,042,300	42,049,091	9,591,057
Loss from operations	(12,042,300)	(42,049,091)	(9,591,057)
Interest income	59,465	26,033	7,555
Interest expense	(1,035,763)	(1,133,987)	(374,891)
Loss on change in fair value of preferred stock warrants	—	—	(860,843)
Net loss	$ (13,018,598)	$ (43,157,045)	$ (10,819,236)
Net loss per share, basic and diluted	$ (0.94)	$ (3.15)	$ (5.36)
Weighted average shares used to compute basic and diluted net loss per share	13,801,003	13,696,033	2,017,601

See accompanying notes.

Table of Contents

NEOTHETICS, INC.

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

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series B-2 Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance at December 31, 2013	1,500,000	$ 1,455,686	12,432,430	$ 23,095,634	4,402,438	$ 6,816,594	19,608,195	$ 26,120,739	—	$ —	508,009	$ 51	$ 2,164,063	$ (58,855,476)	$ (56,691,362)
Issuance of preferred stock for cash, net of $7,285 of offering costs	—	—	—	—	—	—	5,714,288	7,992,718	—	—	—	—	—	—	—
Issuance of preferred stock for cash, net of $566,580 offering costs	—	—	—	—	—	—	—	—	3,333,334	5,433,421	—	—	—	—	—
Common stock issued upon exercise of options	—	—	—	—	—	—	—	—	—	—	54,920	5	76,295	—	76,300
Share-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	612,952	—	612,952
Initial public offering of common stock at $14.00 per share, net of $7,361,037 offering costs	—	—	—	—	—	—	—	—	—	—	4,650,000	465	57,738,498	—	57,738,963
Conversion of preferred stock to common stock	(1,500,000)	(1,455,686)	(12,432,430)	(23,095,634)	(4,402,438)	(6,816,594)	(25,322,483)	(34,113,457)	(3,333,334)	(5,433,421)	8,225,062	822	70,913,970		70,914,792
Conversion of preferred stock warrants to common stock warrants	—	—	—	—	—	—	—	—	—	—	—	—	3,415,020	—	3,415,020
Net exercise of warrants											233,320	23	(23)	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(10,819,236)	(10,819,236)
Balance at December 31, 2014	—	$ —	—	$ —	—	$ —	$ —	$ —	—	$ —	13,671,311	$ 1,366	$134,920,775	$ (69,674,712)	$ 65,247,429
Common stock issued upon exercise of options	—	—	—	—	—	—	—	—	—	—	48,167	5	96,499	—	96,504
Common stock issued upon purchase of the employee stock purchase plan	—	—	—	—	—	—	—	—	—	—	8,038	1	42,125	—	42,126
Issuance of restricted shares, net of shares repurchased for minimum tax liability	—	—	—	—	—	—	—	—	—	—	22,500	2	193,498	—	193,500
Share-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	1,384,781	—	1,384,781
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(43,157,045)	(43,157,045)
Balance at December 31, 2015	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	13,750,016	$ 1,374	$136,637,678	$(112,831,757)	$ 23,807,295
Common stock issued upon exercise of options	—	—	—	—	—	—	—	—	—	—	29,300	3	33,539	—	33,542
Issuance of restricted shares, net of shares repurchased for minimum tax liability	—	—	—	—	—	—	—	—	—	—	49,180	5	—	—	5
Debt amendment warrant costs	—	—	—	—	—	—	—	—	—	—	—	—	9,417	—	9,417
Share-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	1,082,865	—	1,082,865
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(13,018,598)	(13,018,598)

Balance at December 31, 2016	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	13,828,496	$ 1,382	$137,763,499	$(125,850,355)	$ 11,914,526

See accompanying notes.

NEOTHETICS, INC.

STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2016	2015	2014
Operating activities			
Net loss	$ (13,018,598)	$ (43,157,045)	$ (10,819,236)
Adjustments to reconcile net loss to net cash used in operating activities:			
Loss on sale of assets	4,858	6,140	—
Depreciation and amortization	69,094	58,425	17,669
Non-cash interest expense on notes payable and debt	100,290	220,447	84,330
Share-based compensation	1,082,869	1,578,279	612,952
Loss on change in fair value of preferred stock warrants	—	—	860,843
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	947,452	(1,051,224)	(783,910)
Accounts payable and accrued expenses	(5,440,958)	4,433,561	455,234
Net cash used in operating activities	(16,254,993)	(37,911,417)	(9,572,118)
Investing activities			
Proceeds from sale of property and equipment	3,100	—	—
Increase in restricted cash	—	(200,000)	—
Purchase of property and equipment	—	(226,128)	(18,078)
Net cash provided by (used in) investing activities	3,100	(426,128)	(18,078)
Financing activities			
Proceeds from bank loan	—	—	10,000,000
Prepayment resulting in debt extinguishment	(9,514,058)	—	—
Principal payments on bank loan	(538,342)	—	(209,698)
Issuance of common stock from exercise of options	33,542	96,506	76,300
Issuance of common stock from employee stock purchase plan	—	42,126	—
Issuance of preferred stock for cash, net of offering costs	—	—	13,568,140
Proceeds from IPO, net of offering costs	—	—	57,738,963
Net cash provided by (used in) financing activities	(10,018,858)	138,632	81,173,705
Net (decrease) increase in cash and cash equivalents	(26,270,751)	(38,198,913)	71,583,509
Cash and cash equivalents, beginning of period	37,748,603	75,947,516	4,364,007
Cash and cash equivalents, end of period	$ 11,477,852	$ 37,748,603	$ 75,947,516
Supplemental disclosure of cash flow activity			
Cash paid for interest	$ 973,115	$ 912,500	$ 351,891
Supplemental disclosure of non-cash financing activities			
Warrants issued for services in connection with issuance of preferred stock	$ —	$ —	$ 142,001
Warrants issued in connection with Loan and Security Agreement	$ —	$ —	$ 207,429
Conversion of preferred stock warrants to common stock warrants	$ —	$ —	$ 3,415,020
Conversion of convertible preferred stock into common stock	$ —	$ —	$ 70,913,970

See accompanying notes.

1. Organization and Basis of Presentation

The Company was incorporated in Delaware on February 1, 2007, under the name Lipothera, Inc. In September 2008, the Company changed its name to Lithera, Inc. In August 2014, the Company changed its name to Neothetics, Inc. The Company is a clinical-stage specialty pharmaceutical company developing therapeutics for the aesthetic market. The Company's focus is on the further development and commercialization of LIPO-202, including for the reduction of localized fat deposits under the chin, or submental fat, and for the reduction of central abdominal bulging pending results from the submental Phase 2 proof of concept trial.

As of December 31, 2016, the Company has devoted substantially all of its efforts to product development, raising capital, and building infrastructure and has not realized revenues from its planned principal operations.

The accompanying financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We have incurred net losses from operations since inception and have an accumulated deficit of $125.9 million at December 31, 2016. We have cash and cash equivalents as of December 31, 2016 totaling $11.5 million. We have prepared cash flow forecasts which indicate, based on our current cash resources available, that we will have sufficient resources to fund our business, including our on-going Phase 2 proof of concept trial for the reduction of submental fat, for at least the next 12 months from the date of this filing. Based on the results of this trial, the Company will need to raise additional funding in the form of an equity or debt financing or through entering into a collaboration in order to fund the completion of any future trials and further development of LIPO-202. The Company may in the future seek additional capital from public or private offerings of its capital stock or it may elect to seek to fund operations through a debt facility. If the Company issues equity or debt securities to raise additional funds, its existing stockholders may experience dilution, it may incur significant financing costs, and the new equity or debt securities may have rights, preferences and privileges senior to those of its existing stockholders. The Company's ability to continue as a going concern and meet its minimum liquidity requirements in the future is dependent on its ability to raise significant additional capital, of which there can be no assurance. If the Company cannot generate sufficient additional financing on acceptable terms, it may be forced to significantly alter its business strategy, substantially curtail its current operations, or cease operations altogether.

2. Summary of Significant Accounting Policies

Use of Estimates

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

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of 90 days or less at the date of purchase to be cash equivalents. Cash and cash equivalents include cash in readily available checking and money market accounts.

Restricted Cash

Restricted cash as of December 31, 2016 represents a $200,000 restricted money market account used to secure the standby letter of credit issued in connection with a lease amendment (see Note 5 "Debt").

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash due to the financial position of the depository institution in which those deposits are held.

Fair Value of Financial Instruments

The carrying amounts of prepaid and other current assets, accounts payable and accrued expenses are reasonable estimates of their fair value because of the short term maturity of these items.

Property and Equipment

Property and equipment, which primarily consist of office furniture and equipment and computer equipment, are stated at cost and depreciated over the estimated useful lives of the assets (three to five years) using the straight-line method.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment. An impairment loss is recorded if and when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. While the Company's current and historical operating losses and negative cash flows are indicators of impairment, management believes that future cash flows to be received support the carrying value of its long-lived assets and, accordingly, has not recognized any impairment losses since inception.

Research and Development Costs

Research and development expenses consist primarily of salaries and related overhead expenses; fees paid to consultants and contract research organizations; costs related to acquiring and manufacturing clinical trial materials; and costs related to compliance with regulatory requirements.

All research and development costs are charged to expense as incurred.

Income Taxes

The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial reporting and the tax reporting basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Valuation allowances are recorded when the realizability of such deferred tax assets is not more likely than not.

The guidance on accounting for uncertainty in income taxes prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. The Company’s policy is to recognize interest expense and penalties related to income tax matters as a component of income tax expense. During 2016 and 2015, the Company had not recognized interest and penalties in the balance sheets or statements of operations. The Company is subject to taxation in the U.S. and state jurisdictions. The Company’s tax years from inception are subject to examination by the United States and California authorities due to the carryforwards of unutilized net operating losses (NOLs) and research and development credits.

Share-Based Compensation

Share-based compensation for the Company includes amortization related to all stock options, restricted stock awards and shares issued under the employee stock purchase plan, based on the grant-date fair value. The fair value of each option and restricted stock award is estimated on the date of grant using the Black-Scholes option pricing model. The expected life of the awards is based on the simplified method described in SEC Staff Accounting Bulletin No. 107. The expected volatility assumption is based upon the historical volatility of a number of publicly traded companies in similar stages of clinical development. The risk-free interest rate is based on the yield of U.S. Treasury bills with a life that approximates the expected life of the awards. The Company recognizes share-based compensation on a straight-line basis over the vesting term of the options.

Option grants to non-employees are valued at fair value and are expensed over the period services are provided. These options are subject to periodic revaluation to reflect the current fair value at each reporting period until the non-employee completes the performance obligation or the date on which a performance commitment is reached. During the year ended December 31, 2016, there were 250,000 shares issued to non-employee consultants. There was no non-cash compensation to consultants for the years ended December 31, 2015 and 2014.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common share equivalents outstanding during the period. Common stock equivalents are only included when their effect is dilutive. The Company’s potentially dilutive securities, which include common stock warrants and outstanding stock options under the stock option plan, have been excluded from the computation of diluted net loss per share as they would

be anti-dilutive. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding due to the Company's net loss position.

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because to do so would be anti-dilutive.

	December 31, 2016	December 31, 2015	December 31, 2014
Warrants for common stock	71,257	71,257	71,257
Common stock options and restricted stock awards issued and outstanding	871,203	1,363,027	1,198,830
	942,460	1,434,284	1,270,087

Recent Accounting Pronouncements

In November 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update (or "ASU") No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (ASU 2016-18), which requires companies to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This guidance will be effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is permitted. The Company is currently evaluating the effect that this guidance will have on our financial statements and related disclosures.

In August 2016, the FASB issued ASU 2016-15, Classification of Certain Cash Receipts and Cash Payments. This pronouncement gives guidance to clarify how certain cash receipts and payments should be presented and classified in the statement of cash flows. The guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is permitted. The Company is currently evaluating the timing of adoption of this guidance and the impact of the adoption of this guidance on its financial statements.

In March 2016, the FASB issued ASU 2016-09 ("ASU 2016-09"), Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. ASU 2016-09 simplifies several aspects of the accounting for employee share-based payments, including accounting for income taxes, forfeitures, statutory tax withholding requirements, and classification on the statement of cash flows. The amendments in this ASU are effective for annual periods beginning after December 15, 2016. Early adoption is permitted. The Company is evaluating the impact of adoption on its financial statements.

In February 2016, the FASB issued ASU 2016-02 ("ASU 2016-02"), Leases. ASU 2016-02 requires that lessees recognize assets and liabilities for the rights and obligations for leases with a lease term of more than one year. The amendments in this ASU are effective for annual periods ending after December 15, 2018. Early adoption is permitted. The Company is evaluating the impact of adoption on its financial statements.

In August 2014, the FASB issued ASU 2014-15 ("ASU 2014-15"), Disclosures of Uncertainties about an Entity's Ability to Continue as a Going Concern. Under the new guidance, management is required to assess an entity's ability to continue as a going concern and to provide related footnote disclosures in certain circumstances. The provisions of this standard are effective for annual periods ending after December 31, 2016, and for annual and interim periods thereafter. We adopted this guidance for the year ended December 31, 2016 and management believes that our existing cash and cash equivalents will be sufficient to fund our operations into the second quarter 2018.

3. Fair Value Measurements

Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, accounts payable, accrued expenses, including warrants issued in connection with financing arrangements, and long-term debt. Fair value estimates of these instruments are made at a specific point in time based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. The carrying amount of cash and cash equivalents, accounts payable, and accrued expenses are generally considered to be representative of their respective fair values because of the short-term nature of these instruments. The Company believes that the fair value of long-term debt approximates its carrying value based on the borrowing rates currently available to the Company for loans with similar terms.

The authoritative guidance for fair value measurements defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers or sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact. The guidance prioritizes three levels of inputs into the following hierarchy:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, 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 assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value on a recurring basis as of December 31, 2016 and 2015 are as follows:

		Fair Value Measurements at Reporting Date Using		
	Balance as of December 31, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market fund[1]	$ 11,477,852	$ 11,477,852	$ —	$ —
Total assets	$ 11,477,852	$ 11,477,852	$ —	$ —

(1) Included as a component of cash and cash equivalents on accompanying balance sheet.

		Fair Value Measurements at Reporting Date Using		
	Balance as of December 31, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market fund[1]	$ 36,752,200	$ 36,752,200	$ —	$ —
Total assets	$ 36,752,200	$ 36,752,200	$ —	$ —

(1) Included as a component of cash and cash equivalents on accompanying balance sheet.

4. Property and Equipment

Property and equipment consist of the following:

	December 31,	
	2016	2015
Office furniture and equipment	$ 254,049	$ 279,547
Less accumulated depreciation and amortization	(144,729)	(93,175)
	$ 109,320	$ 186,372

Depreciation and amortization expense related to furniture and equipment amounted to $69,094, $58,425, and $17,669, for the years ended December 31, 2016, 2015, and 2014 respectively.

5. Debt

Loans

In February 2010, and as amended during 2012, the Company entered into a loan and security agreement (2010 Loan and Security Agreement) with Silicon Valley Bank (SVB), for borrowings of $3,750,000, collateralized by all assets of the Company. In connection with the borrowings, the Company issued warrants to the bank for the purchase of a total of 64,865 shares of Series B convertible preferred stock and warrants to purchase 75,000 shares of Series C convertible preferred stock. Effective upon the IPO, this was converted to a warrant to purchase 24,419 shares of common stock at a weighted average exercise price of $9.90 and expire ten years from the date of issuance.

In 2013, through the payoff of the loan in June 2014 the Company paid interest equal to 7.78% above the 24-month Treasury Rate with a floor of 8.00%. The Company recorded total interest expense of $4,186 for the twelve months ended December 31, 2014, related to the 2010 Loan and Security Agreement, as amended

In June 2014, the Company entered into a Loan and Security Agreement (Loan Agreement) with Hercules Technology Growth Capital Inc. that provided for borrowings up to $10.0 million available to the Company in two tranches. Upon closing of the Loan Agreement, the Company borrowed $4.0 million. In October 2014, the Company entered into the first amendment of the Loan Agreement and borrowed the remaining $6.0 million available under the agreement.

In connection with the Loan Agreement, in June 2014, the Company issued warrants to purchase shares of Series C convertible preferred stock equal to 4% of the amount advanced under the loan. Effective upon the IPO, this was converted to a warrant to purchase 46,838 shares of common stock at $8.54, which expires on June 11, 2024. The fair value of the warrants issued was $207,429, based on the fair value of such Series C warrants at the date of issuance. The warrants' fair value and financing fees of approximately $133,000 were recorded as a debt discount.

In March 2016, the Company entered into the second amendment of the Loan Agreement that provided for a prepayment of the outstanding loan carrying amount of $5.5 million with a prepayment fee of $110,000. In connection with the second amendment, the Company re-priced the outstanding warrants to purchase 46,838 shares of common stock at a new exercise price of $0.62, which will expire in September 2022 unless exercised prior to such expiration date. The Company recorded a debt discount of $9,417 associated with the fair value of the warrants issued in connection with the amendment. In addition, the Company incurred loan amendment fees and legal fees of $52,400, which the Company recorded as a debt discount.

In September 2016, the Company prepaid the remaining outstanding balance under the Loan Agreement at a carrying amount of $4.0 million with a prepayment fee of $120,000 and an end of term fee of $300,000. Accordingly, the Loan Agreement was terminated on September 23, 2016. Upon termination of the Loan Agreement, the prepayment fees of $230,000 and unamortized end of term fee of $260,000 were recorded as interest expense

From June 2014 through payoff in September 2016, the Company paid interest equal to the greater of either 9.0%, plus the Prime Rate as reported in The Wall Street Journal, less 3.25% or 9.0%. The Company recorded total interest expense of $1,035,763, $1,133,987 and $374,891 for the twelve months ended December 31, 2016, December 31, 2015 and December 31, 2014, respectively.

Letter of Credit

In January 2015, the Company executed a lease amendment with LJ Gateway, LLC for new office space. In connection with this lease amendment the Company issued a stand-by letter of credit in the amount of $200,000 in lieu of a security deposit. The standby letter of credit is secured by a restricted money market account. The terms of the standby letter of credit expire in May 2020 and are subject to automatic yearly renewal prior to this date.

6. Convertible Preferred Stock and Stockholders' Equity

Common Stock

On December 1, 2015, the Company entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald, as a sales agent pursuant to which the Company may offer and sell from time to time, through Cantor Fitzgerald shares of Neothetics common stock, par value $0.0001 per share, having an aggregate offering price of up to $20.0 million. The minimum share price for this Controlled Equity Offering is selected at the discretion of the board of directors.

The Company cannot provide any assurances that it will issue any shares pursuant to the Sales Agreement. Subject to the terms and conditions of the Sales Agreement, Cantor Fitzgerald will use commercially reasonable efforts consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations and the rules of the NASDAQ Global Market to sell shares from time to time based upon Neothetics' instructions, including any price, time or size limits specified by Neothetics. Under the Sales Agreement, Cantor Fitzgerald may sell shares by any method deemed to be an "at-the-market" offering as defined in Rule 415 under the U.S. Securities Act of 1933, as amended, or any other method permitted by law, including in privately negotiated transactions. Neothetics will pay Cantor Fitzgerald a commission of 3.0% of the aggregate gross proceeds from each sale of shares and has agreed to provide Cantor Fitzgerald with customary indemnification and contribution rights. Neothetics has also agreed to reimburse Cantor Fitzgerald for legal fees and disbursements, not to exceed $50,000 in the aggregate, in connection with entering into the Sales Agreement.

The Sales Agreement may be terminated by Cantor Fitzgerald or Neothetics at any time upon notice to the other party, or by Cantor Fitzgerald at any time in certain circumstances, including the occurrence of a material and adverse change in Neothetics' business or financial condition that makes it impractical or inadvisable to market the shares or to enforce contracts for the sale of the shares. As of December 31, 2016, no shares were issued pursuant to the Sales Agreement.

Stock Compensation Plan

The Company adopted a Stock Option Plan in 2007, or the 2007 Plan under which 1,271,360 shares of common stock were reserved for issuance to employees, non-employee directors, and consultants of the Company. Effective upon the completion of the Company's IPO, the board of directors determined not to grant any further awards under the 2007 Plan.

In September 2014, the Company's board of directors and stockholders approved and adopted the 2014 Equity Incentive Plan (the 2014 Plan). The 2014 Plan became effective immediately prior to the Company's IPO. A total of 1,000,000 shares of common stock were initially reserved for issuance under the 2014 Plan. This reserve automatically increased on January 1, 2015 and will continue to increase each subsequent anniversary through 2024, by an amount equal to the smaller of (a) 4% of the number of shares of common stock issued and outstanding on the date immediately preceding December 31 and (b) an amount determined by our board of directors. All shares that remained available, expired, or otherwise terminated without having been exercised in full and unvested shares that were forfeited to or repurchased by us under the 2007 Plan were rolled into 2014 Plan. The 2014 Plan provides for the grant of stock options, stock appreciation rights, restricted stock, restricted stock units, or RSU's, performance shares, and units and other cash-based or share-based awards. In addition, the 2014 Plan contains a mechanism through which we may adopt a deferred compensation arrangement in the future. Recipients of stock options shall be eligible to purchase shares of the Company's common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant.

The following table summarizes stock option and restricted stock award transactions under the 2014 Plan during the years ended December 31, 2016, December 2015 and 2014:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Contractual Life — Years	Total Intrinsic Value
Outstanding at December 31, 2013	368,566	$ 1.59	6.2	
Granted	906,752	$ 1.68		
Exercised	(54,920)	$ 1.39		
Forfeited	(21,568)	$ 1.33		
Outstanding at December 31, 2014	1,198,830	$ 1.68	8.3	$ 10,489,128
Granted	400,719	$ 7.28		
Exercised	(97,348)	$ 0.99		$ 767,354
Forfeited	(139,174)	$ 4.49		
Outstanding at December 31, 2015	1,363,027	$ 3.09	7.9	$ 244,998
Granted	563,856	$ 1.09		
Exercised	(78,480)	$ 0.43		$ 37,646
Forfeited	(977,200)	$ 2.27		
Outstanding and exercisable at December 31, 2016	871,203	$ 2.95	8.6	$ 18,363
Vested and options expected to vest at December 31, 2016	840,403	$ 3.00	8.6	$ 15,934

The 2014 Plan allows for the exercise of unvested options, which are subject to repurchase until vesting occurs. All options exercised to date were fully vested at date of exercise. No grants expired during the year ended December 31, 2016.

The weighted average fair value of options granted was $0.46 and 3.14 for the twelve months ended December 31, 2016 and December 31, 2015, respectively. The weight average fair value of options vested was $1.50 at December 31, 2016. Total cash received upon the exercise of stock options was $33,542 for the year ended December 31, 2016.The unrecognized compensation cost related to non-vested stock options and restricted stock awards outstanding at December 31, 2016 and December 31, 2015, net of expected forfeitures, was $420,339 and $3,102,234, respectively, to be recognized over a weighted-average remaining vesting period of approximately 1.7 and 2.6 years, respectively.

Share-Based Compensation

The estimated fair value of each option award granted was determined on the date of grant using the Black-Scholes option-pricing valuation model with the following weighted-average assumptions for options grants.

	Year Ended December 31,		
	2016	2015	2014
Weighted Average Assumptions:			
Risk-free interest rate	1.61%	1.69%	1.85%
Expected dividend yield	0%	0%	0%
Expected volatility	44.89%	43.72%	87.00%
Expected term (in years)	5.4	5.8	6.0

The risk-free interest rate assumption was based on the yield of an applicable rate for U.S. Treasury instruments with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company never paying cash dividends and having no expectation of paying cash dividends in the foreseeable future. The weighted average expected term of options was calculated using the simplified method as permitted by accounting guidance for stock-based compensation. In addition, due to the Company's limited historical data, the estimated volatility was calculated based upon the historical volatility of comparable companies in the biotechnology industry whose share prices are publicly available for a sufficient period of time.

Employee Stock Purchase Plan

In November 2014, the Company adopted the 2014 Employee Stock Purchase Plan (the "ESPP"), which enables eligible employees to purchase shares of the Company's common stock using their after tax payroll deductions of up to 15% of their eligible compensation, subject to certain restrictions.

The ESPP initially authorized the issuance of 170,000 shares of common stock pursuant to purchase rights granted to employees. The number of shares of common stock reserved for issuance automatically increased on January 1, 2015 and will continue to increase on each January 1 thereafter through January 1, 2024, by the smaller of (a) 1.0% of the total issued and outstanding Shares on the preceding December 31, and (b) a number of Shares determined by the Board of Directors of the Company. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code.

The Company estimates the fair value of shares issued to employees under the ESPP using a Black-Scholes option-pricing model. The Black-Scholes model requires the use of subjective and complex assumptions, including (a) the expected stock price volatility, (b) the calculation of the expected term of the award, (c) the risk free interest rate and (d) the expected dividend yield, which determine the fair value of share-based awards.

There were no shares issued under the ESPP during the year ended December 31, 2016.

The weighted average assumptions used to estimate the fair value of shares issued under the ESPP in the years ended December 31, 2015 and 2014 using the Black-Scholes option pricing model were as follows:

	For the Year Ended	
	2015	2014
Weighted Average Assumptions:		
Risk-free interest rate	0.39%	0.34%
Expected dividend yield	0%	0%
Expected volatility	45.13%	45.43%
Expected term (in years)	1.23	1.27

The Company recognized non-cash share-based compensation expense related to its ESPP, restricted stock awards and stock options granted to employees and directors in its research and development and its general and administrative functions as follows:

	Year Ended December 31,		
	2016	2015	2014
Research and development	$ 163,996	$ 410,099	$ 235,867
General and administrative	918,869	974,682	377,085
	$ 1,082,865	$ 1,384,781	$ 612,952

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance is as follows:

	December 31, 2016	December 31, 2015
Warrants issued and outstanding	71,257	71,257
Stock options and restricted stock awards issued and outstanding	871,203	1,363,027
Authorized for future option grants	2,276,079	1,312,734
Employee stock purchase plan	436,175	298,675
	3,654,714	3,045,693

NEOTHETICS, INC.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

7. Income Taxes

As of December 31, 2016, the Company had federal and California tax net operating loss (NOL) carryforwards available to reduce its future taxable income of approximately $119,242,000 and $63,992,000, respectively. The federal NOL begins to expire in 2027 and the state NOL begins to expire in 2017 unless previously utilized. At December 31, 2016, the Company has federal and state research tax credits of $3,803,000 and $2,623,000, respectively. The federal research credit expires in 2027 unless previously utilized. The California research credit will carry forward indefinitely until utilized.

Utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders. Since the Company's formation, the Company has raised capital through the issuance of capital stock on several occasions, including the IPO in 2014, which on their own or combined with the purchasing stockholders' subsequent disposition of those shares, may have resulted in such an ownership change, or could result in an ownership change in the future.

The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since the Company's formation due to the complexity and cost associated with such a study and the fact that there may be additional such ownership changes in the future. If the Company has experienced an ownership change at any time since its formation, utilization of the NOL or R&D credit carryforwards would be subject to an annual limitation under Section 382 of the Code, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term, tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization. Further, until a study is completed and any limitation known, no amounts are being considered as an uncertain tax position or disclosed as an unrecognized tax benefit. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact its effective tax rate. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets, with a corresponding reduction of the valuation allowance.

Until the study is completed, the Company has removed federal and state operating losses of approximately $44,276,000 and federal and state research and development credits of approximately $5,534,000 from its deferred tax asset schedule and has recorded a corresponding decrease to its valuation allowance.

Significant components of the Company's deferred tax assets for federal and state income taxes at December 31, 2016 and 2015 are shown below. A valuation allowance has been established as realization of such deferred tax assets is uncertain.

	2016	2015
Deferred tax assets:		
Accrued compensation	46,000	138,000
Non-qualified Stock Options	173,000	349,000
Other, net	34,000	106,000
Total deferred tax assets	253,000	593,000
Valuation allowance	(253,000)	(593,000)
	$ —	$ —

There was no material income tax expense for the years ended December 31, 2016 and 2015.

A reconciliation of income tax expense as compared to the tax expense calculated by applying the statutory federal and state tax rate to income before taxes for the years ended December 31 is as follows:

	2016	2015	2014
Income tax at statutory rates	39.8%	39.8%	40.0%
Warrant liability remeasurement	0.0%	0.0%	(3.0%)
NOL not recorded due to 382 limitations	(36.7%)	(39.3%)	(34.0%)
Other	(3.1%)	(0.5%)	(3.0%)
Total tax expense	0.0%	0.0%	0.0%

The Company follows the provisions under the Income Taxes topic of the Codification which addresses accounting for the uncertainty in income taxes. The evaluation of a tax position in accordance with this topic is a two-step process. The first step involves recognition. The Company determines whether it is more likely than not that a tax position will be sustained upon tax examination, including resolution of any related appeals or litigation, based on only the technical merits of the position. The technical merits of a tax position derive from both statutory and judicial authority (legislation and statutes, legislative intent, regulations, rulings, and case law) and their applicability to the facts and circumstances of the tax position. If a tax position does not meet the more-likely-than-not recognition threshold, the benefit of that position is not recognized in the financial statements. The second step is measurement. A tax position that meets the more-likely-than-not recognition threshold is measures to determine the amount of benefit to recognize in the financial statements. The tax position is measured as the largest amount of benefit that is greater than 50% likely of being realized upon ultimate resolution with a taxing authority.

The Company files income tax returns in the United States and California. The Company currently has no years under examination by any jurisdiction; however, the Company is subject to income tax examination by federal and state for years beginning in 2013 and 2012, respectively. However, to the extent allowed by law, the taxing authorities may have the right to examine prior periods where NOLs and tax credits were generated and carried forward, and make adjustment up to the amount of the carryforwards. The Company does not have any unrecognized tax benefits as of December 31, 2016 and does not anticipate that the amount of unrecognized tax benefits will significantly change within the next twelve months. The Company has not recognized interest or penalties in its consolidated statements of operations and comprehensive loss since inception.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest and/or penalties in the statements of operations for the years ended December 31, 2016, 2015, and 2014 or for the period from February 1, 2007 to December 31, 2016.

8. Commitments

Operating Leases

The Company entered into a non-cancelable operating lease for its facilities on January 20, 2015. The lease expires in March 2020. Rent expense was $429,927, $388,997 and $228,281 for the years ended December 31, 2016, 2015 and 2014, respectively. The payments escalate over the term of the lease; however, the Company recognizes the expense on a straight-line basis over the term of the lease.

The following table summarizes the minimum lease payments under this commitment.

2017	$	395,520
2018		410,850
2019		431,508
2020		109,293
2021 and thereafter		—
Total	$	1,347,171

9. Subsequent Events

In the first quarter of 2017, the Company entered into an Eleventh Amendment to the Lease with LJ Gateway Office LLC. Concurrent with entering into the Lease Amendment, the Company entered into a Sublease with Abacus Data Systems, Inc. (“Abacus”). This Lease Amendment provides for an additional space consisting of approximately 3,580 square feet located at Suite No. 250, 9171 Towne Centre Drive, San Diego California (the “New Premises”). The Company intends to occupy the New Premises as its headquarters while subleasing the entire Original Premises to Abacus. The base monthly rent for the New Premises will be $10,203 per month commencing on February 13, 2017.

Upon occurrence of Abacus retaining possession of the original premises, Abacus shall receive a discount of 50% off the base rent for months five through nine and will not have to pay base rent for the first month as well as months three and four. Additionally, Abacus will pay to the Company a base rent of $27,768 for the seconds’ month rent and an additional $30,317 security deposit. The base rent will increase by three percent on each annual anniversary.

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SIGNATURES

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

NEOTHETICS, INC.

Date: March 23, 2017

By: /s/ Susan A. Knudson
Name: Susan A. Knudson
Title: Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, 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/ Susan A. Knudson Susan A. Knudson	Chief Financial Officer (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	March 23, 2017
/s/ Martha J. Demski Martha J. Demski	Director	March 23, 2017
/s/ Maxim Gorbachev Maxim Gorbachev	Director	March 23, 2017
/s/ Jeffrey M. Nugent Jeffrey M. Nugent	Director	March 23, 2017
/s/ Kim P. Kamdar Kim P. Kamdar, Ph.D.	Lead Independent Director	March 23, 2017

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NEOTHETICS, INC.
EXHIBIT INDEX

Exhibit Number	Exhibit Title	Filed with this Form 10-K	Incorporated by Reference		
			Form	File No.	Date Filed
3.1	Amended and Restated Certificate of Incorporation.		S-1	333-199449	10/17/2014
3.2	Amended and Restated Bylaws.		S-1	333-199449	10/17/2014
4.1	Form of Stock Certificate.		S-1/A	333-199449	11/10/2014
4.2	Warrant to Purchase Stock, dated February 23, 2010, issued to Silicon Valley Bank.		S-1	333-199449	10/17/2014
4.3	Warrant to Purchase Stock, dated March 30, 2012, issued to Silicon Valley Bank.		S-1	333-199449	10/17/2014
4.4	Warrant to Purchase Stock, dated August 17, 2012, issued to Silicon Valley Bank.		S-1	333-199449	10/17/2014
4.5	Warrant Agreement, dated June 11, 2014, by and between the Registrant and Hercules Technology III, L.P.		S-1	333-199449	10/17/2014
4.6	Fourth Amended and Restated Investors' Rights Agreement, dated September 22, 2014, by and between the Registrant and the investors listed therein.		S-1	333-199449	10/17/2014
4.7	Warrant Modification Agreement, dated March 30, 2016, by and between the Registrant and Hercules Technology III, L.P.		10-Q	001-36754-161641683	05/12/2016
10.1†	Technology Transfer Agreement, dated December 12, 2012, by and between the Registrant and Domain Russia Investments Limited.		S-1	333-199449	10/17/2014
10.2†	Assignment and Assumption Agreement, dated December 12, 2012, by and among the Registrant, Domain Russia Investments Limited and NovaMedica LLC.		S-1	333-199449	10/17/2014
10.3†	Clinical Development and Collaboration Agreement, dated July 2, 2013, by and between the Registrant and NovaMedica LLC.		S-1	333-199449	10/17/2014
10.4†	Contract No. 0702/12, dated July 2, 2013, by and between the Registrant and NovaMedica LLC.		S-1	333-199449	10/17/2014
10.5	Lease, dated July 3, 2008, by and between the Registrant WW&LJ Gateways, LTD.		S-1	333-199449	10/17/2014

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Exhibit Number	Exhibit Title	Filed with this Form 10-K	Incorporated by Reference		
			Form	File No.	Date Filed
10.6	Ninth Amendment to Lease, dated April 21, 2014, by and between the Registrant and LJ Gateways Office LLC (as successor in interest to WW&LJ Gateways, LTD).		S-1	333-199449	10/17/2014
10.7	Tenth Amendment, date January 20, 2015, by and between the Registrant and LJ Gateway Office, LLCS(as successor in interest to WW&LJ Gateways, LTD).		10-K	001-36754-161533653	03/29/2015
10.8	Eleventh Amendment, dated as of January 31, 2017, by and between the Registrant and LJ Gateways Office LLC (as successor in interest to WW&LJ Gateways, LTD).		8-K	001-363754-17609634	02/14/2017
10.9	Sublease, dated as of January 27, 2017, by and between Neothetics, Inc. and Abacus Data Systems, Inc.		8-K	001-363754-17609634	02/14/2017
10.10	Loan and Security Agreement, dated June 11, 2014, by and between the Registrant and Hercules Technology Growth Capital, Inc.		S-1	333-199449	10/17/2014
10.11	First Amendment to Loan and Security Agreement, dated October 21, 2014, by and between the Registrant and Hercules Technology Growth Capital, Inc.		S-1/A	333-199449	11/10/2014
10.12	Second Amendment to Loan and Security Agreement, date March 30, 2016, by and between the Registrant and Hercules Technology Growth Capital, Inc.		10-Q	001-36754-16164168	05/12/2016
10.13+	Separation Agreement, dated January 21, 2016, by and between the Registrant and Lincoln Krochmal		10-K	001-36754-161533653	03/29/2015
10. 14+	Separation Agreement, dated January 21, 2016, by and between the Registrant and George W. Mahaffey		10-K	001-36754-161533653	03/29/2015
10.15+	Executive Employment Agreement, dated October 15, 2014, by and between the Registrant and Susan Knudson.		S-1	333-199449	10/17/2014
10.16+	Letter Agreement, dated July 3, 2014, by and between the Registrant and Martha J. Demski.		S-1	333-199449	10/17/2014
10.17+	Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers.		S-1	333-199449	10/17/2014

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Exhibit Number	Exhibit Title	Filed with this Form 10-K	Incorporated by Reference		
			Form	File No.	Date Filed
10.18+	Amended and Restated 2007 Stock Plan, as amended.		S-1/A	333-199449	11/10/2014
10.19+	Form of Stock Option Agreement under 2007 Stock Plan.		S-1	333-199449	10/17/2014
10.20+	2014 Equity Incentive Plan.		S-1/A	333-199449	11/10/2014
10.21+	Amendment to 2014 Equity Incentive Plan		10-Q	001-36754-161823046	08/11/2016
10.22+	Form of Stock Option Agreement under 2014 Equity Incentive Plan.		S-1/A	333-199449	11/10/2014
10.23+	Form of Restricted Stock Units Agreement under the 2014 Equity Incentive Plan.		S-1/A	333-199449	11/10/2014
10.24+	Form of Restricted Stock Agreement under the 2014 Equity Incentive Plan.		S-1/A	333-199449	11/10/2014
10.25+	Form of Notice of Grant of Restricted Stock Units under the 2014 Equity Incentive Plan.		S-1/A	333-199449	11/10/2014
10.26+	Form of Notice of Grant of Restricted Stock under the 2014 Equity Incentive Plan.		S-1/A	333-199449	11/10/2014
10.27+	Form of Notice of Grant of Stock Option under the 2014 Equity Incentive Plan.		S-1/A	333-199449	11/10/2014
10.28+	2014 Employee Stock Purchase Plan.		S-1/A	333-199449	11/10/2014
10.29+	Non-Employee Director Compensation Policy.		S-1	333-199449	10/17/2014
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.	X			
31.1‡	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended.	X			
32.1‡	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101.INS	XBRL Instance Document	X			
101.SCH	XBRL Taxonomy Extension Schema Document	X			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X			

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101.LAB	XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

(1) Registration Statement (Form S-3 No. 333-208290) and related prospectus of Neothetics, Inc. pertaining to the registration of common stock, preferred stock, debt securities, warrants and units,
(2) Registration Statement (Form S-8 No. 333-203059) pertaining to the 2014 Equity Incentive Plan and 2014 Employee Stock Purchase Plan of Neothetics, Inc., and
(3) Registration Statement (Form S-8 No. 333-200409) pertaining to the Amended and Restated 2007 Stock Plan, as amended, 2014 Equity Incentive Plan and 2014 Employee Stock Purchase Plan;

of our report dated March 23, 2017, with respect to the financial statements of Neothetics, Inc. included in this Annual Report (Form 10-K) of Neothetics, Inc. for the year ended December 31, 2016.

/s/ Ernst & Young LLP

San Diego, California
March 23, 2017

Exhibit 31.1

CERTIFICATION 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

I, Susan Knudson, certify that:

1. I have reviewed this annual report on Form 10-K of Neothetics, Inc. for the fiscal year ended December 31, 2016;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [paragraph omitted in accordance with Exchange Act Rule 13a-14(a)];

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting

Date: March 23, 2017

By: /s/ Susan A. Knudson
Susan A. Knudson
Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Neothetics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Susan Knudson, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U..S.C. 78m); and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 23, 2017

By: /s/ Susan A. Knudson
Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate document.