PRELIMINARY PROSPECTUS (Subject to completion) January 18, 2017

7,692,308 shares

Common stock

This is an initial public offering of shares of our common stock. We are selling 7,692,308 shares of our common stock. Prior to this offering, there has been no public market for our common stock. We have applied to list our common stock on The NASDAQ Global Market under the symbol "BBRX." We expect that the initial public offering price for our common stock will be between $18.00 and $21.00 per share.

We are an "emerging growth company" under applicable Securities and Exchange Commission rules and will be subject to reduced public company reporting requirements for this prospectus and future filings. See "Prospectus Summary—Implications of being an emerging growth company."

Following this offering, Apple Tree Partners IV, L.P. and its affiliates, or Apple Tree, will control a majority of the voting power of our common stock and we will be a "controlled company" within the meaning of the NASDAQ listing standards.

Apple Tree has indicated an interest in purchasing an aggregate of approximately $50 million of shares of our common stock at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may sell more, less or no shares in this offering to Apple Tree, or Apple Tree may determine to purchase more, less or no shares in this offering.

Apple Tree has agreed to purchase $40 million of our common stock in a separate private placement concurrent with the completion of this offering at a price per share equal to the initial public offering price. The sale of such shares will not be registered under the Securities Act of 1933, as amended. The closing of this offering is not conditioned upon the closing of such concurrent private placement.

Our business and investment in our common stock involve significant risks. These risks are described under the caption "Risk Factors" beginning on page 14 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per share	Total
Initial public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds, before expenses, to Braeburn Pharmaceuticals	$	$

(1) We have agreed to reimburse the underwriters for certain FINRA-related expenses. We refer you to "Underwriting" beginning on page 183 for additional information regarding total underwriting compensation.

The underwriters may also purchase up to an additional 1,153,846 shares from us at the initial public offering price, less the underwriting discount, within 30 days from the date of this prospectus.

The underwriters expect to deliver the shares of common stock to investors on or about , 2017.

J.P. Morgan **BofA Merrill Lynch**

Deutsche Bank Securities

Canaccord Genuity

, 2017

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You should rely only on the information contained in this prospectus or in any free writing prospectus prepared by us or on our behalf. We have not, and the underwriters have not, authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdictions where the offer and sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the cover page of this prospectus. Our business, financial condition, results of operations and prospects may have changed since such date.

Through and including , 2017 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

Information contained on our website is not a part of this prospectus. Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about, and to observe any restrictions relating to, this offering and the distribution of this prospectus outside of the United States.

Prospectus summary

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes included elsewhere in this prospectus. You should also consider, among other things, the matters described under "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case appearing elsewhere in this prospectus. Unless otherwise stated, all references to "us," "our," "Braeburn," "we," the "Company" and similar designations refer to Braeburn Pharmaceuticals, Inc.

Overview

We are a commercial-stage pharmaceutical company focused on the development and commercialization of novel long-acting medications for serious disorders of the central nervous system, or CNS. Our proprietary implantable and injectable delivery mechanisms provide differentiated solutions for chronic diseases with high unmet medical needs. Our specialty CNS focus is on fast-growing therapeutic areas recognized as serious public health crises, where long-acting technologies offer important benefits such as increased medication compliance, improved patient convenience, reduced risk of abuse and relapse and reduced public health and societal costs.

Our lead therapeutic area is opioid addiction, which affects 2.6 million people in the United States across all socioeconomic groups. A 2016 survey from the Kaiser Family Foundation indicates that nearly half of all Americans know someone who suffers from opioid addiction. We have one approved product, Probuphine, a six-month buprenorphine implant for the maintenance treatment of opioid addiction, which was approved by the Food and Drug Administration, or FDA, on May 26, 2016. In November 2016, we reported positive top-line results from a Phase 3 trial of weekly and monthly CAM2038, an injectable formulation of buprenorphine, for opioid addiction. CAM2038 achieved non-inferiority compared to oral daily buprenorphine based on the primary endpoint and superiority to oral daily buprenorphine based on a secondary endpoint. Our other therapeutic areas of focus are pain, schizophrenia and spasticity, which refers to feelings of stiffness and a wide range of involuntary muscle spasms. We have four additional late-stage product candidates in our pipeline across our different therapeutic areas, as well as two earlier-stage product candidates.

We believe that long-acting medications for specialty CNS conditions are not just a matter of convenience, but are an essential tool for the effective treatment of these diseases. These are chronic CNS conditions requiring constant vigilance, where the consequences of suboptimal treatment compliance can range from severe to life-threatening. For our therapeutic areas of focus, we are developing weekly, monthly and six-month dosage formulations. We believe that our medications will allow healthcare providers to treat patients throughout the continuum of care, providing personalized drug delivery that is optimized to help patients progress from treatment initiation through long-term maintenance.

As of January 1, 2017, we have 97 employees in the United States; 61 are field-based employees engaged in sales, physician training and other marketing support functions, nine are engaged in positions directly related to sales and marketing, 13 are engaged in positions related to clinical development, product development, regulatory and operations and 14 are engaged in positions related to general and administrative. To date, our post-approval commercialization efforts for Probuphine have been focused on a medical affairs driven introduction, including training healthcare providers to prescribe and implant Probuphine, working with payors to ensure comprehensive reimbursement and implementing our new

specialty pharmacy distribution model. We are planning a full-scale commercial launch of Probuphine with our new fully-deployed field force in the first quarter of 2017, which we intend to further expand if and when we launch CAM2038.

Recent developments

Although our audited consolidated financial statements for the year ended December 31, 2016 are not yet available, we estimate that our cash and cash equivalents were approximately $30.5 million as of December 31, 2016. The foregoing selected, unaudited preliminary financial information has been prepared in good faith based on our internal reporting. The results presented above are preliminary estimates and are not final and remain subject to revision based on the completion of the accounting and financial reporting processes necessary to finalize our audited consolidated financial statements as of and for the year ended December 31, 2016. In addition, Apple Tree has agreed to purchase $40 million of our common stock in a separate private placement concurrent with the completion of this offering at a price per share equal to the initial public offering price.

Our markets

Opioid addiction is a public health epidemic with 12.5 million people misusing opioid pain relievers and over 800,000 people using heroin in the United States in 2015. In 2013, prescription opioid abuse accounted for approximately an estimated $80 billion in U.S. health and social costs. Despite the extreme high social costs and large patient population of opioid addiction, less than half of the estimated 2.6 million people diagnosed with opioid addiction in the United States receive medication.

Our other target markets include pain and schizophrenia, both of which we believe represent high unmet medical needs and market potential. According to the National Institute on Drug Abuse, or NIDA, over 100 million people suffer from chronic pain in the United States, with 23 million adults reporting a significant level of daily pain. The total annual incremental cost of health care due to chronic pain in 2010 was up to $635 billion in the United States.

Schizophrenia affects up to 1% of the U.S population, or approximately 2.4 million individuals, and accounts for 20% of all hospital bed-days in the United States. It is one of the leading causes of disability in the United States, and in 2013, cost the United States approximately $156 billion in direct and indirect expenses.

Opioid addiction: the problem and inherent limitations of current treatments

The U.S. government has declared opioid abuse an unprecedented public health epidemic, with more than 60% of drug overdose deaths involving an opioid. The epidemic is driven by opioid medications prescribed for pain. Between 2000 and 2014, nearly half a million Americans died from drug overdoses and the number of overdose deaths related to opioids quadrupled, closely tracking the increase in prescriptions dispensed for opioids. In 2015, healthcare providers wrote approximately 228 million prescriptions for opioids, more than the number of American adults. On a daily basis, more than 650,000 opioid prescriptions are dispensed, 3,900 people begin to abuse or misuse prescription opioids, and 580 people begin to use heroin. Every day approximately 2,000 people are hospitalized and 78 people die from overdose involving opioids, resulting in approximately 30,000 opioid overdose deaths per year.

The current standard of care for outpatient treatment of opioid addiction is oral daily buprenorphine, which generally should be life-long therapy because opioid addiction is typically a chronic life-long

condition. Although oral daily buprenorphine is an effective treatment for opioid addiction, the burden of daily medication coupled with the inconvenience of the commonly prescribed sublingual formulation contributes to low patient compliance and suboptimal medical outcomes. While relapse can have dire consequences, on average patients take medications only 33% of the time that they need it. Each day a patient is off medication, the odds of relapse increase significantly, and consequently a patient is in significant danger of potential overdose and death. Additionally, buprenorphine is a synthetic opiate and therefore, when dispensed to patients for self-administration, is susceptible to diversion, or selling on the street, misuse, abuse and accidental pediatric exposure.

Opioid addiction: our solutions

We intend to address the limitations of current treatment approaches for opioid addiction by replacing oral daily medications, including sublingual formulations, with a suite of complementary long-acting implantable and injectable medications. Our solutions are designed to establish a continuum of care for patients, providing personalized drug delivery that is optimized to help patients progress from treatment initiation through long-term maintenance. We believe that our product portfolio addresses several limitations of the current treatment pathway in opioid addiction as described below:

- **Enhanced medication compliance and clinical outcomes.** Our long-acting treatments will provide patients and healthcare providers with increased confidence that patients have received their required dose of medication, thereby leading to more successful clinical outcomes.
- **Improved quality of life for patients.** Our long-acting treatments will relieve the burden of daily medication and daily reminders of the disease, as well as reduce the stigma of opioid addiction for patients and their caregivers.
- **Improved social outcomes.** Chronic abuse of opioids can lead to impaired judgment, decision-making, learning, memory and behavior control, making it difficult for addicted patients to carry out normal daily activities. By reducing the risk of relapse and abuse, our long-acting treatments will help patients take care of their families, fulfill their passions and lead more productive and rewarding lives.
- **Help manage a public health epidemic.** Because our products are physician-administered, our long-acting treatments could help reduce the risk of drug abuse, addiction, overdose and life-threatening accidental pediatric exposure.

Opioid addiction: our products

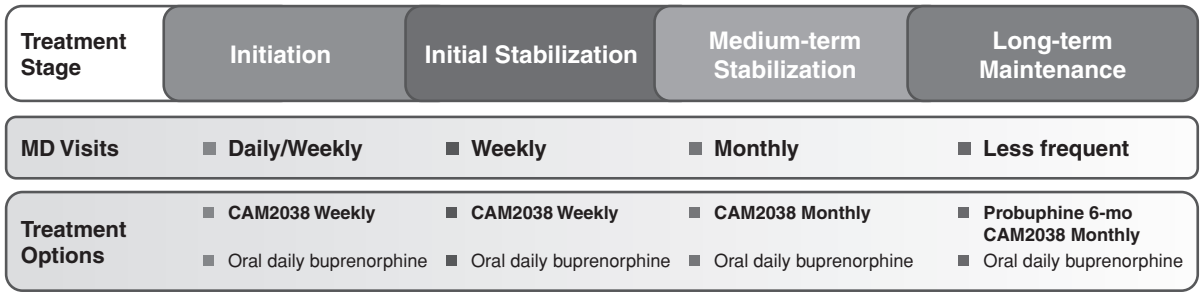
Our marketed product, Probuphine, was approved by the U.S. Food and Drug Administration, or FDA, in May 2016, and is the first and only implantable formulation of buprenorphine for the maintenance treatment of opioid addiction. Probuphine is administered by a healthcare provider who inserts four implants, each smaller than a one-inch matchstick, sub-dermally into the patient's upper arm during a short in-office procedure usually lasting less than 15 minutes. After insertion, Probuphine delivers buprenorphine continuously for six months. Thereafter, the implants can be removed and replaced with new Probuphine implants.

Our lead clinical product candidates, weekly and monthly CAM2038, are subcutaneous injectable formulations of buprenorphine for the treatment of opioid addiction. We believe weekly and monthly CAM2038 will expand our target patient population, including not only patients who have been successfully treated with buprenorphine but also patients new to buprenorphine therapy. In November 2016, we reported positive top-line results from a Phase 3 trial of weekly and monthly CAM2038 for opioid addiction.

CAM2038 achieved non-inferiority compared to oral daily buprenorphine based on the primary endpoint and superiority to oral daily buprenorphine based on a secondary endpoint. Based on the successful results from this pivotal Phase 3 trial, we are working to submit a New Drug Application, or NDA, for weekly and monthly CAM2038 in the first half of 2017. The FDA has granted fast track designation for weekly and monthly CAM2038 for the treatment of opioid addiction.

Probuphine and CAM2038 have the potential to transform and enhance the continuum of care for opioid addiction, as compared to current clinical practice which is limited to the use of oral daily buprenorphine. We believe a weekly buprenorphine injection would be an attractive option for beginning buprenorphine treatment where weekly medical visits to adjust dose is common practice. We believe a monthly injection would be an attractive option for early-stage maintenance treatment where a transition to monthly visits after finding a stable dose is common practice. For longer-term maintenance treatment, we believe a six-month implant would be an attractive option.

Opioid addiction: Enhanced continuum of care aligned with clinical practice



The above graphic depicts the clinical practice for treating opioid addiction and shows how we believe our products, if approved, align with the various stages of treatment as compared to the current standard of care, oral daily buprenorphine.

Additional product candidates

We believe pain, schizophrenia and spasticity can also be more effectively managed using long-acting implantable or injectable medications which will provide enhanced compliance, improved clinical outcomes and improved quality of life for patients.

Our investigational pipeline includes:

- **CAM2038 and Probuphine.** Because buprenorphine has also been approved for the treatment of chronic pain, we believe our long-acting medications, weekly and monthly CAM2038 and Probuphine, have the potential to provide a suite of therapeutic products across the continuum of care for pain. We believe our long-acting medications, if approved, will provide continuous around-the-clock therapy, resulting in improved pain relief, increased convenience and enhanced quality of life. Furthermore, we believe our long-acting pain medications can help address the root causes of the opioid abuse epidemic because they are implanted or injected directly by a healthcare provider, and therefore are not susceptible to the diversion and misuse that occurs with self-administered oral daily opioids.
- **BB0817.** An implant that offers continuous, six-month delivery of risperidone, the most commonly prescribed medication for the treatment of schizophrenia. We believe BB0817 has the potential for unique positioning in the schizophrenia market with a treatment duration that at least doubles that of currently-marketed injectables, which range from two weeks to three months. BB0817 is currently in Phase 3 development.

- **BB0417.** A subcutaneous injectable formulation that offers three to five days of buprenorphine and granisetron, a widely used drug to treat nausea and vomiting, for the potential treatment of acute post-operative pain, nausea and vomiting. We believe that BB0417 has the potential to improve the well-being of post-operative patients and reduce the need for other medications including oral opioid painkillers, which are taken home and self-administered by the patient. BB0417 is currently in Phase 1 development.
- **BB1216.** An implant that offers continuous, six-month delivery of tizanidine, a commonly prescribed muscle relaxant, for the treatment of moderate to severe spasticity. We believe that BB1216 may provide enhanced clinical outcomes with fewer side effects as compared to oral medications and will be more convenient for patients. We also believe that BB1216 will be an attractive alternative to surgical implantation of an intrathecal baclofen pump, as the surgical procedure to implant BB1216 is simpler and safer. BB1216 is currently in animal testing of the formulation, and if this testing is successful, we expect that it will advance directly to Phase 3 development.

Our competitive strengths

Focus on large and underserved specialty CNS markets. Opioid addiction is widely recognized as an unprecedented public health epidemic in the United States, and is a multi-billion dollar market experiencing double-digit growth. Pain and schizophrenia are also fast-growing, multi-billion dollar markets.

Differentiated products addressing high unmet medical needs. Our products utilize proprietary long-acting delivery mechanisms to enhance compliance and lower treatment stigma and to reduce the potential for medication diversion and abuse. As a result, we believe our products will lead to better clinical and social outcomes.

Mitigated clinical and regulatory risk. Our current products apply novel delivery mechanisms to existing FDA-approved therapeutic molecules, and therefore may be able to use the FDA's section 505(b)(2) approval pathway.

Long duration cashflows from products with high barriers to entry. Our products are covered by a range of intellectual property, trade secrets and know-how and are subject to a range of complex clinical and regulatory requirements. In addition, our supply chain is difficult to replicate as it involves the handling of controlled substances, which involves the need for special permits and licenses, and involves several single source suppliers.

Platform for organic growth and expansion. Our product development expertise, and the commercial and manufacturing infrastructure investments we are making, can be leveraged across our diversified product portfolio and for future business development efforts.

Proven, experienced management team. Our management team has an established track record of developing successful clinical and commercial organizations, including multiple blockbuster pharmaceutical brands.

Our growth strategies

Our objective is for our novel long-acting medications to become the standard of care for specialty CNS disorders. We believe that our medications will allow healthcare providers to treat patients through the continuum of care, providing personalized drug delivery that is optimized to help patients progress from

treatment initiation through long-term maintenance. Key elements of our strategy to achieve our objective are to:

- **Grow sales of our recently approved product Probuphine for opioid addiction.** To date, we have trained and certified approximately 2,500 healthcare providers to prescribe and implant Probuphine, and over 70 payors have indicated that they intend to cover Probuphine. We are planning a full-scale commercial launch of Probuphine with our new fully-deployed field force of approximately 60 representatives in the first quarter of 2017, which we intend to further expand if and when we launch CAM2038.
- **Advance our lead product candidates, weekly and monthly CAM2038 for opioid addiction, and the rest of our specialty CNS pipeline, to establish a diversified portfolio of commercial products.** If weekly and monthly CAM2038 are approved, we will market a comprehensive suite of opioid addiction products that we believe will allow healthcare providers to treat patients throughout the continuum of care from treatment initiation through long-term maintenance.
- **Leverage differentiated product profiles to establish leadership positions in underserved markets.** We intend to establish our products as new standards of care in the therapeutic markets in which we operate. In both opioid addiction and pain, we have the potential to be the only company that offers a comprehensive portfolio of long-acting medications including once weekly, once monthly, and six-month formulations.
- **Expand our markets by addressing unmet needs and providing access to innovative therapies.** By addressing currently unmet medical needs, we believe our portfolio will allow healthcare providers to expand the population of patients they are able to effectively treat.
- **Pursue additional product development opportunities via targeted business development.** We believe we will become the partner of choice for development and commercialization in specialty CNS which will provide opportunities to expand our pipeline of long-acting product candidates. We believe that the concentrated and targeted nature of the specialty CNS sector will allow us to benefit from meaningful operating leverage as we further expand our product portfolio.

Our portfolio

The table below summarizes our product portfolio:

Product	Indication	Substance	Form	Phase of Development	Braeburn Commercialization Rights
Probuphine	Opioid addiction	Buprenorphine	6-month implant	Marketed(1)	United States, Canada(2)
CAM2038 Weekly	Opioid addiction	Buprenorphine	Weekly injectable	Phase 3	North America; Asia option rights(3)
CAM2038 Monthly	Opioid addiction	Buprenorphine	Monthly injectable	Phase 3	North America; Asia option rights(3)
CAM2038 Weekly	Chronic pain	Buprenorphine	Weekly injectable	Phase 3	North America; Asia option rights(3)
CAM2038 Monthly	Chronic pain	Buprenorphine	Monthly injectable	Phase 3	North America; Asia option rights(3)
Probuphine	Chronic pain	Buprenorphine	6-month implant	Phase 3	United States, Canada(2)
BB0817	Schizophrenia	Risperidone	6-month implant	Phase 3	Worldwide
BB0417	Acute post-operative pain	Buprenorphine and Granisetron	3 to 5 day injectable	Phase 1	North America; Asia option rights(3)
BB1216	Spasticity	Tizanidine	6-month implant	Clinic ready(4)	Worldwide

(1) The FDA has required that we conduct four post-approval clinical trials to assess the insertion, localization and removal related serious adverse events of Probuphine, the risk of the QT interval in the heart's electrical cycle during treatment with Probuphine, the effect of scarring or inflammation related to a prior implant on the safety of re-implantation / re-insertion, the potential for implant migration, and the bioavailability of Probuphine into the same insertion site, and the safety, feasibility and pharmacokinetics of Probuphine implantation at alternate body sites.

(2) We have exclusively sub-licensed commercialization rights in Canada to Knight Therapeutics, Inc.

(3) We have option rights for China, Japan, South Korea and Taiwan.

(4) If current formulation and testing are successful, we expect BB1216 will advance directly to Phase 3 development.

Risk associated with our business

Our business is subject to many risks and uncertainties of which you should be aware before you decide to invest in our common stock. These risks and additional risks are discussed more fully under "Risk Factors" in this prospectus. Some of these risks include:

- We are largely dependent on the commercial success of products in our lead therapeutic area of opioid addiction, and if we are unable to successfully commercialize our product and product candidates, if approved, in this area, our business, financial condition, results of operations and prospects will be materially adversely affected.
- If Probuphine or any other product candidate for which we receive regulatory approval does not achieve broad market acceptance by physicians, patients or others in the medical community or coverage by third-party payors, our revenues may be adversely affected and our business may suffer.
- If the FDA does not conclude that our product candidates satisfy the requirements for the section 505(b)(2) regulatory approval pathway, or if the requirements under section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

- We obtain some of our raw materials, components and finished goods from a single source or a limited group of suppliers. The partial or complete loss of one of these suppliers could cause significant production delays, an inability to meet customer demand and a substantial loss in revenue.
- We rely on third parties to provide services in connection with the manufacture and distribution of our products, and these third parties may not perform satisfactorily. If we or our contract manufacturers fail to establish commercial manufacturing operations in compliance with regulatory requirements we may not be able to initiate commercial operations or produce sufficient quantities of our products to meet commercial requirements.
- Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy for our product candidates such as Probuphine for the treatment of pain, or any of our other product candidates such as CAM2038, BBO417 and BBO817, which could prevent or significantly delay their regulatory approval.
- We rely on third parties to conduct our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
- Our product candidates are subject to extensive regulation, and we cannot give any assurance that any of our product candidates will receive regulatory approval or be successfully commercialized.
- We have never generated net income from operations or positive cash flow from operations and are dependent upon external sources of financing to fund our business and development.
- Our success depends in part on our ability to obtain, maintain, protect and defend our intellectual property, which is difficult and costly, and we may not be able to ensure that we will be able to do so.
- Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover our trade secrets or that our trade secrets will be misappropriated or disclosed.
- Apple Tree Partners IV, L.P. and its affiliates, or Apple Tree, will continue to own a majority of our common stock after this offering and will be able to control or exercise significant influence over matters subject to stockholder approval.

Concurrent private placement

Apple Tree has agreed to purchase $40 million of our common stock in a concurrent private placement with the completion of this offering at a price per share equal to the initial public offering price. The sale of such shares will not be registered under the Securities Act of 1933, as amended, or the Securities Act. The closing of this offering is not conditioned upon the closing of such concurrent private placement.

Corporate history and information

We were incorporated in Delaware in September 2012 under the name AT Pharmaceuticals, Inc. and subsequently changed our name to Braeburn Pharmaceuticals, Inc. in December 2012. We were a wholly-owned subsidiary of Braeburn Pharmaceuticals BVBA SPRL, or Braeburn BVBA, a wholly-owned portfolio company of Apple Tree, until November 2015, when Braeburn BVBA was voluntarily dissolved. As a result, we became a wholly-owned portfolio company of Apple Tree. Our principal executive offices are located at 47 Hulfish Street, Suite 441, Princeton, New Jersey 08542 and our telephone number is (609) 751-5375.

Our website address is www.braeburnpharmaceuticals.com. The information contained on, or accessible through, our website does not constitute part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Implications of being an emerging growth company

As a company with less than $1.0 billion in revenue during our last fiscal year, we qualify as an ''emerging growth company'' as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we 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 and other requirements that are applicable to other public companies that are not emerging growth companies. In particular, in this prospectus, 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. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. We may take advantage of the exemptions provided by the JOBS Act for up to five years or such earlier time that we are no longer an emerging growth company. 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. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the first day of the year following the first year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30.

The Braeburn name and logo are our trademarks. This prospectus also includes trademarks, trade names and service marks of other persons, including those which have been licensed to us for certain uses. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

The offering

Common stock offered by us	7,692,308 shares
Common stock to be sold by us to Apple Tree in the concurrent private placement	$40 million (or 2,051,282 shares based on an assumed initial public offering price of $19.50, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus).
Common stock to be outstanding immediately after this offering and the concurrent private placement	29,506,794 shares (30,660,640 shares if the underwriters exercise in full their option to purchase additional shares in full)
Underwriters' option to purchase additional shares from us	1,153,846 shares
Use of proceeds	We estimate that the net proceeds from the sale of shares of common stock will be approximately $137.2 million, or $158.2 million if the underwriters exercise in full their option to purchase additional shares, based upon an assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering for commercialization of Probuphine, advancement of product candidates in clinical development and for working capital and other general corporate purposes. See "Use of Proceeds" for additional information.
Risk factors	You should carefully read "Risk Factors" in this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
Reserved Share Program	At our request, the underwriters have reserved for sale, at the initial public offering price, up to 5% of the shares offered by this prospectus for sale to some of our directors, officers, employees, business associates and related persons. If these persons purchase reserved shares it will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus.
Proposed trading symbol	"BBRX"

As of January 1, 2017, there were no shares of our common stock outstanding. Therefore, the number of shares of common stock to be outstanding after this offering and the concurrent private placement is

based on 19,763,204 shares of our common stock issuable upon the conversion upon the closing of this offering of all outstanding shares of our convertible preferred stock. The number of shares of our common stock to be outstanding after this offering excludes:

- 1,100,000 shares of common stock reserved for future issuance under our 2017 Stock Option and Incentive Plan, plus annual increases thereunder, as described in the section "Executive Compensation—Stock Option Plans—2017 Stock Option and Incentive Plan," which will become effective on the date immediately prior to the date on which the registration statement of which this prospectus is part is declared effective;
- 1,013,417 shares of common stock reserved for future issuance under our 2015 Equity Incentive Plan as of January 1, 2017, after giving effect to the reverse stock split and taking into account awards that have been granted as described below;
- 738,553 shares of our common stock issuable upon the exercise of outstanding options as of January 1, 2017 at a weighted average exercise price of $10.20 per share; and
- 2,692,474 shares of our common stock issuable upon vesting of restricted stock units outstanding as of January 1, 2017.

Unless otherwise indicated, all information in this prospectus reflects or assumes the following:

- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, which will occur immediately prior to the completion of this offering;
- a 1-for-2.7 reverse split of our common stock and a proportional adjustment to the existing conversion ratio of our convertible preferred stock effected on January , 2017;
- no shares issued upon vesting of restricted stock units or upon exercise of stock options after January 1, 2017;
- no exercise by the underwriters of their option to purchase up to an additional 1,153,846 shares of common stock in this offering; and
- no shares purchased by Apple Tree in the offering, for which it has indicated a non-binding indication of interest in purchasing an aggregate of approximately $50 million of the shares of our common stock at the initial public offering price.

Summary financial data

You should read the following summary financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus. We derived the statement of operations data for the years ended December 31, 2014 and 2015 from our audited consolidated financial statements included elsewhere in this prospectus. The statements of operations data for the nine months ended September 30, 2016 and 2015 and the balance sheet data as of September 30, 2016 have been derived from our unaudited consolidated financial statements appearing at the end of this prospectus and have been prepared on the same basis as the audited consolidated financial statements. Our historical results are not necessarily indicative of results that should be expected in the future and results of interim periods are not necessarily indicative of results for the entire year.

	Year ended December 31,		Nine months ended September 30,	
	2014	2015	2015	2016
	(in thousands)			(unaudited)
Statement of Operations Data:				
Revenue	$ —	$ 25	$ —	$ 42
Cost of sales	—	—	—	44
Gross profit	—	25	—	(2)
Expenses:				
Research and development	37,195	31,374	16,345	50,933
Selling, general and administrative	3,076	6,964	4,031	27,095
Total expenses	40,271	38,338	20,376	78,028
Loss from operations	(40,271)	(38,313)	(20,376)	(78,030)
Other income / (expense), net	(185)	(650)	(646)	1,214
Loss before income tax expense / (benefit)	(40,456)	(38,963)	(21,022)	(76,816)
Income tax expense / (benefit)	—	1,600	1,602	—
Net loss	$ (40,456)	$(40,563)	$(22,624)	$ (76,816)
Other comprehensive income / (loss)				
Unrealized gain / (loss) during period, net of tax benefit of $18 and $0 for the year ended December 31, 2015 and 2014 and $0 and $0 for the nine months ended September 30, 2016 and 2015, respectively	(925)	2,140	1,635	(28)
Comprehensive loss	$ (41,381)	$ (38,423)	$(20,989)	$(76,844)

	As of September 30, 2016		
	Actual	Pro forma(1)	Pro forma as adjusted(2)(3)
		(in thousands) (unaudited)	
Balance Sheet Data:			
Cash and cash equivalents(4)	$ 23,528	$ 23,528	$ 200,769
Prepaid expenses and other current assets	5,912	5,912	5,912
Investment in Titan Pharmaceuticals	—	—	—
Property and equipment, net	11,407	11,407	11,407
Intangible assets, net	14,342	14,342	14,342
Other non-current assets	1,613	1,613	1,613
Total assets	56,802	56,802	196,302
Accounts payable, accrued expenses, and other current liabilities	18,469	18,469	18,469
Financing obligation and other long-term liabilities	4,660	4,660	4,660
Total liabilities	23,129	23,129	23,129
Common shares	—	2	3
Preferred shares	22	—	—
Additional paid-in-capital	233,572	238,134	375,373
Accumulated deficit	(199,921)	(204,462)	(204,462)
Total liabilities and shareholders' equity / (deficit)	$ 56,802	$ 56,802	$ 196,302

(1) Pro forma balance sheet data gives effect to (i) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 16,503,945 shares of common stock, par value $0.0001, upon the completion of this offering, and (ii) the issuance of 991,110 shares of common stock related to restricted stock units that were both service-based vested and liquidity-based vested as of the completion of this offering.

(2) Pro forma as adjusted basis gives effect to (i) the conversion of all outstanding shares of our convertible preferred stock into shares of common stock upon the completion of this offering, (ii) the sale of 7,692,308 shares of our common stock offered in this offering, based on the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and (iii) the sale of $40 million of our common stock in a concurrent private placement to Apple Tree based on the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus.

(3) A $1.00 increase or decrease in the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase or decrease each of cash and cash equivalents, additional paid-in capital, total stockholders' deficit (equity) and total capitalization on a pro forma as adjusted basis by approximately $7.2 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase or decrease of one million shares in the number of shares offered by us would increase or decrease each of cash and cash equivalents, additional paid-in capital, total stockholders' deficit (equity) and total capitalization on a pro forma as adjusted basis by approximately $18.1 million, assuming no change in the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A one million share increase in the number of shares offered by us together with a concomitant $1.00 increase in the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase each of cash and cash equivalents, total stockholders' equity and total capitalization by $26.2 million after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Conversely, a one million share decrease in the number of shares offered by us together with a concomitant $1.00 decrease in the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would decrease each of cash and cash equivalents, total stockholders' equity and total capitalization by $24.4 million after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(4) Does not include the $22 million capital contribution from Apple Tree in October 2016 or the $22 million capital contribution from Apple Tree in December 2016.

Risk factors

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information appearing elsewhere in this prospectus, including our consolidated financial statements and related notes, before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks that we currently do not know about may also impair our business. Certain statements below are forward-looking statements. See "Special Note Regarding Forward-Looking Statements" in this prospectus.

Risks related to the commercialization of our product and product candidates

We are largely dependent on the commercial success of products in our lead therapeutic area of opioid addiction, and if we are unable to successfully commercialize our product and product candidates, if approved, in this area, our business, financial condition, results of operations and prospects will be materially adversely affected.

Our lead therapeutic area of focus is opioid addiction, where we seek to address the limitations of current treatment approaches by replacing oral daily medications with a suite of complementary long-acting implantable and injectable medications. The commercial success of these products depends on several factors, including:

- our ability to successfully launch products and educate prescribers and patients on the applicable product's efficacy and safety;
- our ability to train and certify healthcare providers to insert and remove implants of Probuphine in accordance with the Probuphine Risk Evaluation and Mitigation Strategy, or REMS;
- the perceived and actual advantages of our approved product, Probuphine, and our product candidates, including CAM2038, if approved, over current treatment options;
- the willingness of healthcare providers to prescribe, and the target patient population to try novel products;
- the competitiveness of our pricing;
- the willingness of healthcare providers to accept alternative reimbursement models, such as the "buy-and-bill" system, where prescribers are required to buy Probuphine inventory themselves and then bill patients or payors following the procedure, or the specialty pharmacy distribution model, where a specialty pharmacy carries inventory and ships it to healthcare providers as requested and prescribed, and directly handles the subsequent billing and payment process with payors. We expect that a majority of our sales of Probuphine will be through the specialty pharmacy distribution model, and the remainder will be sold through the "buy-and-bill" system;
- our ability to establish and maintain adequate levels of coverage for our approved product, Probuphine, from commercial health plans and government health programs, which we refer to collectively as third-party payors, particularly in light of the availability of other branded and generic competitive products;
- the willingness for patients to pay out-of-pocket in the absence of third-party coverage and the success of patient assistance programs; and
- our ability to promote products through marketing and sales activities and any other arrangements.

The estimates of the number of patients with the disease of opioid addiction, or the prospective patients who may be treated with our approved products, may be inaccurate. In addition, patients may be unwilling to pay for or try our products over the current treatment options. Furthermore, the number of healthcare providers who are eligible to prescribe Probuphine is limited as the U.S. Department of Health and Human Services, or HHS, places a limit on the number of patients who may be treated with buprenorphine at up to 275 patients per qualified provider. If we are unable to successfully commercialize Probuphine and the other product candidates in our opioid addiction portfolio, if approved, or if the market opportunity is less than we expected, as a result of marketing factors or labeling restrictions, we may be unable to generate revenues, and our business, financial condition and results of operation will be materially adversely affected.

If Probuphine or any other product candidate for which we receive regulatory approval does not achieve broad market acceptance by physicians, patients or others in the medical community or coverage by third-party payors, our revenues may be adversely affected and our business may suffer.

The commercial success of Probuphine or any other product candidate for which we obtain marketing approval from the U.S. Food and Drug Administration, or FDA, or other regulatory authorities will depend upon the acceptance of these products by physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of any of our approved products by third-party payors is also necessary for commercial success. Our long-acting implantable and injectable medications may not be widely or rapidly accepted by physicians as the payment and reimbursement model differs from some of the existing treatment options for opioid addiction. For example, the current standard of care for outpatient treatment of opioid addiction is oral daily buprenorphine, which typically requires frequent patient visits and a per visit fee, which the patient may pay directly to the healthcare provider in cash. Reimbursement for injectable and implantable drug products that require administration by a healthcare provider require drug codes as well as a separate procedure code for the insertion and removal procedures and less frequent office visits. Physicians may prefer more frequent patient visits and the accompanying reimbursement and payment model, which oftentimes includes cash payments, and our product and product candidates may not gain market acceptance as a result. Furthermore, CAM2038 is a long-acting injectable medication, and healthcare providers may be hesitant to prescribe CAM2038, if approved, because an injectable cannot be withdrawn if adverse events occur. The degree of market acceptance of long-acting injectables and implantables, including Probuphine and any product candidate for which we may receive regulatory approval, will depend on a number of factors, including:

- acceptance by physicians and patients of the product as a safe and effective treatment, including the willingness of patients to try a long-acting injectable or implantable product and the willingness of physicians to prescribe a long-acting injectable or implantable product which they may consider more difficult to monitor or to be trained and certified in accordance with a REMS program, such as the Probuphine REMS;
- any negative publicity or political action related to our or our competitors' products;
- the relative convenience and ease of administration of our product compared to the products offered by others;
- the prevalence and severity of adverse side effects associated with our product;
- limitations or warnings contained in the product's FDA-approved labeling;
- the clinical indications for which the product is approved;

- in the case of Probuphine and product candidates that are controlled substances, the U.S. Drug Enforcement Administration, or DEA, scheduling classification;
- availability and perceived advantages of alternative treatments;
- the effectiveness of our or any current or future collaborators' sales, marketing and distribution strategies;
- patient awareness of our therapies;
- pricing and cost effectiveness;
- our ability to obtain sufficient third-party payor coverage and reimbursement, as well as the ease of use and transparency of such processes and systems once in place; and
- the willingness of patients to pay out of pocket in the absence of third-party payor coverage.

Our efforts to educate the medical community and third-party payors on the benefits of Probuphine or any of our other product candidates for which we obtain marketing approval from the FDA or other regulatory authorities in order to gain broad market acceptance may require significant resources and may never be successful. If our products do not achieve an adequate level of acceptance by physicians, third-party payors, pharmacists, and patients, we may not generate sufficient revenue from these products, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The insurance coverage and reimbursement status of newly-approved products is uncertain. If we are unable to achieve and maintain adequate levels of coverage and reimbursement for Probuphine or any of our other product candidates for which we may receive regulatory approval on reasonable pricing terms, their commercial success may be severely limited.

Successful sales of our products depend on the availability of adequate coverage and reimbursement from third-party payors, as well as the ease of use and transparency of such processes and systems once in place. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products such as ours when more established or lower cost therapeutic alternatives are already available or subsequently become available. Decisions regarding the extent of coverage and amount of reimbursement to be provided for products and product candidates that we develop will be made on a plan-by-plan basis. As a result, the coverage determination process is often a time-consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained.

Reimbursement for injectable and implantable drug products that require administration by a healthcare provider generally requires a drug code, and separate reimbursement codes are required for the injection, insertion and removal procedures, as applicable. We have obtained a drug code for Probuphine, but our application for a procedure code was recently denied. However, we are pursuing multiple strategies to try to obtain G-codes and a permanent CPT code for the procedures in early 2017. The miscellaneous code 17999 can be used in the interim. See "Business—Reimbursement" for further detail on our strategies to obtain G-codes. The lack of a drug code or procedure code that covers our product or describes the procedures performed using our products, or a change to an existing code that describes such procedures,

may adversely affect reimbursement for our products and these procedures, including lower reimbursement rates, denials and delays in reimbursement if pre-authorization is required.

Even if coverage is approved, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our products may depend on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

In addition, regional healthcare authorities and individual hospitals are increasingly using competitive bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This can reduce demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Third-party payors, whether governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for Probuphine or any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

The Probuphine REMS may slow our sales and marketing efforts, which could impact our sales revenue. There is currently a REMS program in place for Probuphine as required by the FDA, which is called the Probuphine REMS program. The program was implemented in May 2016 and is designed to mitigate the risk of complications of migration, protrusion, expulsion and nerve damage associated with the insertion and removal of Probuphine and the risks of accidental overdose, misuse and abuse. The Probuphine REMS program requires training and certification of healthcare providers who prescribe and implant Probuphine and provide patient counseling. Probuphine distribution is restricted to healthcare providers who have completed training and received certification under the Probuphine REMS program. Healthcare providers may be unwilling to undergo training and certification in order to be able to prescribe or implant Probuphine due to time constraints or concerns with the product. Should this occur, our ability (or the ability of potential future commercial partners) to generate revenue from sales of Probuphine, could be materially compromised, could have a material adverse effect on our business, results of operations, financial condition and prospects. In addition, if a patient suffers an injury during the insertion and removal of Probuphine, it may give rise to liability against us by patients, clinicians or others or result in non-compliance with the Probuphine REMS program. Non-compliance with the Probuphine REMS program may bring serious consequences to us, including warning letters from the FDA, fines, criminal charges and other prohibitions and exclusions as well as reputational damage.

If the market opportunities for Probuphine, CAM2038 or any other product candidates for which we may receive regulatory approval are smaller than we believe they are, our product revenues may be adversely affected and our business may suffer.

We currently focus our research, product development and commercialization efforts on treatments for serious CNS disorders through the use of implantable and injectable medications. Our understanding of both the number of people who have these disorders, as well as the subset of people with these disorders who have the potential to benefit from treatment with our products, is based on estimates in published literature. These estimates may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of these disorders. The number of patients in the United States and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with any of our product or product candidates for which we receive regulatory approval for such indications or patients may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects.

Further, there are several factors that could contribute to making the actual number of patients who receive our potential products less than the potentially addressable market. Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our products, if and when approved, may require significant resources and may never be successful. In addition, our buprenorphine-based product and product candidates are subject to HHS regulations limiting the number of patients that qualified physicians can treat with buprenorphine to 275 patients, which rules may be subject to change. Moreover, to be eligible for treatment with Probuphine, a patient must first have achieved sustained clinical stability on a dose of no more than 8 mg of oral buprenorphine. Accordingly, the number of opioid addiction patients who may realize the benefits of Probuphine will be limited by the number of patients who achieve clinical stability on 8mg/day or less of oral buprenorphine and any discontinued use of oral buprenorphine prior to or after achieving clinical stability. This may prove difficult as, on average, opioid addiction patients take medication only 33% of the time that they need it.

Guidelines and recommendations published by various organizations can reduce the use of our products, if approved.

Government agencies promulgate regulations and guidelines directly applicable to us and to our product and product candidates. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. For example, the Centers for Disease Control and Prevention, or CDC, has issued new guidelines about the use of opioid pain killers for chronic pain that caution healthcare providers to be selective in prescribing opioids, to start with low doses, to weigh risks and benefits when using opioids for chronic pain and to use doses equivalent to 90 mg/day or more of morphine only after a careful risk assessment. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our products.

We may be subject to enforcement action if we engage in improper marketing or promotion of our products.

Our promotional materials and training methods must comply with the Federal Food, Drug and Cosmetic Act, or the FDCA, and FDA regulations and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or "off-label", use. Companies may not promote drugs for off-label use, which include uses that are not described in the product's labeling and that differ from those approved by

the FDA. Physicians may prescribe drug products for off-label uses and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDCA and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services, or OIG, the FDA, and the Department of Justice, or DOJ, all actively enforce laws and regulations prohibiting promotion of off-label use and the promotion of products for which marketing approval has not been obtained.

Other federal, state and foreign regulatory agencies, including the U.S. Federal Trade Commission, have issued guidelines and regulations that govern how we promote our products, including how we use endorsements and testimonials.

If we are found to be out of compliance with the requirements and restrictions described above, and we are investigated for or found to have improperly promoted off-label use, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions, and the off-label use of our products may increase the risk of product liability claims. In addition, management's attention could be diverted from our business operations and our reputation could be damaged.

A fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We have been granted fast track designation for CAM2038 for the treatment of opioid addiction and may seek fast track designation for product candidates in the future. The FDA has broad discretion on whether to grant this designation or not, and even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. For example, the FDA denied our application for fast track designation for CAM2038 for the treatment of chronic pain and for BBO817 for the treatment of schizophrenia. Moreover, we may not experience a faster development process, review or approval compared to conventional FDA procedures for CAM2038 for the treatment of opioid addiction, or any other product candidates for which we seek a fast track designation. The fast track designation does not guarantee priority review, and the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

If the FDA does not conclude that our product candidates satisfy the requirements for the section 505(b)(2) regulatory approval pathway, or if the requirements under section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We intend to seek FDA approval through the section 505(b)(2) regulatory pathway for our current product candidates. Our product candidates, as well as Probuphine for opioid addiction, are drug/device combination products that will be regulated under the drug provisions of the FDCA, enabling us to submit NDAs for approval of our product candidates. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of a New Drug Application, or 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.

We may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval under the section 505(b)(2) regulatory pathway. The FDA may then approve the new formulation for all or only some of the indications sought by us. If any of this were to occur, the time and financial resources required to obtain FDA approval for our product candidates, and

complications and risks associated with the approval of our product candidates, would likely substantially increase. We may need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to perform one or more additional clinical trials, provide additional data and information or meet additional standards to support the change from the approved product under the section 505(b)(2) regulatory pathway could result in competitive products reaching the market before our product candidates, which could impact our competitive position and prospects. We cannot assure you that our product candidates will receive the requisite approvals for commercialization, or that a competitor would not obtain approval first, including subsequent market exclusivity from the FDA, which could result in a delay in potential approval of our product candidates.

In addition, notwithstanding the approval of a number of products by the FDA under section 505(b)(2) over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of section 505(b)(2). If the FDA's interpretation of section 505(b)(2) is successfully challenged, the FDA may be required to change its section 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under section 505(b)(2).

Negative publicity and political action regarding our product and product candidates could delay or impair our ability to market our products, present significant distractions to our management and result in the incurrence of significant costs.

Products used for certain indications, including those for the treatment of opioid addiction and pain, are from time to time subject to negative publicity and political influences, including relating to illegal use, overdoses, abuse, diversion, serious injury and death. We market and develop long-acting injectable and implant formulations of our products as opposed to oral daily medications. Any concerns raised by the FDA or other governmental bodies at the federal, state or local level for injectable or implant formulations of products for specialty CNS conditions, or the use of opioid therapies to treat opioid addiction or pain may make it more difficult for us to obtain regulatory approval and commercialize our product and product candidates. Public perception relating to our buprenorphine-based product and product candidates may also be influenced by claims that treating opioid addiction or pain with buprenorphine may result in addiction to buprenorphine.

Negative publicity, political influences and actions by our competitors could negatively affect our ability to market Probuphine and any product candidate for which we receive marketing approval. Furthermore, negative publicity and political action could also cause a diversion of our management's time and attention, cause us to incur additional significant costs with respect to litigation, marketing or otherwise, and could also result in an increased number of product liability claims, whether or not these claims have a valid basis.

We face intense competition, including from generic products, and if our competitors market and/or develop treatments for opioid addiction, chronic pain or schizophrenia that are marketed more effectively, approved more quickly or demonstrated to be safer or more effective than Probuphine or our product candidates, our commercial opportunities will be reduced or eliminated.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as our product or product candidates, including large pharmaceutical companies, smaller pharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions, many of which have greater

financial resources, sales and marketing capabilities, including larger, well-established sales forces, manufacturing capabilities, experience in obtaining regulatory approvals for product candidates and other resources than we do.

The commercial opportunity for Probuphine and our product candidates could be significantly harmed if competitors are able to develop alternative formulations and/or drug delivery technologies outside the scope of our capabilities. Our principal competition in the opioid addiction market comes from manufacturers of oral buprenorphine products, including Indivior PLC, which markets the Suboxone and Subutex brands. Additionally, we anticipate that our primary competitors for CAM2038 and Probuphine, if approved for pain, will be manufacturers of opioid analgesics such as oxycodone that are available at doses equivalent to 80 mg per day of morphine, or lower doses depending on CAM2038's dosing flexibility. Also, we expect our primary competitor for BBO817, if approved by FDA, to be the manufacturer of long-acting injectable formulations of risperidone. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- research and development resources and experience, including personnel and technology;
- drug development, clinical trial and regulatory resources and experience;
- sales and marketing resources and experience;
- manufacturing and distribution resources and experience;
- name recognition; and
- resources, experience and expertise in prosecution and enforcement of intellectual property rights.

As a result of these factors, our competitors may obtain regulatory approval of their product candidates more rapidly than we are able to or may obtain patent protection or other intellectual property rights, which may limit or block us from developing or commercializing our products, if approved. Our competitors may also develop, acquire or license products that are more effective, more useful, better tolerated, subject to fewer or less severe side effects, more widely prescribed or accepted or less costly than ours and may also be more successful than we are in manufacturing and marketing their products. In addition, state pharmacy laws may permit pharmacists to substitute generic products for branded products if the products are therapeutic equivalents, or may permit pharmacists and pharmacy benefit managers to seek prescriber authorization to substitute generics in place of our products, which could significantly diminish demand for Probuphine or other product candidates for which we receive marketing approval. If we are unable to compete effectively with the marketed therapeutics of our competitors or if such competitors are successful in developing products that compete with Probuphine or any of our product candidates that are approved, our business, results of operations, financial condition and prospects may be materially adversely affected.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time we may consider strategic transactions, such as asset purchases and out-licensing or in-licensing of products, product candidates or technologies. For example, in December 2012, we entered into a License Agreement with Titan Pharmaceuticals, Inc., or Titan, pursuant to which Titan granted us an exclusive right and license to commercialize Probuphine in the United States and its territories, including Puerto Rico and Canada. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our

operations, solvency and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown and contingent liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- the timing and likelihood of payment of milestones or royalties;
- write-downs of assets or goodwill or impairment charges;
- increased operating expenditures, including additional research, development and sales and marketing expenses;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel; and
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership.

Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above or that we will achieve an economic benefit that justifies such transactions, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may not be able to enter into strategic transactions on a timely basis or on acceptable terms, which may impact our development and commercialization plans.

We have relied, and expect to continue to rely, on strategic collaborations and licensing agreements with third parties for the development and commercialization of our products. Our ability to reach definitive agreements with strategic partners depends on a number of factors, including the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such products to patients, the potential of competing drugs and the existence of uncertainty with respect to ownership of the technology. The terms of any additional strategic transaction that we may establish may not be favorable to us, and the contracts governing such strategic transaction may be subject to differing interpretations exposing us to potential litigation. We may also be restricted under existing collaboration or licensing arrangements from entering into future agreements on certain terms with potential strategic partners. We may not be able to negotiate additional strategic transactions on a timely basis, on acceptable terms, or at all. If we are unable to negotiate and enter into new collaboration and license agreements, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital,

which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our products or bring them to market and generate product revenue.

We obtain some of our raw materials, components and finished goods from a single source or a limited group of suppliers. The partial or complete loss of one of these suppliers could cause significant production delays, an inability to meet customer demand and a substantial loss in revenue.

We use a number of single-source suppliers for certain of our raw materials, components and finished goods, including:

- the suppliers of the active ingredients for Probuphine and CAM2038;
- the supplier of the finished Probuphine implants; and
- the manufacturer of the Probuphine applicator.

We do not currently have a supplier of ethylene-vinyl acetate, or EVA, for our use for manufacture of Probuphine. Our prior supplier of EVA discontinued manufacturing and we are in the process of qualifying a new EVA manufacturer. In addition, the vendor that currently sterilizes the Probuphine implants has indicated that it will no longer sterilize Schedule III controlled substances, including Probuphine. See the risk factor below entitled, *"Probuphine is a controlled substance subject to DEA regulations and failure to comply with these regulations, or the cost of compliance with these regulations, may adversely affect our business."* While we are in the process of qualifying another sterilization vendor and will also be transitioning to a new sterilization process, we cannot guarantee that such qualification or transition will be successful. Our use of these and other single-source suppliers of raw materials, components and finished goods exposes us to several risks, including disruptions in supply, price increases, late deliveries and an inability to meet customer demand. This could lead to customer dissatisfaction, damage to our reputation or customers switching to competitive products. Any interruption in supply could be particularly damaging to our ability to develop and commercialize Probuphine, CAM2038 or any of our other product candidates.

Finding alternative sources for these raw materials, components and finished goods would be difficult and in many cases entail a significant amount of time, disruption and cost. Any disruption in supply from any single-source supplier or manufacturing location could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects.

We rely on third parties to provide services in connection with the manufacture and distribution of our products, and these third parties may not perform satisfactorily. If we or our contract manufacturers fail to establish commercial manufacturing operations in compliance with regulatory requirements we may not be able to initiate commercial operations or produce sufficient quantities of our products to meet commercial requirements.

We rely on third parties for the timely supply of specified raw materials, equipment, contract manufacturing, formulation or packaging services, product distribution services, customer service activities and product returns processing. For example, we work with various third parties for the manufacture and distribution of Probuphine. Currently, we contract with Titan for clinical and commercial supply of Probuphine. In turn, Titan has contracted with DPT Laboratories, Ltd., or DPT, for the manufacture of Probuphine. DPT's manufacture of Probuphine depends on delivery to DPT of the active ingredient buprenorphine hydrochloride and milled EVA, which Titan currently sources from Teva and Southwest Research Institute, respectively. Meanwhile, we purchase Probuphine applicators directly from its manufacturer, Manan. Probuphine and Probuphine applicators are packaged and labeled by Sharp Corporation, or Sharp, and we purchase finished commercial Probuphine kits directly from Sharp. Furthermore, we rely on our exclusive specialty pharmacy distributor, Avella of Dear Valley, Inc., to purchase and distribute Probuphine. We expect that a majority of our sales of Probuphine will be through this specialty pharmacy distribution model, with the remainder through the "buy-and-bill" system.

Our reliance on third parties for the activities described above will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or manufacture our product and product candidates in accordance with regulatory requirements, or proprietary specifications, or adhere to asceptic product processing best practices, or if there are disagreements between us and these third parties, we may not be able to meet customer demand for our approved product and may not be able to complete, or may be delayed in completing, the clinical trials required for approval of our product candidates, or may not be able to obtain regulatory approval of our product candidates due to deficiencies at these third parties which could materially adversely affect our business, financial condition, results of operations and prospects. For example, in September 2016, the European Medicines Agency, or EMA, announced its recommendation that non-critical medicines manufactured at Pharmaceutics International, Inc., or Pii, the contract manufacturer of CAM2038 for our clinical trials, should no longer be available in the EU due to good manufacturing practice issues related to the risk of cross-contamination and quality assurance systems deficiencies. If we use Pii as the manufacturer of commercial supply of CAM2038 and Pii is unable to comply with regulatory requirements, regulatory authorities may not approve our marketing applications for CAM2038. If our exclusive specialty pharmaceutical distributor does not obtain required medical benefits contracts for Probuphine, it may cause delays in the shipment and distribution of Probuphine. Under certain circumstances, third parties may terminate their relationship with us, and in such instances, we may need to locate an appropriate replacement third-party relationship, which may not be readily available or on acceptable terms.

If we are unable to successfully build out, equip, validate and maintain a commercial manufacturing facility in compliance with regulatory requirements, or if we fail to establish and maintain relationships with contract manufacturers for approved products, our timelines for the implementation of our manufacturing processes could be delayed and our business could be adversely affected.

Prior to implementing the manufacturing processes for our approved products at our own facility, which we do not expect to occur prior to the second half of 2018, or the facility of a contract manufacturer, we will be required to:

- demonstrate that the disposable components and sterilization and packaging methods used in the manufacturing process are suitable for use in manufacturing in accordance with current good manufacturing practice, or cGMP;
- build and validate processing equipment that complies with cGMP;
- equip a commercial manufacturing facility to accommodate the automated manufacturing process;
- perform process testing with final equipment and disposable components to demonstrate that the methods are suitable for use in cGMP manufacturing; and
- demonstrate consistency and repeatability of the manufacturing processes in the production of such products to fully validate the manufacturing and control process using the actual cGMP processing equipment.

We and our contract manufacturers will need regulatory approval to use our manufacturing processes or the contract manufacturer's manufacturing processes for commercial purposes. If we or any of our contract manufacturers are unable to successfully implement the processes required and demonstrate that the qualifications for cGMP compliance have been met, the filing for regulatory approval of the commercial use of our manufacturing processes or our contract manufacturer's manufacturing processes may be delayed or

denied and we may not be able to initiate commercial manufacturing of our products. In such event, our commercial manufacturing costs will be higher than anticipated and we may not be able to manufacture sufficient product to meet our expected commercial requirements.

We have commenced the build-out of a new facility to manufacture Probuphine, CAM2038 and our other product candidates, if approved, on a commercial scale. We do not have experience in manufacturing products on a commercial scale and we have limited resources for such build-out. If, due to our lack of manufacturing experience and resources, we cannot manufacture our products on a commercial scale successfully or manufacture sufficient product to meet our expected commercial requirements, our business may be materially harmed.

We currently contract with third parties for the manufacture of Probuphine, CAM2038 and our other product candidates. We plan to continue contracting with third parties in the future but are also in the early stages of building our own manufacturing facility in North Carolina, initially as a secondary source and potentially as the primary source of all finished clinical and commercial drug products. Although our personnel have experience in managing on-site and contract manufacturing and quality control, to bring our own manufacturing facility on line we will need to build out our own internal capacity. We do not have experience in manufacturing products on a commercial scale or using automated processes and we have limited personnel to devote to the build-out of the new facility. In addition, because we are aware of only one company that has manufactured Probuphine for commercial sale and one company that has manufactured CAM2038 for clinical use, there are limited precedents from which we can learn. If we do not receive regulatory approval for our other product candidates, our costs for the construction and maintenance of the manufacturing facility may exceed revenue derived from the sale of products manufactured at such facility. If we do not have sufficient revenues to cover the costs of the manufacturing facility, we may need to shut down the facility at a loss or borrow or raise funds to maintain the facility until sufficient revenues can be generated. We may encounter difficulties, such as those previously encountered by Pii related to cross-contamination and quality assurance deficiencies, in the manufacture of our products due to our limited manufacturing experience and resources. These difficulties could delay the build-out and equipping of a commercial manufacturing facility and regulatory approval of the manufacture of our products, increase our costs or cause production delays or result in us not manufacturing sufficient product to meet our expected commercial requirements, any of which could damage our reputation and hurt our profitability. If we are unable to successfully increase our manufacturing capacity to commercial scale, our business may be materially adversely affected.

We may experience manufacturing problems or delays that could limit our growth or adversely affect our operating results.

Our products and product candidates are manufactured using complex processes, sophisticated equipment and strict adherence to specifications and quality systems procedures. Several factors could cause production interruptions, including equipment malfunctions, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error or disruptions in our or our suppliers' operations. Identifying and resolving the cause of any such manufacturing issues could require substantial time and resources. We do not have any existing back-up facilities in place or plans for such back-up facilities for the manufacturing of any of our product or product candidates in the event that our or our contract manufacturers' processes are interrupted. If we are unable to keep up with demand for our products by successfully manufacturing and shipping in a timely manner, our revenue could be impaired, market acceptance for our products could be adversely affected and our customers might instead purchase our competitors' products.

Our product candidates are subject to extensive regulation, and we cannot give any assurance that any of our product candidates will receive regulatory approval or be successfully commercialized.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products, among other things, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market any of our product candidates in the United States unless and until we receive regulatory approval from the FDA. We cannot provide any assurance that we will ever obtain regulatory approval for any of our product candidates, or that any such product candidates will be successfully commercialized, even if we receive regulatory approval.

Under the policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, as renewed in 2012 by the Food and Drug Administration Safety and Innovation Act, or FDASIA, the FDA is subject to a two-tiered system of review times for new drugs: standard review and priority review. For drugs subject to standard review that do not contain a new molecular entity, the FDA has a goal to complete its review of NDA and respond to the applicant within ten months from the date of receipt of an NDA while the time frame for drugs subject to priority review is six months. The review process and the PDUFA target action date may be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission. The FDA's review goals are subject to change, and the duration of the FDA's review may depend on the number and type of other NDAs that are submitted to the FDA around the same time period.

The FDA may also refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. Although the FDA is not bound by the recommendation of an advisory committee, the matters discussed at the advisory committee meeting, and in particular any concerns regarding safety, could limit our ability to successfully commercialize our product candidates subject to advisory committee review.

As part of its review of an NDA, the FDA may inspect the facility or facilities where the drug candidate is manufactured. After the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities, the FDA will issue an action letter, which will be either an approval letter, authorizing commercial marketing of the drug for a specified indication, a denial or a Complete Response Letter containing the conditions that must be met in order to secure approval of the NDA. For example, in connection with Probuphine for opioid addiction, we received a Complete Response Letter from the FDA in April 2013, indicating that further conditions needed to be met. These conditions may include deficiencies identified in connection with the FDA's evaluation of the NDA submission or the clinical and manufacturing procedures and facilities. Until any such conditions or deficiencies have been resolved, the FDA may refuse to approve the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example:

- the FDA may not deem a product candidate safe and effective;
- the FDA may not find the data from nonclinical studies and clinical trials sufficient to support approval;
- the FDA may require additional nonclinical studies or clinical trials;
- the FDA may find deficiencies with our or any of our third-party manufacturers' processes and facilities; or
- the FDA may change its approval policies or adopt new regulations.

Any of our product candidates may not be approved even if they achieve their specified endpoints in clinical trials. The FDA may disagree with our trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. For our product candidates, weekly and monthly CAM2038 for opioid addiction, the FDA has stated that it has concerns that interpretation of our Phase 3 trial findings to support a finding of efficacy may be limited as a consequence of certain elements of the study design that were employed in conducting the trial. For weekly and monthly CAM2038 for pain, the FDA noted that our formulation may not be well suited to a broader pain population and may instead only be relevant in a very narrow pain population requiring very large and consistent doses due to the possible lack of effectiveness of rescue opioids and the fact that our trial design employ high doses and large steps for dosing increments and given the potential safety concerns of the high dose.

In addition, for BBO817 for the treatment of schizophrenia, the FDA may not agree with our approach of demonstrating effectiveness of BBO17 by bridging to the pharmacokinetics of oral risperidone, and therefore may require that we conduct a Phase 3 pivotal trial. The FDA may also approve a product candidate for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials. In addition, the FDA may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates. Approval may be contingent on a REMS, which limits the labeling, distribution or promotion of a drug product.

If we are unable to obtain regulatory approval for any product candidates on the timeline we anticipate, we may not be able to execute our business strategy effectively and our ability to generate future revenues may be limited.

Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy for our product candidates such as Probuphine for the treatment of pain, or any of our other product candidates such as CAM2038, BBO417 and BBO817, which could prevent or significantly delay their regulatory approval.

Probuphine and CAM2038 for the treatment of pain, BBO417 for the treatment of acute post-operative pain, nausea and vomiting, CAM2038 for the treatment of opioid addiction, BBO817 for the treatment of schizophrenia and any of our other product candidates are prone to the risks of failure inherent in drug development. Before obtaining U.S. regulatory approval for the commercial sale of any of our product candidates, we must gather substantial evidence from well-controlled clinical trials that demonstrate to the satisfaction of the FDA that the product candidate is safe and effective, and similar regulatory approvals would be necessary to commercialize our product candidates in other countries.

In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products after approval.

The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of our clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in a delay or failure in obtaining approval or approval for a more limited indication than originally sought. For example, in our safety and efficacy study of Probuphine in adult patients with opioid addiction who were stabilized on 8 mg/day or

less of sublingual buprenorphine, our primary efficacy analysis demonstrated that the proportion of responders was 96.4% in the Probuphine arm and 87.6% in the sublingual buprenorphine arm, which satisfied a test of non-inferiority of Probuphine to sublingual buprenorphine. Various sensitivity analyses of the primary endpoint also demonstrated non-inferiority of Probuphine to sublingual buprenorphine.

However, the Probuphine label reflects more conservative efficacy analyses employed by the FDA, which resulted in substantially lower proportions of responders in both arms. Although our pre-specified primary endpoint in the trial was the proportion of responders with a responder defined as at least four out of six months negative for evidence of illicit opioid use, the FDA compared the response rates between the treatment arms for maintaining no evidence of illicit opioid use throughout the entire six-month treatment period. The FDA also used more conservative methods in evaluating urine toxicology, whereby a single missing urine sample disqualified a patient as a potential responder. Finally, while supplemental use was permitted in both treatment arms, the FDA determined that any use of supplemental buprenorphine by subjects in the Probuphine treatment arm to disqualify a patient as a potential responder, while patients in the sublingual buprenorphine were considered responders even if they received supplemental buprenorphine. The FDA considered this difference in treatment to be appropriate since, in real-world settings, titration is anticipated with sublingual buprenorphine treatment whereas the FDA thought supplemental use among Probuphine patients could mean the dose was inadequate.

A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. If Probuphine for the treatment of chronic pain or any of our other product candidates are not shown to be safe and effective in clinical trials or as a result of disagreements in trial interpretation between us and the FDA, the programs could be delayed or terminated, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Delays in the commencement or completion of clinical trials for Probuphine, CAM2038, BBO417, BBO817 or any of our other product candidates could result in increased costs to us and delay or limit our ability to pursue regulatory approval for, or generate revenues from, such product candidates, if approved.

Clinical trials are very expensive, time consuming and difficult to design and implement. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Delays in the commencement or completion of clinical testing for any of our product candidates could significantly affect our product development costs and business plan.

The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- obtaining regulatory authorization to commence a clinical trial;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, clinical investigators and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, clinical investigators and trial sites;
- failure to perform in accordance with FDA good clinical practices, or GCP, or applicable regulatory guidelines;
- manufacturing or obtaining sufficient quantities of a product candidate for use in clinical trials;

- obtaining Institutional Review Board, or IRB, or ethics committee approval to initiate and conduct a clinical trial at a prospective site;
- identifying, recruiting and training suitable clinical investigators;
- identifying, recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for the treatment of similar indications;
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy, personal issues or for any other reason they choose, or who are lost to further follow-up;
- severe or unexpected drug-related side effects experienced by patients in a clinical trial;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- delays in validating any endpoints utilized in a clinical trial;
- disagreements with the FDA with respect to our clinical trial design and our interpretation of data from clinical trials, or changes by the FDA of the requirements for approval even after it has reviewed and commented on the design for our clinical trials;
- reports from nonclinical or clinical testing of other CNS therapies that raise safety or efficacy concerns;
- uncertainty regarding proper dosing; and
- scheduling conflicts with participating clinicians and clinical institutions.

In addition, if a significant number of patients fail to stay enrolled in any of our current or future clinical trials of Probuphine, CAM2038, BBO417, BBO817 or any of our other product candidates and such failure is not adequately accounted for in our trial design and enrollment assumptions, our clinical development program could be delayed as such trials may be deemed failures. Clinical trials may also be delayed or repeated as a result of ambiguous or negative interim results or unforeseen complications in testing. For example, in the ongoing clinical trial of BBO817, we have observed extrusion or expulsion of the implant in some of our patients, which could lead us, or the FDA, to halt the trial to make product improvements. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRB or ethics committee overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or other regulatory authorities due to a number of factors, including:

- inability to design appropriate clinical trial protocols;
- inability by us, our employees, our CROs or their employees to conduct the clinical trial in accordance with all applicable FDA, DEA or other regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- discovery of serious or unexpected toxicities or side effects experienced by study participants or other unforeseen safety issues;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;

- lack of effectiveness of any product candidate during clinical trials;
- slower than expected rates of patient recruitment and enrollment rates in clinical trials;
- inability of our CROs or other third-party contractors to comply with all contractual requirements or to perform their services in a timely or acceptable manner;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- unfavorable results from on-going clinical trials and nonclinical studies.

Additionally, changes in applicable regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for Probuphine, CAM2038, BBO417, BBO817 and our other product candidates may be harmed, which may have a material adverse effect on our business, results of operations, financial condition and prospects.

Our product candidates may cause adverse events that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.

Adverse events caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt nonclinical studies and clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Some serious adverse events, or SAEs, have been observed in our clinical trials of our product candidates, but typically have not been found to specifically relate to the drug or the administration procedure. For example in our Phase 3 trial of Probuphine for opioid addiction, there were two SAEs in the Probuphine arm, convulsion and bipolar I disorder, but none of the SAEs occurred at the implant site or were related to the Probuphine or implant insertion/removal. In addition, there were a total of 18 patients who experienced one or more SAEs in the Phase 3 trial of CAM2038 for opioid addiction, with 13 patients in the sublingual buprenorphine group and five patients in the CAM2038 group experiencing at least one SAE. The reported SAEs in the sublingual buprenorphine group were haemophilia, abscess limb, acute hepatitis C, cellulitis, localised infection, osteomyelitis, pneumonia, sepsis, subcutaneous abscess, accidental overdose, intentional overdose, seizure, bipolar disorder, substance-induced mood disorder, suicidal ideation, and chronic obstructive pulmonary disease and in the CAM2038 group, the SAEs were vomiting, non-cardiac chest pain, road traffic accident, abortion spontaneous, and suicidal ideation. There was only one SAE that was possibly related to the drug, which was vomiting in the CAM2038 group. The rest of the SAEs in the Phase 3 trial of CAM2038 for opioid addiction were unrelated to the treatment drug. To make the determination of relatedness, the principal investigator used progress notes, laboratory results, hospital admissions/discharge notes, death certificate, and imaging results, in each case, as applicable. The principal investigator determines the relatedness to the treatment drug and procedure as not related, unlikely, possibly, probably and definitely related. We have the right to review all the relatedness determinations and question the results. For the SAEs for the Phase 3 trial of CAM2038 for opioid addiction, we did not question any of the relatedness determinations.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable side

effects caused by such product candidates (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product or product candidates and could significantly harm our business, prospects, financial condition and results of operations.

Even if we receive marketing approval for our product candidates, we may still face future development and regulatory difficulties.

Even if we receive marketing approval for our product candidates, regulatory authorities may still impose significant restrictions on our product candidates, indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. For example, as a condition of the marketing approval for Probuphine, the FDA has required that we conduct four post-approval clinical trials to assess potential safety risks associated with the insertion and removal of Probuphine, potential prolongation of the QT interval in the heart's electrical cycle during treatment with Probuphine and the potential for repeat administration of Probuphine into the same insertion site. The FDA has established a schedule for carrying out the required studies, subject to post-approval negotiations.

Our product candidates will also be subject to ongoing FDA requirements governing the labeling, packaging, storage and promotion of the product and record keeping and submission of safety and other post-market information. The FDA has significant post-marketing authority, including, for example, the authority to require labeling changes based on new safety information and to require post-marketing studies or clinical trials to evaluate serious safety risks related to the use of a drug.

The FDA also has the authority to require, as part of an NDA or post-approval, the submission of a REMS. For example, the FDA has required a REMS program to be put in place for Probuphine as discussed in the risk factor entitled, "*The Probuphine REMS may slow our sales and marketing efforts, which could impact our sales revenue.*" Any REMS required by the FDA may lead to increased costs to assure compliance with new post-approval regulatory requirements and potential requirements or restrictions on the sale of approved products, all of which could lead to lower sales volume and revenue.

Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs and other regulations. If we or a regulatory agency discover problems with our product candidates, such as adverse events of unanticipated severity or frequency, or problems with the facility where our product candidates are manufactured, a

regulatory agency may impose restrictions on our product candidates, the manufacturer or us, including requiring withdrawal of our product candidates from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may, among other things:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications submitted by us;
- restrict the marketing or manufacturing of the product;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products or request that we initiate a product recall.

We rely on third parties to conduct our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We rely heavily on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs for the conduct and execution of our nonclinical studies and clinical trials and control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of these studies and clinical trials and the management of data developed through such studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities.

Nevertheless, we are responsible for ensuring that each of our nonclinical studies and clinical trials is conducted in accordance with the applicable protocol and regulatory requirements. We and our third-party contractors such as CROs are required to comply with applicable requirements such as Good Clinical Practice, or GCP, and Good Laboratory Practice, or GLP. The FDA enforces these GCP and GLP requirements, as applicable, through periodic inspections of trial sponsors, principal investigators and trial and research sites. If we, our CROs or other third-party contractors fail to comply with applicable GLP or GCP, requirements, the data generated in our nonclinical studies and/or clinical trials may be deemed unreliable and the FDA may require us to perform additional studies or trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA and similar foreign regulators will determine that any of our nonclinical studies or clinical trials comply or complied with GLP or GCP standards. In addition, our clinical trials must be conducted with product produced under cGMP requirements, and require a large number of test subjects. Our inability to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party contractors or CROs terminate, we may not be able to enter into arrangements with alternative third-party contractors or CROs on commercially reasonable terms, or at all. Additionally, if CROs do not successfully carry out their contractual duties or obligations or

meet expected deadlines for our clinical trials, if they 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 protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate additional revenues could be delayed.

Switching or adding additional CROs can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, results of operations, financial condition and prospects.

If we are unable to attract and retain key personnel, we may not be able to manage our business effectively or develop our product candidates or commercialize our products.

Our success depends on our continued ability to attract, retain and motivate highly qualified management and key clinical development, regulatory, sales and marketing and other personnel. As of January 1, 2017, we have 97 employees in the United States; 61 are field-based employees engaged in sales, physician training and other marketing support functions, nine are engaged in positions directly related to sales and marketing, 13 are engaged in positions related to clinical development, product development, regulatory and operations and 14 are engaged in positions related to general and administrative. In order to execute on our business plan, we will need to expand our employee base. If we are not able to expand and retain our expanded employee base, we may not be able to effectively manage our business or be successful in commercializing our products.

We are highly dependent on the development, regulatory, commercial and financial expertise of our senior management team. We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development and commercialization objectives, our ability to raise additional capital, our ability to implement our business strategy and our ability to maintain effective internal controls for financial reporting and disclosure controls and procedures as required by the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. The loss of the services of any members of our senior management team, especially our Chief Executive Officer and President, Behshad Sheldon, could negatively impact the development and commercialization of Probuphine or any of our product candidates that may receive marketing approval. Further, if we lose any members of our senior management team, we may not be able to find suitable replacements, and our business may be harmed as a result.

Although we have employment agreements with each of our executive officers, these agreements are terminable by them at will at any time with or without notice and, therefore, do not provide any assurance that we will be able to retain their services. We do not maintain ‘‘key man’’ insurance policies on the lives of our senior management team or the lives of any of our other employees. In addition, we have clinical advisors who assist us in formulating our clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours. If we are unable to attract and retain key personnel, our business, results of operations, financial condition and prospects will be adversely affected.

Our inability to successfully acquire, develop and market additional product candidates or approved products would impair our ability to grow our business.

We may in-license, acquire, develop and/or market additional products and product candidates for the treatment of serious disorders of the CNS. Because our internal research and development capabilities are limited, we may be dependent upon other pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners and finance these arrangements.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including nonclinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any products that we develop or approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

Our computer systems, or those of our collaborators or contractors, may fail or suffer security breaches, which could result in a disruption of our business and operations.

Our internal computer systems and those of our current and any future partners, contractors and consultants are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches can cause interruptions in our operations, and can result in a material disruption of our commercialization activities, drug development programs and our business operations. The loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval and post-market study compliance efforts and significantly increase our costs to recover or reproduce the data. Similarly, we rely on a large number of third parties to supply components for and manufacture our products and product candidates, 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 commercialization of any of our other product candidates could be delayed.

We face potential product liability exposure and product liability lawsuits could cause us to incur substantial liabilities and could limit commercialization of any products or product candidates.

The commercial use of our product and clinical use of our product and product candidates expose us to the risk of product liability claims. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities regulated by the FDA or an applicable foreign regulatory authority. Our product and product candidates are designed to affect important bodily functions and processes. Any side

effects, manufacturing defects, misuse or abuse associated with our product candidates could result in injury to a patient or even death. In addition, a liability claim may be brought against us even if our product or product candidates merely appear to have caused an injury.

Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our product or product candidates, among others. If we cannot successfully defend ourselves against product liability claims we will incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- the inability to commercialize our product or product candidates, if approved;
- decreased demand for our product or, if approved, product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants; or
- loss of revenues.

Currently, we maintain insurance coverage against commercial products and clinical trial liability in an amount of up to $10 million. We believe that our clinical trial insurance is sufficient to cover our needs. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and have a material adverse effect on our business, results of operations, financial condition and prospects.

Even if we obtain FDA approval for our product candidates in the United States, we may never pursue or receive regulatory approval or commercialize our product candidates outside of the United States, which could limit our market opportunities and adversely affect our business.

If we elect to market our product candidates outside of the United States, we, or any potential partner, must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our products. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed in these "Risk Factors" regarding FDA approval in the United States, as well as other risks. For example, in the European Economic Area (comprised of 27 European Union, or EU, member states plus Iceland, Liechtenstein and Norway), we can take advantage of the hybrid application pathway of the EU Centralized Procedure, which is similar to the FDA's 505(b)(2) pathway. Hybrid applications may rely in part on the results of nonclinical tests and clinical trials contained in the authorization dossier of the reference product, but must be supplemented with additional data. In territories where data is not freely available, we or our partners may not have the ability to commercialize our products without negotiating rights from third parties to refer to their clinical data in our regulatory applications, which could require the expenditure of significant additional funds. We, or any potential partner, may be unable to obtain rights to the necessary clinical data and may be required to develop our own proprietary safety and effectiveness dossiers.

Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Inability to obtain regulatory approval in other countries or any delay or setback in obtaining such

approval could have the same adverse effects detailed in these "Risk Factors" regarding FDA approval in the United States. In addition, we, or any potential partner, may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution if we are unable to comply with applicable foreign regulatory requirements.

Our business involves the use of hazardous and highly regulated 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, and can result in significant fines, penalties or liabilities.

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 and product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to various environmental laws and regulations, including those governing the use, manufacture, storage, handling, release and disposal of, and exposure to, these hazardous materials. Such laws and regulations have generally become more stringent over time. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending use and disposal. We cannot completely eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, injury to our employees and others, environmental damage resulting in costly clean-up and liabilities under applicable environmental laws and regulations. We cannot guarantee that we or our third-party manufacturers will be in compliance with such laws and regulations or eliminate the risk of contamination or injury from these materials. In such an event, we may be liable for any resulting fines, penalties and other damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage.

Risks related to our financial position and capital requirements

We have never generated net income from operations or positive cash flow from operations and are dependent upon external sources of financing to fund our business and development.

We have financed our operations primarily through the proceeds from the issuance of our common stock and preferred stock. For the years ended December 31, 2015 and 2014, we incurred net losses of $40.6 million and $40.5 million, respectively, and our cash used in operating activities was $49.3 million and $50.4 million, respectively, and for the nine months ended September 30, 2016 and 2015, we incurred net losses of $76.8 million and $22.6 million, respectively, and our cash used in operating activities was $70.2 million and $30.9 million, respectively. As of September 30, 2016 and December 31, 2015, we had accumulated deficits of $199.9 million and $123.1 million, respectively. These losses and negative cash flow from operations have had a material adverse effect on our stockholders' equity and working capital.

We expect to continue to incur net losses and negative cash flow from operating activities for at least the next two years primarily as a result of the expenses incurred as we:

- commercialize Probuphine;
- continue product candidate development activities;
- build-out our new manufacturing facility;
- seek to identify additional product candidates;
- initiate nonclinical studies and clinical trials for any product candidates we identify and choose to develop;

- seek regulatory approval for any of our product candidates that successfully complete clinical trials;
- hire additional clinical, operational, financial, quality control and scientific personnel;
- establish a sales, marketing and commercialization infrastructure for any products that obtain regulatory approval; and
- operate as a public company.

As a result, we may remain dependent upon external sources of financing to fund our business and the development and commercialization of our approved product and product candidates. To the extent we need to raise additional capital in the future, we cannot ensure that debt or equity financing will be available to us in amounts, at times or on terms that will be acceptable to us, or at all. Any shortfall in our cash resources could require that we delay or abandon certain development and commercialization activities and could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

To become and remain profitable, we must develop and eventually commercialize product candidates with significant market potential. This will require us to be successful in a range of challenging activities, and we may never succeed in any or all of these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. See ''Risks Related to the Commercialization of our Product and Product Candidates''.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

Our limited operating history makes it difficult to evaluate our business to date and to assess our future viability.

We commenced our operations in 2012 as an affiliate company of Braeburn Pharmaceuticals BVBA SPRL, a private company with limited liability organized under the laws of Belgium. Our operations to date have been limited to organizing and staffing our company, scaling up manufacturing operations with our third-party contract manufacturers, building a sales and marketing organization, conducting product development activities for Probuphine and our product candidates and in-licensing rights to Probuphine and our product candidates. Consequently, any predictions about our future performance may not be as accurate as they would be if we had a longer history of developing and commercializing pharmaceutical products.

We are an early stage growth company with concentrated resources, and a small management team utilizing nascent systems and procedures with limited operating experience, and as a result, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors.

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern, and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements as of and for the years ended December 31, 2015 and 2014 with respect to this uncertainty. Our ability to continue as a going concern

could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on our consolidated financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. We are an early commercial stage company and have not generated significant revenues or been profitable since inception, and it is possible we will never achieve profitability. Of our product candidates, only Probuphine has received governmental approval. None of our other product candidates can be marketed until governmental approvals have been obtained. Accordingly, Probuphine is the only current source of revenues to sustain our present activities, and no other revenues will likely be available until, and unless, our other product candidates are approved by the FDA, EMA or comparable regulatory agencies in other countries and successfully marketed, either by us or a partner, an outcome which may not occur. If we successfully complete this offering and concurrent private placement based upon our currently expected level of operating expenditures, we expect to be able to fund our operations for at least the next 12 months. This period could be shortened if there are any significant increases in planned spending on development programs or more rapid progress of development programs than anticipated. There is no assurance that other financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations and liquidity could be materially negatively affected by economic conditions generally, both in the United States and elsewhere around the world. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, our results of operations and liquidity could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may decline. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are not federally insured. If economic instability continues, we cannot provide assurance that we will not experience losses on these investments.

A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. 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.

Raising additional funds by issuing securities may cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We may need to raise additional funds through public or private equity offerings, debt financings, receivables or royalty financings or corporate collaboration and licensing arrangements. To the extent that we raise additional capital by issuing equity securities or convertible debt, your ownership interest in us will be diluted.

The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants therein, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely affect our ability to conduct our business.

If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our current product or product candidates or proprietary technologies, or grant licenses on terms that are not favorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the commercialization and development of our product or product candidates.

Our ability to use net operating losses and research and development credits to reduce future taxes may be subject to certain limitations.

As of December 31, 2015, we had federal and state net operating loss, or NOLs, carryforwards of $29.7 million and $29.7 million, respectively, which begin to expire in various amounts in 2033. As of December 31, 2015, we also had federal research and development tax credit carryforwards of $0.6 million, which begin to expire in 2035. These NOLs and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an ''ownership change'' is subject to limitations on its ability to utilize its pre-change NOLs or tax credits to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with this offering, our ability to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U. S. federal and state taxable income. As described above under ''Risk Factors—Risks Related to our Financial Position,'' we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOL or credit carryforwards.

Risks related to regulation of our product and product candidates

Probuphine is a controlled substance subject to DEA regulations and failure to comply with these regulations, or the cost of compliance with these regulations, may adversely affect our business.

Probuphine contains buprenorphine, a regulated Schedule III ''controlled substance'' under the CSA, which establishes, among other things, certain registration, production quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Our failure to comply with DEA requirements could result in the loss of our ability to supply Probuphine, significant restrictions on Probuphine, civil penalties or criminal prosecution.

The DEA, and some states, also conduct periodic inspections of registered establishments that handle controlled substances. Facilities that conduct research, manufacture, store, distribute, import or export

controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and prospects. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also have controlled substances laws. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs, as well. While some states automatically schedule a drug when the DEA does so, in other states there has to be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

Our products may not be prescribed and dispensed in the manner permitted by the U.S. Drug Addiction Treatment Act of 2000, or DATA 2000.

In the United States, the DEA classifies controlled substances into five schedules. DATA 2000 permits physicians who meet certain requirements to treat opioid addiction with Schedule III, IV and V narcotic medications that have been specifically approved by the FDA for that indication. Physicians who qualify for a waiver under DATA 2000 by meeting various conditions (including with regard to training and acceptance of limits on the number of patients who can be treated under the waiver) may prescribe and diagnose such medications in settings (for example, their own offices) other than those traditionally associated with opioid addiction treatment, such as methadone clinics.

If buprenorphine is in the future viewed as having a greater potential for abuse than is reflected by its current classification, it may be reclassified as a Schedule II substance, in which case our current and future products which contain buprenorphine would no longer qualify under DATA 2000 and would have to be prescribed and dispensed in the same way as other Schedule II substances approved for the treatment of opioid addiction, such as methadone, which would significantly limit the settings and circumstances in which these products can be prescribed, and therefore have a material adverse effect on sales of our products containing buprenorphine. In addition, increased incidence of misapplication by prescribing physicians, including overriding government-imposed restrictions on patient limits per physician, could result in more stringent requirements. Such developments could have a material adverse effect on our business, results of operations and financial condition.

Healthcare reform measures and changes in policies, funding, staffing and leadership at the FDA and other agencies could hinder or prevent the commercial success of Probuphine and any of our other product candidates that may be approved by the FDA.

In the United States, there have been a number of legislative and regulatory changes to the healthcare system in ways that could affect our future results of operations and the future results of operations of our customers. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established a new Part D prescription drug benefit, which became effective January 1, 2006. Under the prescription drug benefit, Medicare beneficiaries can obtain prescription drug coverage from private sector plans that are permitted to limit the number of prescription drugs that are covered in each therapeutic

category and class on their formularies. If Probuphine or any of our other product candidates that are approved by the FDA are not widely included on the formularies of these plans, our ability to market our products to the Medicare population could suffer.

Furthermore, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. In March 2010, the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was signed into law, which includes measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the ACA of greatest importance to the pharmaceutical industry are the following:

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting any "transfer of value" made or distributed to physicians and teaching hospitals and reporting any investment interests held by physicians and their immediate family members during each calendar year. Manufacturers were required to begin data collection on August 1, 2013 and report such data to the Centers for Medicare & Medicaid Services, or CMS, by the 90th day of each subsequent calendar year;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;
- a licensure framework for follow-on biologic products;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board which, beginning in 2014, has authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Other legislative changes have also been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to market our products and generate revenues. In addition, legislation has been introduced in Congress that, if enacted, would permit more widespread importation or re-importation of pharmaceutical products from foreign countries into the United States, including from countries where the products are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could lead to a decision to decrease our prices to better compete, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications have fluctuated over the last ten years, and we cannot predict the review time for any of our submissions with any regulatory authorities. In addition, review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

If we do not comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a specialty pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;
- the Health Insurance Portability and Accountability Act or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- federal "sunshine" requirements that require drug manufacturers to report and disclose any "transfer of value" made or distributed to physicians and teaching hospitals, and any investment or ownership interests held by such physicians and their immediate family members. Manufacturers are required to report data to the government by the 90th day of each calendar year; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate it. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians, including the tracking and reporting of gifts, compensation and other remuneration to physicians. Certain states mandate implementation of commercial compliance programs to ensure compliance with these laws and impose restrictions on drug manufacturer marketing practices and tracking

and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may be found out of compliance of one or more of the requirements.

Moreover, the FDA provides guidelines with respect to appropriate promotion and continuing medical and health education activities. Although we endeavor to follow these guidelines, the FDA or the Office of the Inspector General of the U.S. Department of Health and Human Services may disagree, and we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management's attention could be diverted and our reputation could be damaged.

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

The FDA may determine that our NDA for CAM2038 for opioid addiction or any other NDA that we submit is not sufficiently complete to permit a substantive review.

Based on the results of the Phase 3 clinical trial for CAM2038 for opioid addiction, we intend to submit an NDA to the FDA for weekly and monthly CAM2038 for opioid addiction in the first half of 2017. Within 60 days of the agency's receipt of our NDA, the FDA will make a threshold determination of whether the NDA is sufficiently complete to permit a substantive review. This 60 day review is referred to as the filing review. If the NDA is sufficiently complete, the FDA will file the NDA. If the agency refuses to file the NDA, it will notify us and state the reason(s) for the refusal. The FDA may refuse to file our NDA for various reasons, including but not limited to, if

- the NDA is incomplete because it does not on its face contain the information required under the FDCA or the FDA's regulations;
- the NDA does not contain a statement that each preclinical laboratory study was conducted in compliance with the GLP requirements, or for each study not so conducted, a brief statement of the reason for the noncompliance;
- the NDA does not contain a statement that each clinical trial was conducted in compliance with the FDA's institutional review board, or IRB, regulations or was not subject to those regulations, and the agency's informed consent regulations or a brief statement of the reason for noncompliance; and
- the drug is a duplicate of a listed drug approved before receipt of the NDA and is eligible for approval under an Abbreviated New Drug Application, or ANDA, for generic drugs.

In its procedures, the FDA has stated that it could find a section 505(b)(2) NDA incomplete and refuse to file it if the NDA:

- fails to include appropriate literature or a listed drug citation to support the safety or efficacy of the drug product;
- fails to include data necessary to support any aspects of the proposed drug that represent modifications to the listed drug(s) relied upon;
- fails to provide a bridge, e.g., via comparative bioavailability data, between the proposed drug product and the listed drug product to demonstrate that such reliance is scientifically justified;
- uses an unapproved drug as a reference product for a bioequivalence study; and
- fails to provide a patent certification or statement as required by the FDA's regulations where the 505(b)(2) NDA relies on one or more listed drugs.

Additionally, the FDA will refuse to file our NDA if an approved drug with the same active moiety is entitled to five years of exclusivity, unless the exclusivity period has elapsed or unless four years of the five year period have elapsed and our NDA contains a certification of patent invalidity or non-infringement.

If the FDA refuses to file our NDA, we may amend the NDA and resubmit it. In such a case, the FDA will again review the NDA and determine whether it may be filed. There can be no assurance that the FDA will file our NDA. If the agency refuses to file our NDA, we will need to address the deficiencies cited by the FDA, which could substantially delay the review process.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. If we commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- language barriers for technical training;
- reduced or no protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

Import/export regulations and tariffs may change and increase our costs.

We are subject to risks associated with the regulations relating to the import and export of products and materials. We cannot predict whether the import and/or export of our products will be adversely affected by changes in, or enactment of, new quotas, duties, taxes or other charges or restrictions imposed by any country in the future. Any of these factors could adversely affect our business, results of operations, financial condition and prospects.

Risks related to intellectual property

Our success depends in part on our ability to obtain, maintain, protect and defend our intellectual property, which is difficult and costly, and we may not be able to ensure that we will be able to do so.

Our commercial success depends in large part on obtaining and maintaining patent, trademark and trade secret protection of our product, Probuphine, our current product candidates and any future product candidates, and their respective components, formulations, methods used to manufacture them and methods of treatment, as well as successfully defending our patents and other intellectual property rights against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing Probuphine or our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents, trade secrets and other similar intellectual property that cover these activities.

We in-license certain intellectual property for Probuphine from Titan and for CAM2038 and BBO417 from Camurus AB, or Camurus, and we may in-license other intellectual property in the future. We rely on these licensors to file and prosecute patent applications and maintain patents and otherwise protect certain of the intellectual property we license from them. We have not had and do not have primary control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. Therefore, we cannot be certain that these patents and patent applications will be prosecuted, maintained, defended and enforced in a manner consistent with the best interests of our business. If our licensors fail to maintain, prosecute, enforce or defend such patents or patent applications or otherwise lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize Probuphine, CAM2038, BBO417 and other product candidates that are the subject of such licensed rights could be materially adversely affected.

The patent positions of pharmaceutical, biopharmaceutical and medical device companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in patents in these fields has emerged to date in the United States. There have been recent changes regarding how patent laws are interpreted, and both the U.S. Patent and Trademark Office, or PTO, and Congress have recently made significant changes to the patent system. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the AIA, was signed into law, which made several significant changes to patent law in the United States. The AIA includes provisions that switched the United States from a ''first-to-invent'' system to a ''first-to-file'' system, allow third-party submission of prior art to the PTO during patent prosecution and set forth additional procedures to attack the validity of a patent by PTO-administered post-grant proceedings. Many of the substantive changes to patent law associated with the AIA, and in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly it is not clear what, if any, impact the AIA will have on the operation of our business. In addition, there have been three recent U.S. Supreme Court decisions that now show a trend of the Supreme Court, which is distinctly negative on patents. The trend of these decisions along with resulting changes in patentability requirements being implemented by the PTO could make it increasingly difficult and expensive for us and our licensors to obtain and maintain patents on our products and product candidates. We cannot accurately predict future changes in the interpretation of patent laws or changes to patent laws and those changes may materially affect the scope, validity and enforceability of our patents, our ability to obtain patents and/or the patents and applications of our collaborators and licensors. The patent situation in these fields outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property, narrow the scope of our patent protection or eliminate our patent protection. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced with respect to the patents we own or to which we have a license or to what extent those claims will be held to be valid and enforceable, nor can we predict the same with respect to any third-party patents that may relate to our products or product candidates.

The degree of protection for our intellectual property is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Even if our owned or in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. For example:

- we or our licensors, as the case may be, may not be able to detect infringement of our owned or in-licensed patents, which may be especially difficult with respect to patents directed to manufacturing processes or formulations;

- we or our licensors, as the case may be, might not have been the first to make the inventions covered by our owned or in-licensed issued patents or pending patent applications;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- our competitors or other third parties may independently develop similar or alternative technologies to, or duplicate any of, our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that our owned or in-licensed U.S. patents or patent applications are or will not be Orange-Book eligible;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents of which we or they are not aware;
- it is possible that others, such as our competitors, may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished patent applications maintained in secrecy that may later issue with claims covering our products or product candidates or products similar to ours;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our products or our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or may be held invalid or unenforceable as a result of challenges by third parties in litigation, administrative proceedings or other intellectual property related disputes;
- we may not develop additional proprietary technologies for which we can obtain patent protection; or
- the patents of others may have an adverse effect on our business.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenge may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. In addition, because our product and product candidates contain previously-approved active ingredients, such as buprenorphine, risperidone, tizanidine or granesitron, such product and product candidates are not eligible for any patent term extension. Moreover, some of our owned and in-licensed patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. If any of our owned or in-licensed patents are found to be invalid or unenforceable, or if we are otherwise unable to obtain and maintain adequate intellectual property rights, it could have a material adverse impact on our business, financial conditions, results of operations and prospects, including our ability to commercialize or license our products.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our in-licensed patent rights and technology for Probuphine was funded in part by the U.S. government. As a result, the U.S. government has certain rights to such patent rights and technology, which include march-in rights. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf. Accordingly, Titan has granted the U.S. government a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States, the invention described in the patents and patent applications relating to Probuphine. If the U.S. government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. The government's rights may also permit it to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of any of the foregoing rights or by any third party of its reserved rights could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

We also may rely on trade secrets and confidentiality agreements to protect our technology, products and proprietary know-how, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, we may be required to share our trade secrets with third party licensors, collaborators, consultants, contractors or other advisors and we have limited control over the protection of trade secrets used by such third parties. Although we use reasonable efforts to protect our trade secrets, including by entering into confidentiality agreements, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our trade secrets and proprietary information to competitors and we may not have adequate remedies for any such disclosure. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, trade secret laws in the United States vary, and some United States courts as well as courts outside the United States are sometimes less willing or unwilling to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If our trade secrets or confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace, business, financial condition and results of operations and prospects may be materially adversely affected and our ability to successfully penetrate our target markets and generate revenues from Probuphine and our product candidates, if approved by the FDA or other regulatory authorities, could be materially adversely affected.

Our proprietary position depends upon patents that are formulation or method-of-use patents, which may not prevent a competitor or other third party from using the same product candidate for another use.

Composition-of-matter patents on the active pharmaceutical ingredient, or API, in prescription drug products are generally considered to be the strongest form of intellectual property protection for drug products because such patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. We do not currently have any claims in our owned or in-licensed issued patents or pending patent applications that cover the composition-of-matter of

Probuphine or our product candidates and cannot be certain that claims in any future patent applications will cover the composition-of-matter of our current or future product candidates.

Method-of-use patents protect the use of a product for the specified method and formulation patents cover formulations of the API. These types of patents do not prevent a competitor or other third party from developing or marketing an identical product for an indication that is outside the scope of the patented method or from developing a different formulation that is outside the scope of the patented formulation. Moreover, with respect to method-of-use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute. In addition, there are numerous publications and other prior art that may be relevant to our owned and in-licensed formulation and method-of-use patents and may be used to challenge the validity of such patents in litigation or other intellectual property-related proceedings. If such challenges are successful, our owned and in-licensed patents may be narrowed or found to be invalid and we may lose valuable intellectual property rights. Any of the foregoing could have a material adverse effect on our business, financial conditions and results of operations and prospects.

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

We have entered into license agreements with third parties and may need to obtain additional licenses from others in the future in order to develop and commercialize our current and future products and product candidates. It is possible that we may be unable to obtain additional licenses we may need at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our product candidates or the methods for manufacturing them, or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to obtain any additional licenses we may need, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly.

Our existing intellectual property agreements with Titan, Camurus and Endo Pharmaceuticals, Inc., or Endo, and our future intellectual property agreements may, impose various diligence, milestone payment, royalty, insurance and other obligations on us. We may need to outsource and rely on third parties to meet these obligations including for many aspects of the clinical development, sales and marketing of our products covered under our agreements. Delay or failure by these third parties could adversely affect the continuation of our agreements with these third parties. If we fail to comply with our obligations under such agreements, our licensors may have the right to terminate the agreement, in which event we would not be able to develop or market the affected products. If we lose such licensed intellectual property rights, our business, results of operations, financial condition and prospects may be materially adversely affected. We may enter into additional intellectual property agreements, including licenses, in the future and if we fail to comply with obligations under those agreements, we could suffer similar consequences.

Moreover, the agreements under which we license intellectual property from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property, or increase what we believe to be our financial or other obligations under the relevant agreement. We may be required to pay milestones and royalties based on our revenues from sales of our products utilizing the technologies licensed or sublicensed and these royalty payments could adversely affect the overall profitability for us of any products that we may seek to

commercialize. Any of the foregoing, including if we lose intellectual property rights which we have licensed from third parties, may have a material adverse effect on our business, results of operations, financial condition and prospects.

Issued patents covering our products and technology could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

Our and our licensors' patents and patent applications, if issued, may be challenged, invalidated or circumvented by third parties. For example, if another party has filed a U.S. patent application on inventions similar to those owned or in-licensed to us, we or, in the case of in-licensed intellectual property, the licensor may have to participate in an interference proceeding declared by the PTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such proceedings may be decided against us if the other party had independently arrived at the same or similar invention prior to our own or, if applicable, our licensor's invention, resulting in a loss of our U.S. patent position with respect to such invention. If another party has reason to assert a substantial new question of patentability against any of our claims in our owned and in-licensed U.S. patents, the third party can request that the PTO reexamine the patent claims, which may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential interference and reexamination proceedings, we or our licensors may become a party to post-grant review, *inter partes* review, or derivation proceedings in the PTO, and equivalent proceedings in foreign jurisdictions (e.g., patent opposition proceedings in the European Patent Office or other jurisdictions) where either our owned or in-licensed patents or patent applications are challenged, or we are challenging the patents or patent applications of others. The costs of these proceedings could be substantial, and it is possible that our efforts would be unsuccessful. Also, we may allege that third parties infringe our or our licensors' patents and the defendant could counterclaim that such patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Any such patent litigation or proceeding could result in the loss of our or our licensors' patent or loss or reduction in the scope of one or more of the claims of such patent. Even if we are successful, such litigation or proceedings may be costly and may distract our management and other personnel from their normal responsibilities. Any of the foregoing could have a material adverse effect on our business, prospects, financial condition and results of operations.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary and intellectual property rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to opioid addiction, chronic pain and schizophrenia and the fields relating to medical implants and injection depots. As the medical device, biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our products or product candidates infringe the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of medical devices, drugs, products or their methods of use. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege that they have patents or other intellectual property rights encompassing our products, product candidates, technology or methods.

In addition, there may be issued patents of third parties of which we are currently unaware, that are infringed or are alleged to be infringed by our products, product candidates or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for our technology, products or product candidates covered by our owned and in-licensed issued patents or pending patent applications or that we or, if applicable, our licensor were the first to invent the technology, product or product candidate. Our competitors may have filed, and may in the future file, patent applications covering our or similar products, product candidates and technologies and any such patent application may have priority over our owned and in-licensed patent applications or patents, which could further require us to obtain rights or license rights to such patent applications, which may not be available on commercially reasonable terms or at all.

We may be exposed to, or threatened with, litigation by third parties having patent or other intellectual property rights alleging that our products, product candidates and/or proprietary technologies infringe their intellectual property rights. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages for having violated the third party's patents.

If a third-party's patent was found to validly cover our products and/or product candidates, proprietary technologies or their uses, we or our collaborators could be enjoined by a court and required to pay damages, which may be substantial, and could be unable to commercialize Probuphine or our product candidates or use our proprietary technologies unless we or they obtained a license to the patent. Such a license may not be available to us or our collaborators on acceptable terms, or at all and may be non-exclusive thereby giving our competitors and other third parties access to the same technologies licensed to us. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our products, technologies or methods pending a trial on the merits, which could be years away.

Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity or enforceability. A court of competent jurisdiction could hold that any asserted third party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize our products and/or product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

There is a substantial amount of litigation involving patent and other intellectual property rights in the medical device, biotechnology and pharmaceutical industries generally. If a third party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;

- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court order prohibiting us from selling or licensing the product unless the third party licenses its patent rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Moreover, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Further, we may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, 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.
Periodic maintenance fees, renewal fees, annuity fees and various other government fees on our owned and in-licensed patents and patent applications are or will be due to be paid to the PTO in several stages and various government patent agencies outside of the United States over the lifetime of such patents and patent applications and any patent rights we may own or license in the future. We have systems in place to remind us to pay these fees, and we employ outside firms to remind us or our licensors to pay annuity fees due to foreign patent agencies on our foreign patents and pending foreign patent applications. The PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors or other third parties might be able to enter the market and this circumstance would have a material adverse effect on our business.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.
Filing, prosecuting and defending patents on products and product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States, assuming that rights are obtained in the United States. Our licenses from Titan and Camurus with respect to Probuphine, CAM2038 and BBO417 are also limited to territories that include a limited number of jurisdictions. Accordingly, our licensors or other third parties hold exclusive rights to intellectual property

covering those products in other jurisdictions and if we do not obtain a license to such rights, we will not have sufficient rights to commercialize those products in those other jurisdictions. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. In addition, the statutory deadlines for pursuing patent protection in certain foreign jurisdictions are based on the priority date of each of our patent applications and we or our licensors may not timely file foreign patent applications.

Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to medical devices, biotechnology or pharmaceuticals. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Furthermore, 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, could put 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. 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 develop or license.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the medical device, biotechnology and pharmaceutical industries, many of our employees, consultants or advisors are currently, or were previously, employed at universities or other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these individuals or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management, which would adversely affect our financial condition.

In addition, we may not be successful in executing agreements that require our employees, consultants or advisors who may be involved in the conception or development of intellectual property to assign such intellectual property to us. Even if we execute such agreements, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover our products or the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to develop and/or practice products or technology that is similar to our products or technology or aspects of our products or technology but that is not covered by the claims of patents, should such patents issue from our patent applications;
- we or our licensors might not have been the first to make the inventions covered by a pending patent application that we own or license;
- we or our licensors might not have been the first to file patent applications covering an invention;
- third parties may independently develop similar or alternative products or technologies without infringing our intellectual property rights;
- pending patent applications that we own or license may not lead to issued patents;
- patents, if issued, that we own or license may not provide us with any competitive advantages, or may be narrowed or held invalid or unenforceable, as a result of legal challenges by our competitors or other third parties;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we may not be able to obtain and/or maintain necessary or useful licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may be asserted against us and have an adverse effect on our business.

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

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover our trade secrets or that our trade secrets will be misappropriated or disclosed.

Because we currently contract with third parties for the manufacture of Probuphine, CAM2038, BBO417 and our other product candidates and may enter into similar contracts in the future, we must, at times, share our proprietary technology and other confidential information, including trade secrets, with such third parties. We seek to protect our proprietary technology and other confidential information, in part, by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, contractors, advisors, employees and consultants prior to beginning research or disclosing any such proprietary technology or confidential information. These agreements typically limit the rights of the third parties to use or disclose our proprietary or confidential information. Despite the contractual provisions employed when working with third parties and our efforts to protect our proprietary technology and confidential information, the need to share trade secrets and other confidential information increases the risk that such trade secrets and confidential information become known by our competitors or other third parties, are independently developed or published by third parties, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's or third party's discovery of our know-how and trade secrets or any other unauthorized use or disclosure of such know-how and trade secrets would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks relating to the securities markets and an investment in our stock

We expect that our stock price will fluctuate significantly and investors may not be able to resell their shares at or above the initial public offering price.

The trading price of our common stock following this offering may be highly volatile and could be subject to wide fluctuations in response to various factors, many of which are beyond our control. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including those discussed in this ''Risk Factors'' section and elsewhere in this prospectus and the following:

- the results of our efforts to discover, develop, acquire or in-license product candidates;
- success of competitive products or technologies;
- results or delays in clinical trials or changes in the development status of our future product candidates;
- any delay in our regulatory filings for any product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products, including clinical trial requirements for approvals;
- our inability to obtain or delays in obtaining adequate product supply for any approved product or inability to do so at acceptable prices;

- any failure to commercialize any product candidates or if the size and growth of the markets we intend to target fail to meet expectations;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to our or our competitors' product candidates;
- introductions or announcements of new products offered by us or significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our collaborators or our competitors and the timing of such introductions or announcements;
- our ability to effectively manage our growth;
- our ability to successfully treat additional types of genetic-based diseases;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in estimates to or projections of financial results, development timelines or recommendations by securities analysts;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- market conditions in the pharmaceutical and biotechnology sectors or the economy generally;
- our ability or inability to raise additional capital through the issuance of equity or debt or collaboration arrangements and the terms on which we raise it;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation or interference matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation; and
- general economic, industry and market conditions.

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.

The stock market in general, and market prices for the securities of biopharmaceutical companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance.

In several recent situations when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock and an active trading market for our shares may never develop or be sustained following this offering. The initial price to the public for our common stock was determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. The lack of an active market may impair investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the market value of their shares and may impair our ability to raise capital. Further, Apple Tree Partners IV, L.P, together with its affiliates, or Apple Tree, owned all of our outstanding capital stock as of September 30, 2016, and the sales of stock by Apple Tree, or the lack thereof, may have a material adverse effect on our stock price and trading volume.

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. We do not currently have, and may never obtain, research coverage by industry or financial analysts. If no, or few, analysts commence coverage of us, the trading price for our stock would be negatively impacted. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Apple Tree will continue to own a majority of our common stock after this offering and will be able to control or exercise significant influence over matters subject to stockholder approval.

Apple Tree owned all of our capital stock as of December 31, 2016. Upon completion of this offering and concurrent private placement, Apple Tree will beneficially own 73.9% of our capital stock (or 71.1% if the underwriters' exercise their option in full to purchase additional shares), excluding any shares that Apple Tree may purchase in this offering. Accordingly, after this offering, Apple Tree will be able to determine the composition of the board of directors, retain the voting power to approve all matters requiring stockholder approval, including mergers and other business combinations, and continue to have significant influence over our operations. The interests of Apple Tree could deviate from the interests of our other stockholders. In addition, the concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us that you may believe are in your best interests as one of our stockholders. This in turn could have a material adverse effect on our stock price and may prevent attempts by our stockholders to replace or remove the board of directors.

Because we qualify for, and intend to rely on, the exemptions from corporate governance requirements as a result of being a "controlled company" within the meaning of the NASDAQ listing standards, you will not have the same protections afforded to stockholders of companies that are subject to such requirements.

Upon the completion of this offering, Apple Tree will continue to control a majority of our common stock. As a result, we are a "controlled company" within the meaning of the NASDAQ listing standards. Under these rules, a company of which more than 50% of the voting power is held by an individual, a group or another company is a "controlled company" and may elect not to comply with certain NASDAQ corporate governance requirements, including the requirement that a majority of the board of directors consist of independent directors. Following this offering, we intend to rely on certain of these exemptions.

Accordingly, you will not have the same protections afforded to stockholders of companies that are subject to all of the NASDAQ corporate governance requirements.

If you purchase shares of common stock in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. To the extent shares subsequently are issued under outstanding options or restricted stock units, you will incur further dilution. Based on the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, you will experience immediate dilution of $12.19 per share, representing the difference between our pro forma as adjusted net tangible book value per share, which gives effect to this offering and the concurrent private placement, and the assumed initial public offering price. In addition, purchasers of common stock in this offering will have contributed approximately 36% of the aggregate price paid by all purchasers of our stock but will own only approximately 29% of our common stock outstanding after this offering (or 40% and 32%, respectively, if the underwriters exercise their option in full to purchase additional shares). See ''Dilution''.

Our management team has broad discretion to use the net proceeds from this offering and concurrent private placement and its investment of these proceeds may not yield a favorable return. They may invest the proceeds of this offering in ways with which investors disagree.

We expect to use the net proceeds from this offering and concurrent private placement for the commercialization of Probuphine, advancement of product candidates in clinical development and for working capital and other general corporate purposes. We may also use a portion of the net proceeds to acquire, license and invest in complementary products, technologies or businesses; however, we currently have no agreements or commitments to complete any such transaction. However, within the scope of our plan, and in light of the various risks to our business that are set forth in this section, our management will have broad discretion over the use of proceeds from this offering and concurrent private placement, and we could spend the proceeds from this offering and concurrent private placement in ways our stockholders may not agree with or that do not yield a favorable return, if at all. If we do not invest or apply the proceeds of this offering and concurrent private placement in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline. See ''Use of Proceeds''.

Future sales of our common stock or securities convertible or exchangeable for our common stock may depress our stock price.

Our stockholders prior to the sale of shares in our initial public offering may continue to hold a substantial number of shares of our common stock that they are able to sell in the public market, subject in some cases to certain legal restrictions. Significant portions of these shares are held by a small number of stockholders. If these stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. The perception in the market that these sales may occur could also cause the trading price of our common stock to decline.

Our executive officers, directors and the holders of options and restricted stock units, or RSUs, have entered into market standoff agreements with us or lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of our stock for 180 days following the date of this prospectus. We refer to such period as the lock-up period. Upon expiration of the lock-up

period, approximately 1,254,000 shares of our common stock subject to RSUs are expected to have satisfied both the service-based vesting condition and liquidity-based vesting condition and may be eligible for sale in the public market at that time. In order to avoid pressure on our stock's trading volume at the expiration of the lock-up period, beginning as early as 90 days from the date of this prospectus through the end of the lock-up period, we expect to waive the liquidity-based vesting condition with respect to certain RSUs and to permit the sale of a number of shares subject to RSUs in the public market in order to satisfy income tax obligations for such individuals resulting from the vesting and settlement of the outstanding RSUs. We expect that approximately 424,000 shares, 38,000 shares, 396,000 shares and 396,000 shares will be eligible for sale into the public market on the 90th day, the 120th day, the 150th day and the 180th day, respectively, after the date of this prospectus, which may be subject to increase as agreed in writing with the underwriters. Beginning 181 days after the date of this prospectus, the remainder of the shares of our common stock will be eligible for sale in the public market from time to time thereafter, subject in some cases to the volume and other restrictions of Rule 144 promulgated under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than 75% of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than 75% of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions

in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

The continued operation and expansion of our business will require substantial funding. Investors seeking cash dividends in the foreseeable future should not purchase our common stock. Although Braeburn BVBA paid a liquidating cash dividend upon its dissolution in November 2015, we have never paid cash dividends on any of our classes of capital stock to date and we currently intend to retain our available cash to fund the development and growth of our business. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any return to stockholders will therefore be limited to the appreciation in the market price of their stock, which may never occur.

Our certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation will provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws, any action to interpret, apply, enforce, or determine the validity of our certificate of incorporation or bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting. Commencing with our first annual report on Form 10-K, we will be required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal

control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as 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 other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirement.

Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion, which could potentially subject us to sanctions or investigations by the SEC, or other regulatory authorities. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by NASDAQ, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud and the accuracy and timing of our financial reporting may be adversely affected.

Upon consummation of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. These rules and regulations will require, among other things, that we establish and periodically evaluate procedures with respect to our internal controls over financial reporting. Reporting obligations as a public company are likely to place a considerable strain on our financial and management systems, processes and controls, as well as on our personnel. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations reflect the reality that judgments can be faulty, and that breakdowns can occur because of 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 an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If our senior management is unable to conclude that we have effective internal control over financial reporting, or to certify the effectiveness of such controls, or if our independent registered public accounting firm cannot render an unqualified opinion on management's assessment and the effectiveness of our internal control over financial reporting once we cease to be an emerging growth company, or if material weaknesses in our internal controls are identified, we could be subject to regulatory scrutiny and a loss of public confidence, which could have a material adverse effect on our business and our stock price. In addition, if we do not maintain adequate financial and management personnel, processes and controls, we may not be able to manage our business effectively or accurately report our financial performance on a timely basis, which could cause a decline in our common stock price and adversely affect our results of operations and financial condition.

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of January 1, 2017, we have 97 employees in the United States; 61 are field-based employees engaged in sales, physician training and other marketing support functions, nine are engaged in positions directly related to sales and marketing, 13 are engaged in positions related to clinical development, product development, regulatory and operations and 14 are engaged in positions related to general and administrative, and in connection with becoming a public company, we expect to increase our number of employees and the scope of our operations. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, including the construction of a manufacturing facility, and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete will depend, in part, on our ability to effectively manage the future development and expansion of our company.

We will incur increased costs as a result of operating as a public company.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also anticipate that we will incur costs associated with relatively recently adopted corporate governance requirements, including requirements of the SEC, and the NASDAQ Global Market. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers. We are currently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

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

We are an emerging growth company, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to ''emerging growth companies.'' We could remain an ''emerging growth company'' for up to five years, or until the earliest of (1) the last day of the first fiscal year in which our annual gross revenue exceeds $1 billion, (2) the date that we become a ''large accelerated filer'' as defined in Rule 12b-2 under the Securities Exchange Act of 1934, which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter or (3) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three-year period. 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:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;
- 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; and
- reduced disclosure obligations regarding executive compensation.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this prospectus. In particular, we have not included all of the executive compensation 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 certain or all of 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 provides that an emerging growth company may 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 exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

After the completion of this offering, we may be at an increased risk of securities class action litigation. Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Special note regarding forward-looking statements

This prospectus contains forward-looking statements within the meaning of the federal securities laws, and these statements involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- the accuracy of our estimates regarding expenses, future revenues, cash forecasts, and capital requirements;
- the expected timing of progress and reporting results from our clinical trials of Probuphine, CAM2038, BBO817 and our other product candidates and expected timing of regulatory filings and approvals, including the timing for submitting an NDA to the FDA for such product candidates;
- our ability to successfully commercialize Probuphine and launch weekly and monthly CAM2038, if approved, for the treatment of opioid addiction, based on our sales and marketing plans;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our ability to establish our products as new standards of care in the therapeutic markets in which we operate;
- the willingness of healthcare providers to prescribe and patients to use our implantable and injectable medications;
- the performance of our third-party contract manufacturers and clinical research organizations;
- our ability to construct and operate our own manufacturing plant and to find and qualify suitable suppliers;
- the size of markets and the potential market opportunity for which our products are approved and our ability to penetrate such markets;
- the rate and degree of market acceptance of our products for any indication once approved;
- our ability to obtain additional financing when needed;
- our competitive position and the success of competing products that are or become available for the indications that we are pursuing;
- our intellectual property position;
- the loss of key scientific or management personnel; and
- regulatory and political developments in the United States and foreign countries.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this prospectus.

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this prospectus primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in ‘‘Risk Factors’’ and elsewhere in this prospectus. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this prospectus. You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to the registration statement, of which this is a part, completely and with the understanding that the results, events and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this prospectus relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this prospectus to reflect events or circumstances after the date of this prospectus or to reflect new information or the occurrence of unanticipated events, except as required by law. 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. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

Industry and market data

We obtained the industry and market data in this prospectus from our own internal estimates and research as well as from industry and general publications and research, surveys, studies and trials conducted by third parties. Some data is also based on our good faith estimates, which are derived from management's knowledge of the industry and independent sources. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We are responsible for all of the disclosure contained in this prospectus, and we believe these industry and general publications and third-party research, surveys, studies and trials are reliable. In addition, while we believe the market opportunity information included in this prospectus is generally reliable and is based on reasonable assumptions, such data involves risks and uncertainties and are subject to change based on various factors, including those discussed under the heading ''Risk Factors.'' These and other factors could cause our results to differ materially from those expressed in the estimates made by third parties and by us.

Use of proceeds

We estimate that the net proceeds from the sale of shares of our common stock that we are selling in this offering will be approximately $137.2 million, based upon an assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters' option to purchase additional shares from us is exercised in full, we estimate that our net proceeds would be approximately $158.2 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase or decrease in the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus would increase or decrease the net proceeds that we receive from this offering by approximately $7.2 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions payable by us. Similarly, each increase or decrease of one million in the number of shares of common stock offered by us would increase or decrease the net proceeds that we receive from this offering by approximately $18.1 million, assuming the assumed initial public offering price remains the same and after deducting the estimated underwriting discounts and commissions payable by us. A one million share increase in the number of shares offered by us together with a concomitant $1.00 increase in the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase the net proceeds to us from this offering by $26.2 million after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Conversely, a one million share decrease in the number of shares offered by us together with a concomitant $1.00 decrease in the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, would decrease the net proceeds to us from this offering by $24.4 million after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We currently expect to use the net proceeds from the offering as follows:

- commercialization of Probuphine, advancement of product candidates in clinical development; and
- the remaining proceeds, if any, to fund new and ongoing research and development activities, working capital and other general corporate purposes, which may include funding for the hiring of additional personnel, capital expenditures and the costs of operating as a public company.

Based on our current plans, we believe our cash, cash equivalents and short-term investments, together with the net proceeds to us from this offering and the concurrent private placement, will be sufficient to fund our operations for at least the next 12 months.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from nonclinical studies and any ongoing clinical trials or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering and the concurrent private placement.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

Dividend policy

We have never declared or paid any cash dividends on our capital stock. However, in connection with its dissolution in November 2015, Braeburn BVBA transferred its assets to Apple Tree, including its cash which was deemed to be a liquidating cash dividend by Braeburn BVBA. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be made at the discretion of our board of directors. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Capitalization

The following table sets forth our cash, cash equivalents and capitalization as of September 30, 2016:

- on an actual basis;
- on a pro forma basis to give effect to (i) the conversion of all outstanding shares of our convertible preferred stock, into an aggregate of 16,503,945 shares of common stock, par value $0.0001 upon the completion of this offering and the filing of our amended and restated certificate of incorporation upon the completion of this offering, and (ii) the issuance of 991,110 shares of common stock related to restricted stock units granted under the 2015 Equity Incentive Plan that were both the service-based vested and liquidity-based vested at the completion of our proposed initial public offering; and
- on a pro forma as adjusted basis to give further effect to (i) the sale of 7,692,308 shares of our common stock offered in this offering, based on an assumed an initial public offering price of $19.50 per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and (iii) the sale of $40 million shares of our common stock in a concurrent private placement to Apple Tree (or 2,051,282 shares of common stock, based on the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus).

Our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of the offering determined at pricing. You should read this information together with our audited consolidated financial statements and related notes appearing elsewhere in this

prospectus and the information set forth under the heading "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of September 30, 2016		
	Actual	Pro Forma	Pro Forma As Adjusted
	(unaudited)	(in thousands, except share amounts)	
Cash and cash equivalents(1)	$ 23,528	$ 23,528	$ 200,769
Stockholders' equity:			
Convertible preferred stock (Series A Preferred Stock), $0.0001 par value; 350,000,000 shares authorized, 222,803,262 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	22	–	–
Preferred Stock, $0.0001 par value; 1,000,000 shares authorized, no shares issued or outstanding, actual; no shares authorized, issued or outstanding, pro forma; no shares authorized, issued or outstanding, adjusted	–	–	–
Common Stock, $0.0001 par value; 90,000,000 shares authorized, no shares issued or outstanding, actual; 90,0000 shares authorized, 17,495,055 shares issued and outstanding, pro forma; 90,000,000 shares authorized, 27,238,645 shares issued and outstanding, adjusted(1)	–	2	3
Accumulated other comprehensive income	–	–	–
Additional paid-in capital	233,572	238,134	375,373
Accumulated deficit	(199,921)	(204,462)	(204,462)
Total stockholders' equity	33,673	33,673	170,914
Total capitalization	$ 33,673	$ 33,673	$ 170,914

(1) Does not reflect the $22 million capital contribution from Apple Tree in October 2016 in connection with the issuance and sale of 22,000,000 shares of our series A preferred stock or the $22 million capital contribution from Apple Tree in December 2016 in connection with the further issuance and sale of 22,000,000 shares of our series A preferred stock.

A $1.00 increase or decrease in the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase or decrease each of cash and cash equivalents, additional paid-in capital, total stockholders' deficit (equity) and total capitalization on a pro forma as adjusted basis by approximately $7.2 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase or decrease of one million shares in the number of shares offered by us would increase or decrease each of cash and cash equivalents, additional paid-in capital, total stockholders' deficit (equity) and total capitalization on a pro forma as adjusted basis by approximately $18.1 million, assuming no change in the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A one million share increase in the number of shares offered by us together with a concomitant $1.00 increase in the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase each of cash and cash equivalents, total stockholders' equity and total capitalization by $26.2 million after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Conversely, a one million share decrease in the number of shares offered by us together with a concomitant $1.00 decrease in the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would decrease each of cash and cash equivalents, total stockholders' equity and total capitalization by $24.4 million after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock shown as outstanding on an actual, pro forma and pro forma as adjusted basis in the table above is based on no shares of common stock outstanding as of September 30, 2016, in addition to the 16,503,945 shares of our common stock issuable upon the conversion of our convertible preferred stock, which excludes:

- 1,100,000 shares of common stock reserved for future issuance under our 2017 Stock Option and Incentive Plan, plus annual increases thereunder, as described in the section "Executive Compensation—Stock Option Plans—2017 Stock Option and Incentive Plan," which will become effective on the date immediately prior to the date on which the registration statement of which this prospectus is part is declared effective;
- 1,013,417 shares of common stock reserved for future issuance under our 2015 Equity Incentive Plan, after giving effect to the reverse stock split and taking into account awards that have been granted as described below; and
- 75,925 shares of our common stock issuable upon the exercise of outstanding options as of September 30, 2016 at a weighted average exercise price of $2.38 per share.

Dilution

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering. Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the pro forma as adjusted net tangible book value per share of common stock immediately after completion of this offering.

Net tangible book value per share is determined by dividing our total tangible assets less our total liabilities by the number of shares of common stock outstanding. As of September 30, 2016, there were no shares of common stock outstanding. Our pro forma net tangible book value (deficit) as of September 30, 2016 was $14.7 million, or $0.89 per share, based on the total number of shares of our common stock outstanding as of September 30, 2016, after giving effect to the conversion of all outstanding shares of our convertible preferred stock as of September 30, 2016 into an aggregate of 16,503,945 shares of common stock, which conversion will occur immediately prior to the completion of this offering.

After giving effect to the sale by us of 7,692,308 shares of common stock in this offering based on the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and the sale of 2,051,282 shares of our common stock in the concurrent private placement to Apple Tree, based on the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, our pro forma as adjusted net tangible book value as of September 30, 2016 would have been $192.0 million, or $7.31 per share. This represents an immediate increase in pro forma net tangible book value of $6.42 per share to our existing stockholders and immediate dilution of $12.19 per share to investors purchasing shares of common stock in this offering at the assumed initial public offering price. The following table illustrates this dilution:

Assumed initial public offering price per share		$19.50
Historical net tangible book value per share as of September 30, 2016	$0.00	
Pro forma increase in net tangible book value per share attributable to the conversion of preferred stock	$0.89	
Pro forma net tangible book value per share as of September 30, 2016	$0.89	
Increase in net tangible book value per share attributable to new investors	$6.42	
Pro forma net tangible book value per share after this offering		$ 7.31
Dilution per share to new investors		$12.19

Each $1.00 increase or decrease in the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, our pro forma as adjusted net tangible book value per share to new investors by $0.30, and would increase or decrease, as applicable, dilution per share to new investors in this offering by $12.88 or $11.49, respectively, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions payable by us. An increase of one million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase the pro forma as adjusted net tangible book value per share after this offering by $0.40 and decrease the dilution per share to new

investors participating in this offering by $11.79, assuming the assumed initial public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A decrease of one million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value per share after this offering by $0.43 and increase the dilution per share to new investors participating in this offering by $12.62, assuming the assumed initial public offering price remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. A one million share increase in the number of shares offered by us together with a concomitant $1.00 increase in the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase the pro forma as adjusted net tangible book value per share after this offering by $0.72 and increase the dilution per share to new investors participating in this offering by $12.46, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Conversely, a one million share decrease in the number of shares offered by us together with a concomitant $1.00 decrease in the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value per share after this offering by $0.70 and decrease the dilution per share to new investors participating in this offering by $11.89, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

If the underwriters exercise their option to purchase additional shares from us in full, the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering would be $7.77 per share, and the dilution in pro forma net tangible book value per share to new investors in this offering would be $11.73 per share.

The following table presents, on a pro forma as adjusted basis as of September 30, 2016, after giving effect to the conversion of all outstanding shares of convertible preferred stock into common stock immediately prior to the completion of this offering, the differences between the existing stockholders, Apple Tree as the concurrent private placement investor, and the new investors purchasing shares of our common stock in this offering with respect to the number of shares purchased from us, the total consideration paid or to be paid to us, which includes net proceeds received from the issuance of common stock and convertible preferred stock, cash received from the exercise of stock options, and the average price per share paid or to be paid to us at an assumed offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares purchased		Total consideration		Average price per share
	Number	Percent	Amount	Percent	
Existing stockholders	16,503,945	63%	$ 222,803,262	54%	$ 13.50
Concurrent private placement investor	2,051,292	8%	40,000,000	10%	$ 19.50
New investors	7,692,308	29%	150,000,000	36%	$ 19.50
Total	26,247,535	100%	$ 412,303,262	100%	$ 15.73

Except as otherwise indicated, the above discussion and tables assume no exercise of the underwriters' option to purchase additional shares. If the underwriters exercise their option to purchase additional

shares in full from us, our existing stockholders would own 68% and our new investors would own 32% of the total number of shares of our common stock outstanding upon the completion of this offering.

The number of shares of our common stock to be outstanding after this offering is based on 16,503,945 shares of our common stock issuable upon the conversion of our convertible preferred stock, and excludes:

- the $22 million capital contribution from Apple Tree in October 2016 in connection with the issuance and sale of 22,000,000 shares of our series A preferred stock and the $22 million capital contribution from Apple Tree in December 2016 in connection with the issuance and sale of 22,000,000 shares of our series A preferred stock;
- 1,100,000 shares of common stock reserved for future issuance under our 2017 Stock Option and Incentive Plan, plus annual increases thereunder, as described in the section "Executive Compensation—Stock Option Plans—2017 Stock Option and Incentive Plan," which will become effective on the date immediately prior to the date on which the registration statement of which this prospectus is part is declared effective;
- 1,013,417 shares of common stock reserved for future issuance under our 2015 Equity Incentive Plan, after giving effect to the reverse stock split and taking into account awards that have been granted as of January 1, 2017 as described below;
- 75,925 shares of our common stock issuable upon the exercise of outstanding options as of September 30, 2016 at a weighted average exercise price of $2.38 per share; and
- 1,036,882 shares of our common stock issuable upon vesting of restricted stock units outstanding as of September 30, 2016.

New investors will experience further dilution if any of our outstanding options are exercised, new options are issued and exercised under our equity incentive plans or we issue additional shares of common stock, other equity securities or convertible debt securities in the future.

Selected financial data

You should read the following selected historical consolidated financial data below together with ''Capitalization,'' ''Management's Discussion and Analysis of Financial Condition and Results of Operations'' and the consolidated financial statements, related notes and other financial information included elsewhere in this prospectus. We derived the statements of operations data for the years ended December 31, 2014 and 2015 and the balance sheet data as of December 31, 2014 and 2015, from our audited consolidated financial statements included elsewhere in this prospectus. The statements of operations data for the nine months ended September 30, 2016 and 2015 and the balance sheet data as of September 30, 2016 have been derived from our unaudited consolidated financial statements appearing at the end of this prospectus and have been prepared on the same basis as the audited consolidated financial statements. Our historical results are not necessarily indicative of results to be expected in any future period.

	Year ended December 31,		Nine months ended September 30,	
	2014	2015	2015	2016
		(in thousands)		
			(unaudited)	
Statement of Operations Data:				
Revenue	$ –	$ 25	$ –	$ 42
Cost of sales	–	–	–	44
Gross profit	–	25	–	(2)
Expenses:				
Research and development	37,195	31,374	16,345	50,933
Selling, general and administrative	3,076	6,964	4,031	27,095
Total expenses	40,271	38,338	20,376	78,028
Loss from operations	(40,271)	(38,313)	(20,376)	(78,030)
Other income / (expense), net	(185)	(650)	(646)	1,214
Loss before income tax expense / (benefit)	(40,456)	(38,963)	(21,022)	(76,816)
Income tax expense / (benefit)	–	1,600	1,602	–
Net loss	(40,456)	(40,563)	(22,624)	(76,816)
Other comprehensive income / (loss)				
Unrealized gain / (loss) during period, net of tax benefit of $18 and $0 for the year ended December 31, 2015 and 2014 and $215 and $0 for the nine months ended September 30, 2016 and 2015, respectively	(925)	2,140	1,635	(28)
Comprehensive loss	$ (41,381)	$ (38,423)	$ (20,989)	$ (76,844)
Net loss per common share, basic and diluted	$ (1.85)	$ (0.36)	$ (0.26)	–
Net loss per preferred share, basic and diluted	–	$ (0.33)	$ (0.26)	$ (0.45)
Weighted average basic and diluted common shares outstanding	21,867,489	76,932,160	76,019,503	–
Weighted average basic and diluted preferred shares outstanding	–	39,826,161	10,000,000	170,923,700

	December 31,		September 30,
	2014	2015	2016
		(in thousands)	(unaudited)
Balance Sheet Data:			
Cash and cash equivalents	$ 8,755	$ 5,507	$ 23,528
Prepaid expenses and other current assets	325	3,017	5,912
Investment in Titan Pharmaceuticals	2,888	5,045	–
Property and equipment, net	176	423	11,407
Intangible assets, net	–	–	14,342
Other non-current assets	50	98	1,613
Total assets	12,194	14,090	56,802
Accounts payable, accrued expenses, and other current liabilities	14,435	7,314	18,469
Financing obligation and other long-term liabilities	365	9	4,660
Total liabilities	14,800	7,323	23,129
Total shareholders' equity / (deficit)	(2,606)	6,767	33,673
Total liabilities and shareholders' equity / (deficit)	$ 12,194	$14,090	$56,802

Management's discussion and analysis of financial condition and results of operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with "Selected Financial Data" and our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion and analysis, and other parts of this prospectus, contains forward-looking statements and numerous risks and uncertainties, including but not limited to those described in the "Risk Factors" section of this prospectus. Our actual results, including timing therein, may differ materially from those contained in any forward-looking statements.

You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors, and related estimates and judgments that may cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Overview

We are a commercial-stage pharmaceutical company focused on the development and commercialization of novel long-acting medications for serious disorders of the central nervous system, or CNS. Our proprietary implantable and injectable delivery mechanisms provide differentiated solutions for chronic diseases with high unmet medical needs. Our specialty CNS focus is on fast-growing therapeutic areas recognized as serious public health crises, where long-acting technologies offer important benefits such as increased medication compliance, improved patient convenience, reduced risk of abuse and relapse and reduced public health and societal costs.

Our lead therapeutic area is opioid addiction, which is sometimes referred to as opioid use disorder or opioid dependence, and is a chronic, relapsing brain disease characterized by long-lasting structural and functional changes in the brain. Our other therapeutic areas of focus are pain, schizophrenia and spasticity, which refers to feelings of stiffness and a wide range of involuntary muscle spasms.

We believe that long-acting medications for specialty CNS conditions are not just a matter of convenience, but are an essential tool for the effective treatment of these diseases. These are chronic CNS conditions requiring constant vigilance, where the consequences of suboptimal treatment compliance can range from severe to life-threatening. For example, patients with opioid addiction are currently limited to treatment with daily medications, for which poor compliance can rapidly lead to relapse, overdose and death. For our lead therapeutic areas of focus, we are focused on developing weekly, monthly and six-month dosage formulations that we believe will allow healthcare providers to treat patients throughout the continuum of care from treatment initiation through long-term maintenance. This enables healthcare providers to prescribe personalized care for each patient across a complex patient base having diverse therapeutic needs.

Our marketed product, Probuphine, was approved by the United States Food and Drug Administration, or FDA, on May 26, 2016, and is the first and only implantable formulation of buprenorphine for the maintenance treatment of opioid addiction. Our lead product candidates, weekly and monthly CAM2038, are subcutaneous injectable formulations of buprenorphine for the treatment of opioid addiction. In November 2016, we reported positive top-line results from a Phase 3 trial of weekly and monthly CAM2038 for opioid addiction. CAM2038 achieved non-inferiority compared to oral daily buprenorphine based on the primary endpoint and superiority to oral daily buprenorphine based on a secondary endpoint. Based on the successful results from this Phase 3 trial, we are working to submit a New Drug Application, or NDA, for

weekly and monthly CAM2038 in the first half of 2017. The FDA has granted fast track designation for weekly and monthly CAM2038 for the treatment of opioid addiction.

Our investigational pipeline also includes late-stage programs in the therapeutic areas of pain and schizophrenia. Because buprenorphine has also been approved for the treatment of chronic pain, we believe our long-acting medications, Probuphine and CAM2038, have the potential to provide a suite of therapeutic products across the continuum of care for pain. We believe our long-acting medications, if approved, will provide continuous around-the-clock therapy, resulting in improved pain relief, increased convenience and enhanced quality of life. We are also developing BB0817, an implant that offers continuous, six-month delivery of risperidone, one of the most effective chemical compounds for the treatment of schizophrenia. Schizophrenia requires life-long treatment, and positive outcomes are significantly dependent on medication compliance, making long-acting treatments especially effective. We believe BB0817 has the potential for unique positioning in the schizophrenia market with a treatment duration that at least doubles currently-marketed injectables, which range from two weeks to three months. We also have two product candidates, BB0417 for the treatment of acute post-operative pain, nausea and vomiting, and BB1216 for the treatment of spasticity, which are in earlier-stages of development.

We were incorporated in 2012 as a wholly-owned subsidiary of Braeburn Pharmaceuticals BVBA SPRL, or Braeburn BVBA, a Belgium domiciled entity also founded in 2012. Together, these entities were a wholly-owned portfolio company of Apple Tree Partners IV, L.P. and its subsidiaries. In November 2015, Braeburn BVBA was voluntarily dissolved, and as a result, we became a wholly-owned portfolio company of Apple Tree Partners IV, L.P.

Critical accounting policies and financial overview

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. 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 readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described above and in Note 1 to our consolidated financial statements appearing elsewhere in this prospectus, we believe that the following accounting policies are also critical for fully understanding and evaluating our financial condition and results of operations.

Financial overview

Revenues

Since approval of our lead product, Probuphine, on May 26, 2016, our efforts have focused on training and certifying healthcare providers and working with payors on reimbursement coverage. We are planning a full-scale commercial launch in the first quarter of 2017 with our new fully-deployed field force, consisting

entirely of our employees. We expect personnel and recruiting costs, travel expenses, training expenses and field-related activities of the new field force to add approximately $15.8 million to our operating expenses in the next fiscal year. Our revenues relate to product sales of Probuphine, and supplies related to the Probuphine insertion and removal procedures.

We recognize revenue from product sales when: (i) the price is substantially fixed or determinable; (ii) the buyer has paid, or is obligated to pay, and the obligation is not contingent on resale of the product; (iii) the obligation would not be changed in the event of theft or physical damage to the product; (iv) the buyer acquiring the product for resale has economic substance apart from that provided by the seller; (v) there is no significant obligation for future performance to directly bring about resale of the product by the buyer; and (vi) returns can be reasonably estimated. We record as deferred revenue any amounts not satisfying all revenue recognition criteria.

Gross-to-net adjustments against receivable balances primarily relate to cash discounts and rebates for co-pay/co-insurance reimbursements, and are recorded in the same period the related revenue is recognized, resulting in a reduction to product sales revenue and the recording of accounts receivable net of allowance. Gross-to-net adjustment accruals related to estimated Medicaid rebates, other sales rebates, and returns are recognized in the same period the related revenue is recognized, resulting in a reduction to product sales revenue, and are included in accrued expenses in the accompanying unaudited condensed consolidated balance sheets.

As Probuphine is a new product, is not an extension of an existing line of product, and we have no historical experience with products in a similar therapeutic category, revenue is deferred until the right of return no longer exists and pricing is fixed or determinable (or, sufficient historical experience to estimate gross-to-net adjustments are developed). Specific considerations for Probuphine are as follows:

- *Rebates*: We may offer, or may be required to offer, purchase price rebates on the sale of Probuphine including but not limited to mandated discounts under the Medicaid Drug Rebate Program. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or legal requirements with public sector (e.g. Medicaid) benefit providers. The allowance for rebates is based on statutory discount rebate rates and expected utilization by eligible participants. Our estimate for expected utilization for rebates is based on very limited comparative operating history, together with our assessment of actual and pending prescriptions for which it has validated the insurance benefits.

  Allowances for rebates also include co-pay or co-insurance rebates to patients. We may assist patients covered under private insurance (non-federal health care programs) for out-of-pocket costs for co-pays or co-insurance, up to a maximum benefit based upon patient financial need. We also may assist patients who self-pay for out-of-pocket costs up to a maximum benefit based upon patient financial need. Our estimate for allowance for rebates for co-pay or co-insurance is based on very limited comparative operating history, together with our assessment of actual and pending claim data received for reimbursement.

- *Returns*: Under the "buy and bill" model, we will accept product returns, and will not invoice the relevant physician, if our products are returned to us within 30 days of receipt by the physician. Pursuant to an agreement with our exclusive specialty pharmacy distributor, Avella of Dear Valley, Inc., or Avella, we will only accept returns for product that is damaged during transit to Avella, and provided that we received confirmation of such damage within two days of receipt of the relevant product by

Avella, and if the product is returned to us within five business days of receipt by Avella. We do not record any sales revenue until after the relevant right of return lapses.

- *Cash discounts*: We extend a cash discount on sales to our exclusive specialty pharmacy distributor, Avella.

We include shipping and handling costs in cost of sales, as appropriate.

Research and development expense

Research and development, or R&D, expenses relate to our investments in clinical studies and the development of new products and therapies. Our research and development efforts include the development of product offerings along the continuum of care for opioid addiction, pain, schizophrenia and spasticity. Our research and development program is also leveraging our core understanding of long-acting implantable and injectable technologies. R&D expenses include but are not limited to the following:

- fees paid to consultants and clinical research organizations, or CROs, including in connection with our nonclinical and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis;
- payments, including milestone and technology access payments, made under third-party licensing agreements where such products have no alternative future where the relevant product is not approved for sale by the FDA;
- costs related to acquiring clinical trial materials;
- costs related to compliance with regulatory requirements;
- inventory costs where such inventory is not capable of being held for sale because it is not approved by the FDA; and
- costs related to salaries, bonuses and other compensation for employees in research and development functions.

We expense research and development costs as they are incurred. We expect research and development expense to be our largest category of operating expense and to fluctuate from period to period based on the timing of specific research, clinical studies, product launches, development and testing initiatives. However, as we increase our commercialization activities for Probuphine, we expect our sales and marketing expenses will increase period over period. Further, invoicing from third-party contractors for R&D services performed during a particular reporting period may lag several months. Management frequently must estimate the costs of such services based on, for example, our estimate of management fees, site management and monitoring costs and data management costs. Differences between actual clinical trial costs from estimated clinical trial costs may be material and are adjusted in the period in which they become certain. Historically, these differences have not been material; however, material

differences could occur in the future. The historic direct costs relating to each of our product candidates are summarized as follows:

	Years ended December 31,		Nine months ended September 30,	
	2015	2014	2016	2015
			(in thousands)	
			(unaudited)	(unaudited)
Probuphine, addiction	$ 8,787	$ 6,987	$ 4,400	$ 7,503
CAM2038, addiction(1)	16,308	20,720	28,604	6,346
CAM2038, pain	840	—	4,365	469
BB0817(2)	2,908	9,207	8,227	1,194
Research and development	$28,843	$36,914	$45,596	$15,512

(1) The expense for the year ended December 31, 2014 includes approximately $20.0 million for payments for CAM2038 made under a third-party licensing agreement with Camurus AB, or Camurus, which had no alternative future use as CAM2038 is not yet approved for sale by the FDA.

(2) The expense for the year ended December 31, 2014 includes approximately $9.2 million for payments relating to the MedLaunch Implant Program with FX Therapeutics, Inc., or FX, and Endo Pharmaceuticals, Inc., or Endo, in relation to BB0817 which had no alternative future use as BB0817 is not yet approved for sale by the FDA.

Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict, and often are delayed. We anticipate we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success or failure of each product candidate, the estimated costs to continue the development program relative to our available resources, as well as an ongoing assessment as to each product candidate's commercial potential.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of compensation for employees in executive, finance, legal and sales and marketing functions. Other selling, general and administrative expenses include facility-related costs not otherwise included in research and development expense; advertising and other similar expenses incurred to direct products for commercial use; and professional fees for legal and accounting services.

We expect that our selling, general and administrative expenses will increase in future periods as a result of our continued efforts to bring our product candidates to market, including increased payroll, commercial and sales operations expenses, and increased service fees for legal, accounting and investor relations expenses. In addition, we expect to incur increased expenses as a result of being a public company.

Inventory valuation

Inventories are stated at the lower of cost or estimated realizable value. Inventories are stated at the actual cost per lot determined using the specific identification method. We capitalize inventory costs associated with our products after regulatory approval by the FDA when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. Prior to the receipt of FDA approval for our lead product, Probuphine, on May 26, 2016, we determined to expense all previously incurred inventory costs associated with Probuphine as research and development costs because the inventory was not capable of being held for sale prior to such approval and, further, we had previously received a Complete Response Letter from the FDA for Probuphine in April 2013 following a positive outcome from an earlier FDA Advisory Committee affirmative vote.

We periodically analyze our inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value, and write-down such inventories as appropriate. In addition, our product is subject to strict quality control and monitoring which we perform throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, we record a charge to cost of sales to write down such unmarketable inventory to its estimated realizable value.

Impairment of long-lived assets

The useful life of our long-lived assets is determined using the period of expected future cash flows, adjusted for entity-specific factors. Current facts or circumstances are periodically evaluated to determine if the carrying value of depreciable assets to be held and used may not be recoverable. If such circumstances exist, an estimate of undiscounted future cash flows generated by the long-lived asset, or the appropriate grouping of assets, is compared to the carrying value to determine whether an impairment exists at its lowest level of identifiable cash flows. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. An estimate of the asset's fair value is based on quoted market prices in active markets, if available. If quoted market prices are not available, the estimate of fair value is based on various valuation techniques using Level 3 fair value inputs, including a discounted value of estimated future cash flows. There were no impairments of long-lived assets as of September 30, 2016 and December 31, 2015, respectively.

Leases

We have non-cancelable leases for our manufacturing and office spaces. The leases are reviewed for classification as operating or capital leases. For operating leases, rent is recognized on a straight-line basis over the lease period. For capital leases, we record the leased asset with a corresponding liability. Payments are recorded as reductions to the liability with an appropriate interest charge recorded based on the then-outstanding remaining liability.

For the build-to-suit lease of our manufacturing facility in Durham, North Carolina, we considered the nature of the renovations and our involvement during the construction period of newly leased office space and determined that we are considered to be the owner of the construction project during the construction period. As such, we are required to capitalize the fair value the asset, including potentially the building, construction costs incurred and capitalized interest, on our consolidated balance sheet along with a corresponding financing liability (''build-to-suit accounting''). Upon occupancy for build-to-suit leases, we will assess whether the circumstances qualify for sales recognition under the sale-leaseback accounting guidance. If the lease meets the sale-leaseback criteria, we will remove the asset and related financial obligation from the balance sheet and evaluate the lease for treatment as a capital or operating lease. If upon completion of construction, the project does not meet the sale-leaseback criteria, the leased property will be treated as a capital lease for financial reporting purposes.

Stock-based compensation

We recognize all share-based payments to employees, including grants of employee stock options and restricted share units, or RSUs, at estimated fair value and otherwise pursuant to the requirements of the Braeburn Pharmaceuticals, Inc., 2015 Equity Plan, or 2015 Plan. Equity shares generally vest over a 4-year period, with 25% vesting on the first anniversary of the vesting start date, and 2.08% vesting every month thereafter. The vesting start date of these initial grants has typically been set as the employees' date of hire. Issuances of equity shares to grantees following the initial grant, may vest quarterly or monthly commencing from the relevant grant date. These equity shares and RSUs will not become exercisable until the occurrence of a ''liquidation event'', which is defined as 180 days following either an initial public

offering or certain change of control transactions, which is considered a performance condition. If a liquidation event occurs following termination of the grantee's service, then the grantee will remain eligible to vest that proportion of equity shares calculated as if the liquidation event and termination date had occurred on the same day. If and when a liquidation event occurs, we will amortize the fair value of stock option or RSU grants on a straight-line basis over the remaining service period of the individual stock option or RSU grant, which generally equals the remaining vesting period. The 2015 Plan also provides that, in the event of certain change of control transactions prior to termination of service, all outstanding, unvested equity shares shall automatically vest. Equity shares granted under the 2015 Plan expire on the tenth anniversary of the date they were granted.

We determined that the performance condition was not probable of achievement at the date of grant because the occurrence of either an initial public offering or change of control is outside of our control, and therefore has not recognized any stock-based compensation expense since inception. As of September 30, 2016, there was approximately $3.0 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the 2015 Plan. This cost is expected to be recognized as compensation expense over the weighted average remaining service period of approximately 1.2 years.

We do not have sufficient history to estimate the volatility of its common stock price or the expected life of the options. We calculate expected volatility based on reported data for similar publicly traded companies for which historical information is available and will continue to do so until the historical volatility of its common stock is sufficient to measure expected volatility for future option grants.

Fair value of common stock

We are a private company with no active public market for our common stock. We utilize significant estimates and assumptions in determining the fair value of our common stock. We performed these valuations as of September 1, 2015 and July 1, 2016, or the Valuation Dates.

The following table presents the grant dates of outstanding employee stock options and RSUs that we granted from January 1, 2014 through September 30, 2016 along with the corresponding exercise price for each grant and our estimate of the fair value per share of our common stock on each grant date, which we utilize to calculate stock-based compensation expense.

	Restricted stock			Nonqualified stock options		
Date of grant	Number of shares	Exercise price per share	Current estimate of common stock fair value per share on grant date	Number of shares	Exercise price per share	Current estimate of common stock fair value per share on grant date
September 2015	829,659	$–	$2.73	–	$ –	$ –
October 2015	159,805	$–	$2.73	–	$ –	$ –
January 2016	47,524	$–	$2.73	–	$ –	$ –
April 2016	–	$–	$ –	12,962	$2.73	$2.73
July 2016	–	$–	$ –	62,963	$4.13	$4.13
Shares granted as of September 30, 2016	1,036,988			75,925		

As of December 31, 2015 and September 30, 2016, there were no vested shares.

In conducting the valuations, our board of directors, with input from management, considered objective and subjective factors that we believed to be relevant for the valuation conducted, including our best estimate of our business condition, prospects and operating performance at the Valuation Dates. In determining the estimated fair value of our common stock, we considered an independent valuation performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aid.

The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each of the Valuation Dates. In accordance with the Practice Aid, our management considered the following methods:

- *Current value method.* The current value method is based on allocating the enterprise value of the Company to the debt and preferred stock based on the higher of the liquidation preference or conversion value. Common stock is assigned the residual amount (if any) after consideration is given to the preferred stock.
- *Option pricing method.* The option-pricing method, or OPM, treats the common stock and preferred stock as call options on the enterprise value. The strike prices of the options are determined based on the characteristics of the capital structure of the company. This includes the number of shares of each equity security, the liquidation preferences of preferred equity and the strike prices of warrants and options.
- *Probability-weighted approach.* The probability-weighted expected return method determines the value of the common stock based upon an analysis of future values for the enterprise using different future outcomes. The share value is based upon the present value of the probability of each future outcome becoming available to the enterprise, and the rights of each share class.

We applied the option pricing method to allocate the estimated enterprise value of the Company between common and preferred stocks, then utilized a probability-weighted approach to determine the common stock value of the Company based on possible exit event scenarios for the Valuation Dates. One of the key inputs into the model used in the OPM is the future estimated cash flows of the Company, which are based on management's estimate of patient populations, market penetration, competitive dynamics and compliance rates, expected launch dates, prices and costs per unit sold, selling, general and administrative expenses and capital expenditures. We used industry standard studies to assess cumulative technical success probabilities for each phase of development. The estimated future cash flows were then converted to present value using an 16% to 18% discount rate. The discount rate was based on studies done of similar-stage biopharmaceutical companies, and reflected our debt to capital structure and the single capital instrument that we had outstanding (convertible preferred stock). Further, we also incorporated the present value of our net operating loss benefit, and our cash balance less interest-bearing debt as at the relevant Valuation Dates to determine the enterprise value of the Company.

We applied a 15% to 20% discount to reflect the lack of marketability of our common stock. We based this discount on (i) put option analysis, (ii) advice from our valuation specialist, and (iii) our plans for obtaining liquidity pursuant to, relevantly, an initial public offering of our securities.

We performed these valuations with the assistance of a third-party valuation specialist on the Valuation Dates.

September 1, 2015 Valuation. We estimated that a share of common stock had a value of $2.73 per share at September 1, 2015. This valuation utilized an 18% discount rate and a 15% to 20% discount for lack of

marketability. We do not believe there was a significant change in the fair value of our stock between September 2015 and April 2016. In forming this decision, we determined not to provide any accretive value to the April 2016 receipt of an affirmative vote for Probuphine from the Psychopharmacologic Drugs Advisory Committee of the FDA, or AdComm, because we had previously received a Complete Response Letter, or non-approval letter, from the FDA in April 2013 following a positive outcome from an earlier AdComm affirmative vote.

July 1, 2016 Valuation. We estimated that a share of common stock had a value of $4.13 per share at July 1, 2016, an increase of $1.40 from the prior valuation at September 1, 2015. This valuation utilized a 16% discount factor and a 15% to 20% discount for lack of marketability. The increase in the common stock valuation reflected the approval of our marketed product, Probuphine, by the FDA on May 26, 2016.

Related party transactions

Transactions with affiliates of common parent

We transact with certain affiliates of our parent, Apple Tree Partners IV, L.P., or its controlled entities. Transactions involving related parties cannot be presumed to be carried out on an arm's-length basis, as the requisite conditions of competitive, free-market dealings may not exist.

Apple Tree Life Sciences, Inc.

Up until January 1, 2016, we received certain services from Apple Tree Life Sciences, or ATLS, a wholly-owned subsidiary of Apple Tree Partners IV, L.P. These services included administrative services relating to accounting, finance, legal, human resources and other administrative services, together with research and development services, including regulatory and clinical support. ATLS charged us a service fee consisting of allocated internal time incurred on our projects by their employees, plus a pre-determined mark-up. Further, we paid or reimbursed ATLS at cost for any expenses incurred by third parties on our behalf.

Since January 1, 2016, no such costs have been incurred from ATLS, or any other related entity of Apple Tree Partners IV, L.P., and we do not expect to incur any such expenses going forward.

Female Opioid-Addiction Research and Clinical Experts (FORCE)

In July 2016, we entered into a charitable contribution agreement with Female Opioid-Addiction Research and Clinical Experts, or FORCE, a non-profit charitable organization of which certain of our employees, including our Chief Executive Officer, are members of the FORCE Board of Directors. We agreed to provide $0.2 million to FORCE, of which we will receive no benefit. In August 2016, we paid $0.2 million to FORCE. In addition, during the nine months ended September 30, 2016, we paid certain expenses on behalf of FORCE totaling $33,000. We do not expect to make any additional future payments on behalf of FORCE.

Other Accounting Policies

Cost of sales

Cost of sales includes products costs, manufacturing costs as well as actual and estimated royalty expenses associated with our "for sale" products. Royalties are generally based on applicable revenue sold and are recognized in the period that the related revenue is earned.

Other (expense) / income

Foreign currency transaction loss

Our books and records are denominated and maintained in United States Dollars, or USD, which we have also determined to be our functional currency. Transactions denominated in currencies other than USD are translated to USD at the prevailing exchange rate on the date of the transactions. Account balances denominated in currencies other than USD are translated to USD at the prevailing exchange rate on the last day of the reporting period. Foreign currency exchange gains and losses resulting from these translations are included in other (expense) / income.

Prior to the dissolution of Braeburn BVBA, we held foreign-currency denominated cash accounts, which were re-measured to USD at each reporting period and recorded as foreign currency gain or loss. As of December 31, 2015 and September 30, 2016, we did not have any foreign-currency denominated cash accounts.

Income tax expense

At December 31, 2015, we had federal and state net operating loss carryforwards of approximately $29.7 million and $29.7 million, respectively. At December 31, 2014, we had federal and state net operating loss carryforwards of approximately $0.3 million and $0.3 million, respectively. These net operating loss carryforwards expire in various amounts starting in 2033. At December 31, 2015 and 2014, we had federal research credit carryforwards in the amount of approximately $0.6 million and $0, respectively. These carryforwards begin to expire in 2035.

Since we may need to raise additional funding to finance our operations, we may undergo further ownership changes in the future, which could trigger an ownership change pursuant to Section 382 and Section 383 of the Internal Revenue Code of 1986, as amended. If an ownership change is triggered, it will limit our ability to use some of our net operating loss and research tax credit carryforwards. As a result, if we generate taxable income, our ability to use some of our loss carryforwards to offset U.S. federal taxable income or tax may be subject to limitations, which could result in increased future tax liability to us.

Prepaid expenses

Prepaid expenses are assets resulting from payments that are made before the criteria for expense recognition have been met. Prepaid expenses may arise from advance payments for setting up clinical trials and clinical trial sites, construction projects, insurance premiums, leases, professional dues, memberships and subscriptions. The payment is expected to yield economic benefits over one or more future months. We recognize expense over the applicable services period.

Results of operations for the nine months ended September 30, 2016 and 2015

Revenues

	Nine months ended September 30,		% change
	2016	2015	2015 to 2016
	(unaudited, in thousands)		
Product sales, net	$42	$–	N/A

For the nine months ended September 30, 2016 and 2015, we recognized net product sales revenue of $42 thousand for the sales of Probuphine and supplies related to the Probuphine insertion and removal

procedures. We deferred approximately $0.2 million and $0 as of September 30, 2016 and 2015, respectively. Following receipt of FDA approval for Probuphine on May 26, 2016, we focused our post-approval commercialization efforts for Probuphine on training healthcare providers to prescribe and implant Probuphine as required under our REMS, and working with payors to ensure reimbursement for Probuphine. We are planning a full-scale commercial Probuphine launch in the first quarter of 2017 with our new fully-deployed field force.

We record product sales net of allowances and accruals for rebates, distribution-related fees and discounts, product returns and other sales-related deductions. These allowances and accruals will continue to grow in relation to an increase in the sales of Probuphine. The following table summarizes the provisions, and credits/payments, for discounts, rebates and chargebacks, distribution-related fees, and returns and other sales-related deductions:

	Discounts, rebates and chargebacks	Distribution-related fees	Returns and other sales-related deductions	Total
			(unaudited, in thousands)	
Balance as of December 31, 2015	$–	$–	$–	$–
Provision related to current period sales	8	–	5	13
Credits/payments	–	–	(5)	(5)
Balance as of September 30, 2016	$8	$–	$–	$8

Cost of product sales

Upon receipt of marketing approval of Probuphine from the FDA in May 2016, we began capitalizing inventory costs associated with commercial supplies of Probuphine. Costs for manufacturing supplies of Probuphine prior to receipt of FDA approval were recognized as research and development expenses in the period that the costs were incurred. Therefore, to the extent we utilize inventory that had previously been expensed as a research and development expenditure, the associated costs are not included in cost of sales when revenue is recognized from the sale of those supplies.

We previously expensed approximately $1.1 million in commercial lots of Probuphine prior to approval as research and development expense, and based on our current plans and assumptions, we believe that we will have sold all of our previously expensed supply of Probuphine product by the third quarter of 2017. Once we begin charging capitalized inventory to cost of product sales, we expect that the cost of product sold as a percentage of net revenue will be in the high single digits. The shelf life of Probuphine is three years, and as of September 30, 2016, the weighted average remaining life of the pre-launch inventories was approximately 1.2 years.

Research and development expenses

	Nine months ended September 30,		% change
	2016	2015	2015 to 2016
	(unaudited, in thousands)		
Research and development	$50,933	$16,345	212%

Research and development expenses were approximately $50.9 million for the nine months ended September 30, 2016 compared to approximately $16.3 million for the same period in 2015, an increase of approximately $34.6 million. The increase was primarily due to an increase of approximately $26.9 million

in clinical costs related to the start of two Phase 3 CAM2038 clinical trials (HS-11-421 and HS-14-499), a Phase 2 CAM2038 PK study (HS-13-478), and two BBO817 clinical trials, partially offset by a $6.6 million decrease in clinical costs related to Probuphine. Manufacturing and clinical supply costs also increased by approximately $10.8 million period-over-period due to the aforementioned studies. Research activities related to ATI-9242, for which we terminated development in November 2016, increased by approximately $1.7 million period-over-period. We also realized an increase in regulatory costs of approximately $0.7 million and personnel and personnel-related costs of approximately $0.6 million.

Selling, general and administrative expenses

	Nine months ended September 30,		% change
	2016	2015	2015 to 2016
	(unaudited, in thousands)		
Selling, general and administrative	$27,095	$4,031	572%

Selling, general and administrative expenses were approximately $27.1 million for the nine months ended September 30, 2016 compared to approximately $4.0 million for the same period in 2015, an increase of approximately $23.1 million. The increase was primarily due to (i) the costs of training approximately 2,400 healthcare providers, including certification under our REMS training program following FDA approval of Probuphine in May 2016, an increase of approximately $7.0 million; (ii) an increase of approximately $10.1 million in external costs, which includes an increase of approximately $6.5 million in marketing and market access related expenses; and (iii) an increase of approximately $5.3 million in personnel and personnel-related costs. We expect these costs to increase in the near future, especially in early 2017, as we complete our initial REMS training program and enable a full-scale commercial Probuphine launch in the first quarter of 2017.

Gain on sale of investments, net

We recorded a gain on sale of marketable investment securities of approximately $1.2 million and $0 for the nine months ended September 30, 2016 and 2015, respectively, related to the sale of shares of Titan Pharmaceuticals, Inc., or Titan, stock.

Income tax expense

We reported an income tax expense of approximately $0 and $1.6 million for the nine months ended September 30, 2016 and 2015, respectively. On May 21, 2015, there was an intercompany transfer of intellectual property from Braeburn Pharmaceuticals BVBA, a Belgian entity, to Braeburn Pharmaceuticals, Inc., a US entity. This event triggered a taxable gain for Belgian tax purposes that exceeded the amount of Belgian net operating losses available. This was a one-time event that will have no impact on future operating results.

Results of operations for the years ended December 31, 2015 and 2014

The following table summarizes selected operating statement data for the years ended December 31, 2015 and 2014:

Revenues

	Years ended December 31,		% change
	2015	2014	2014 to 2015
	(in thousands)		
Service revenue	$25	$–	N/A

For the year ended December 31, 2015, we recorded $25 thousand related to a research evaluation agreement we entered into in fiscal year 2015. We do not expect any additional future revenue related to this agreement moving forward.

Research and development expenses

	Years ended December 31,		% change
	2015	2014	2014 to 2015
	(in thousands)		
Research and development	$31,374	$37,195	(16%)

Research and development expenses were approximately $31.4 million for the year ended December 31, 2015 compared to approximately $37.2 million for the same period in 2014, a decrease of approximately $5.8 million.

Research and development expenses for the year ended December 31, 2014 were primarily composed of approximately $20.0 million for payments made under a third-party licensing agreement with Camurus, $9.2 million for payments relating to the MedLaunch Implant Program, or MedLaunch, which includes an $8.0 million option agreement with FX and a $1.2 million purchase of MedLaunch assets from Endo, approximately $5.9 million related to Probuphine clinical development costs and approximately $1.1 million in personnel and personnel-related costs.

Research and development expenses for the year ended December 31, 2015 were primarily composed of approximately $22.0 million related to clinical development costs, approximately $5.4 million related to product development costs and approximately $2.9 million in personnel and personnel-related costs. Clinical development costs primarily consist of approximately $13.8 million related to CAM2038 for treatment of opioid addiction, approximately $5.6 million related to Probuphine for treatment of opioid addiction and approximately $1.6 million related to BBO817 for the treatment of schizophrenia.

General and administrative expenses

	Years ended December 31,		% change
	2015	2014	2014 to 2015
	(in thousands)		
General and administrative	$6,964	$3,076	126%

General and administrative expenses were approximately $7.0 million for the year ended December 31, 2015 compared to approximately $3.1 million for the same period in 2014, an increase of approximately $3.9 million. The increase was primarily due to an increase of approximately $2.5 million in external costs, which includes an increase of approximately $1.0 million in legal fees, and an increase of approximately $1.4 million in personnel and personnel-related costs.

Interest (expense) / income, net

Interest income consists primarily of interest income earned on cash and cash equivalents and restricted cash. Our interest income has not been significant due to low interest earned on nominal cash and investment balances. Interest expense consists of interest accrued on a five-year loan agreement with Apple Tree Investments SARL, a subsidiary of Apple Tree Partners IV, L.P., for approximately €0.3 million,

which we issued in December 2014. The loan was repaid (with accrued interest of approximately $20 thousand) in November 2015.

Income tax expense

We reported an income tax expense of approximately $1.6 million and $0 as of December 31, 2015 and 2014, respectively. On May 21, 2015, there was an intercompany transfer of intellectual property from Braeburn Pharmaceuticals BVBA, a Belgian entity, to Braeburn Pharmaceuticals, Inc., a US entity. This event triggered a taxable gain for Belgian tax purposes that exceeded the amount of Belgian net operating losses available. This taxable gain on the transfer of intellectual property resulted in a (41.6%) impact on our effective tax rate for the year ended December 31, 2015. This was a one-time event that will have no impact on future operating results.

Liquidity and capital resources for the nine months ended September 30, 2016 and 2015

We have experienced net losses and negative cash flows from operations since our inception. As of September 30, 2016 and 2015, we had sustained cumulative losses of approximately $199.9 million and $104.5 million, respectively. As of September 30, 2016 and 2015, we had approximately $23.5 million and $6.9 million in cash and cash equivalents, respectively.

We have funded our operations to date exclusively through the issuance of common and preferred equity securities to our parent company, Apple Tree Partners IV, LP. We expect to incur substantial expenditures and losses in the foreseeable future arising from the further development of our product candidates. We will require significant additional financing to develop our product candidates, prepare regulatory filings and obtain regulatory approvals, establish our manufacturing operations and establish our sales and marketing capabilities. We will seek funds through additional equity financings from Apple Tree Partners IV, LP. or through other sources of financing. Our current financial condition, and exclusive dependence on Apple Tree Partners IV, LP. as our sole source of funding, raises substantial doubt about our ability to continue as a going concern. Our failure to raise capital as and when needed would have a material adverse impact on our financial condition and our ability to pursue our business strategies, including but not limited to insolvency.

Cash flows

The tables below set forth our significant sources and uses of cash for the periods set forth below.

	Nine months ended September 30,	
	2016	**2015**
	(unaudited, in thousands)	
Cash provided by (used in):		
Operating activities	$ (70,159)	$(30,875)
Investing activities	$ (15,570)	$ (304)
Financing activities	$103,750	$ 30,049

Net cash used in operating activities

Net cash used in operating activities during the nine months ended September 30, 2016 was approximately $70.2 million, an increase of approximately $39.3 million from cash used in operating activities during the nine months ended September 30, 2015 of approximately $30.9 million. The approximately $70.2 million

used in operating activities during the nine months ended September 30, 2016 was driven by net loss of approximately $76.8 million and an increase in accounts payable and accrued expenses of approximately $10.6 million partially offset by an increase in prepaid and other assets of approximately $2.3 million. The increase in accounts payable and accrued expenses is related to a lag in invoicing from third-party contractors for services performed during the reporting period, coupled with an increase in operating expenses. The approximately $30.9 million used in operating activities during the nine months ended September 30, 2015 was primarily driven by net loss of approximately $22.7 million and a decrease in due to affiliated entities of approximately $10.6 million.

Net cash used in investing activities

Net cash used in investing activities during the nine months ended September 30, 2016 was approximately $15.6 million, which represents an increase of approximately $15.3 million from the cash used in investing activities during the nine months ended September 30, 2015 of approximately $0.3 million. The increase in cash used in investing activities was primarily due to a $15.0 million milestone payment to Titan pursuant to the relevant licensing agreement and otherwise following receipt of FDA approval for Probuphine in late May 2016 and capital expenditures of approximately $5.8 million, partially offset by the sale of Titan stock for approximately $6.2 million.

Net cash provided by financing activities

Net cash provided by financing activities during the nine months ended September 30, 2016 was approximately $103.8 million, which represents an increase of approximately $73.8 million from cash provided by financing activities during the nine months ended September 30, 2015. The cash provided by financing activities during the nine months ended September 30, 2016 was attributable to proceeds from the issuance of preferred stock of approximately $103.8 million to Apple Tree Partners IV, LP. The cash provided by financing activities during the nine months ended September 30, 2015 was attributable to proceeds from the issuance of Braeburn BVBA common stock of approximately $20.0 million and preferred stock of approximately $10.0 million.

Liquidity and capital resources for the years ended December 31, 2015 and 2014

We have experienced significant net losses and negative cash flows from operations since our inception. As of December 31, 2015 and 2014, we had sustained cumulative losses of approximately $123.1 million and $81.8 million, respectively. As of December 31, 2015 and 2014, we had approximately $5.5 million and $8.8 million in cash and cash equivalents, respectively.

Cash flows

The tables below set forth our significant sources and uses of cash for the periods set forth below.

	Years ended December 31,	
	2015	2014
	(in thousands)	
Cash provided by (used in):		
Operating activities	$(49,347)	$(50,408)
Investing activities	$ (511)	$ (12)
Financing activities	$ 47,445	$ 58,885

Net cash used in operating activities

Net cash used in operating activities during the year ended December 31, 2015 was approximately $49.3 million, a decrease of approximately $1.1 million from cash used in operating activities during the year ended December 31, 2014 of approximately $50.4 million. The approximately $49.3 million used in operating activities during the year ended December 31, 2015 was driven by net loss of approximately $40.6 million and a decrease in due to affiliated entities of approximately $10.7 million. The approximately $50.4 million used in operating activities during the year ended December 31, 2014 was primarily driven by net loss of approximately $40.6 million and a decrease in due to affiliated entities of approximately $12.7 million.

Net cash used in investing activities

Net cash used in investing activities during the year ended December 31, 2015 was approximately $0.5 million, which represents an increase of approximately $0.5 million from the cash used in investing activities during the year ended December 31, 2014 of $12 thousand. The increase in cash used in investing activities was due to an increase in capital expenditures of approximately $0.3 million and in increase in restricted cash of approximately $0.2 million.

Net cash provided by financing activities

Net cash provided by financing activities during the year ended December 31, 2015 was approximately $47.4 million, which represents a decrease of approximately $11.5 million from cash provided by financing activities during the year ended December 31, 2014 of approximately $58.9 million. The approximately $47.4 million provided by financing activities during the year ended December 31, 2015 was primarily attributable to proceeds from the issuance of Braeburn BVBA common stock of approximately $20.0 million and preferred stock of approximately $28.5 million. The approximately $58.9 million provided by financing activities during the year ended December 31, 2014 was primarily attributable to proceeds from the issuance of Braeburn BVBA common stock of approximately $58.5 million.

Contractual obligations and commitments

The following table summarizes our contractual obligations at December 31, 2015 and the effects such obligations are expected to have on our liquidity and cash flows in future periods:

	Total	Less than a year	1 - 3 Years	3 - 5 Years	More than five years
			(in thousands)		
Contractual Obligations:					
Clinical and regulatory obligations	$58,879	$ 51,159	$7,720	$ –	$ –
Supply agreements	7,693	7,693	–	–	–
Facility related obligations	11,748	11,748	–	–	–
Operating lease obligations	9,591	355	2,012	1,689	5,536
Total contractual cash obligations	$ 87,911	$70,955	$9,732	$1,689	$5,536

Clinical and regulatory obligations. Represents obligations by us to make payments under clinical contracts.

Supply agreements. Represents obligations by us to make payments under supply agreements.

Facility related obligations. Represents obligations related to the North Carolina facility.

Operating lease obligations. Represents future minimum lease payments under non-cancelable operating leases.

Payments under our licenses described in the notes to our consolidated financial statements are not considered contractual obligations due to the uncertainty of the occurrence of the triggering events under those agreements, including the potential future milestone and royalty payments. These payments generally become due and payable only upon the achievement of certain clinical development, regulatory or commercial milestones including, for example, initial sales following receipt of FDA approval of the relevant product. As of December 31, 2015, the total amount of contingent payments that could become due if the regulatory and sales milestones are achieved is $337.3 million.

Subsequent to December 31, 2015, we executed material amendments to two existing agreements. We entered into the First Amendment to the Camurus license agreement, which obligates us to reimburse $1.5 million towards a Phase 1 clinical trial. We also amended our agreement for an ongoing BBO817 clinical trial that increased the total contract value by approximately $1.9 million. See ''Business—Third Party Agreements.''

Future funding requirements

To date, we have not generated significant revenue from the sale of Probuphine. Further, we do not know when, or if, we will generate any significant revenue from product sales associated with any of our product candidates because this is entirely dependent upon the receipt of FDA regulatory approval and the resultant commercialization efforts, the occurrence of which is uncertain and unpredictable. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates.

Upon the completion of this offering, we expect to incur additional costs associated with operating as a public company. In addition, subject to obtaining FDA regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution.

Based upon our current operating plan and subject to revenue accruing from product sales of Probuphine and related operating assumptions therein, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses, and capital expenditure requirements for at least the next 12 months. In particular, we expect that these funds will allow us to complete our pivotal Phase 3 addiction clinical trial for our lead product candidate, CAM2038 for opioid addiction, and file a New Drug Application with the FDA, as well as progress our other late-stage programs in the therapeutic areas of pain and schizophrenia. We may require additional capital to fund future clinical trials of our product candidates, and to obtain regulatory approval for, and to commercialize, our product candidates.

Our future capital requirements will depend on many factors, including:

- the commercial success of our launch of Probuphine and our ability to derive meaningful revenues therein;
- the progress, costs, results and timing of our clinical trials;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;

- the willingness of the FDA or other regulatory agencies to accept our trial data, as well as our other completed and planned clinical and nonclinical studies and other work, as the basis for review and approval of our product candidates in the United States;
- the number and characteristics of product candidates that we pursue, including our product candidates in nonclinical development;
- the ability of our product candidates to progress through clinical development successfully;
- our need to expand our research and development activities;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- market acceptance of our product candidates;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand, defend and enforce the scope of our owned and in-licensed intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any of our owned or in-licensed patents or other intellectual property rights;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect, or are senior or preferred to, the rights of our existing 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, limit corporate actions or declaring dividends. If we raise additional funds through government or other third-party funding, commercialization, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. There can be no assurance that such additional funding, if available, can be obtained on terms acceptable to us or be sufficient to support our activities. If we are unable to obtain additional financing, future operations would need to be scaled back or discontinued. Accordingly, there is substantial doubt regarding our ability to continue as a going concern.

Off-balance sheet arrangements

We do not have any off-balance sheet arrangements.

Quantitative and qualitative disclosures about market risk

We face limited market risk as our financial instruments as of September 30, 2016 consisted entirely of cash. We expect to invest a portion of our cash in interest-bearing money market accounts and prime money market funds in the near term at which point our financial instruments and financial position will have an inherent market risk related to potential losses arising from adverse changes in interest rates. However, we do not expect this risk to be significant due to the planned short-term maturities and low risk profiles of such cash equivalents.

We occasionally contract with vendors internationally. Transactions with these vendors are predominantly settled in U.S. dollars, and, therefore, we believe that we have only minimal exposure to foreign currency exchange risks. We do not hedge against foreign currency risks.

Business

Overview

Our company

We are a commercial-stage pharmaceutical company focused on the development and commercialization of novel long-acting medications for serious disorders of the central nervous system, or CNS. Our proprietary implantable and injectable delivery mechanisms provide differentiated solutions for chronic diseases with high unmet medical needs. Our specialty CNS focus is on fast-growing therapeutic areas recognized as serious public health crises, where long-acting technologies offer important benefits such as increased medication compliance, improved patient convenience, reduced risk of abuse and relapse and reduced public health and societal costs.

Our lead therapeutic area is opioid addiction, which is sometimes referred to as opioid use disorder or opioid dependence, and is a chronic, relapsing brain disease characterized by long-lasting structural and functional changes in the brain. The most common form of opioid addiction is addiction to prescription pain relievers. Opioid addiction affects 2.6 million people in the United States across all socioeconomic groups. A 2016 survey from the Kaiser Family Foundation indicates that nearly half of all Americans know someone suffering from opioid addiction. Seventy-five percent of people with opioid addiction started taking opioids as a pain medication prescribed by a physician following a medical procedure or accidental injury. Our other therapeutic areas of focus are pain, schizophrenia and spasticity, which refers to feelings of stiffness and a wide range of involuntary muscle spasms. We have one approved product, Probuphine, a six-month buprenorphine implant for the maintenance treatment of opioid addiction. In November 2016, we reported positive top-line results from a Phase 3 trial of weekly and monthly CAM2038, an injectable formulation of buprenorphine, for opioid addiction. CAM2038 achieved non-inferiority compared to oral daily buprenorphine based on the primary endpoint and superiority to oral daily buprenorphine based on a secondary endpoint. We have four additional late-stage product candidates in our pipeline across our different therapeutic areas, as well as two earlier-stage product candidates.

We believe that long-acting medications for specialty CNS conditions are not just a matter of convenience, but are an essential tool for the effective treatment of these diseases. These are chronic CNS conditions requiring constant vigilance, where the consequences of suboptimal treatment compliance can range from severe to life threatening. For example, patients with opioid addiction are currently limited to treatment with daily medications, for which poor compliance can rapidly lead to relapse, overdose and death. For our therapeutic areas of focus, we are developing weekly, monthly and six-month dosage formulations that we believe will allow healthcare providers to treat patients throughout the continuum of care from treatment initiation through long-term maintenance. This enables healthcare providers to prescribe personalized care for each patient across a complex patient base having diverse therapeutic needs.

Opioid addiction: the problem

The U.S. government has declared prescription opioid abuse an unprecedented public health epidemic, having an estimated $80 billion annual economic impact in U.S. health and social costs as of 2013. The number of drug overdose deaths related to opioids quadrupled between 2000 and 2014, closely tracking the increase in prescriptions dispensed for opioids. Every day 3,900 people begin to abuse or misuse prescription opioids and 580 people begin to use heroin. Every day approximately 2,000 people are hospitalized and 78 people die from overdose involving opioids, resulting in approximately 30,000 opioid overdose deaths per year.

Even though the United States is home to only five percent of the world's population, it consumes over eighty percent of the world's prescription opioids. The opioid abuse epidemic predominantly stems from this overuse of opioid medications, prescribed primarily for the treatment of pain.

Opioid addiction: current treatment approaches and inherent limitations

In 2015, approximately 12.5 million people misused opioid pain relievers and over 800,000 people used heroin in the United States. Opioid addiction can be treated effectively with a combination of medication and psychosocial therapy, and society saves up to an estimated $12 for every $1 spent on treatment for opioid addiction. Yet today, less than half of the estimated 2.6 million people who have been diagnosed with opioid addiction in the United States receive medication.

The current standard of care for outpatient treatment of opioid addiction is oral daily buprenorphine, which generally should be life-long therapy because opioid addiction is typically a chronic life-long condition. In 2015, approximately 700,000 patients were on oral daily buprenorphine treatment for opioid addiction. The largest branded oral daily buprenorphine product in the United States is Suboxone sublingual film, which must be held under the tongue for up to 15 minutes without swallowing in order to receive the full dose. Because of the rapidly growing epidemic of opioid abuse, in August 2016 the U.S. Department of Health and Human Services, or HHS, expanded the number of patients that qualified physicians are allowed to treat with buprenorphine from 100 to 275, representing a potentially meaningful increase in the future size of the buprenorphine market.

Although oral buprenorphine is an effective treatment for opioid addiction, the burden of daily medication coupled with the inconvenience of the sublingual formulation contribute to low patient compliance and suboptimal medical outcomes. Despite being a chronic condition where relapse can have dire consequences, on average, patients take medication only 33% of the time that they need it. Each day a patient is off medication, the odds of relapse increase significantly, and consequently a patient is in significant danger of potential overdose and death. Additionally, buprenorphine is a synthetic opiate and therefore, when dispensed to patients for self-administration, it is susceptible to diversion, or selling on the street, misuse, abuse and accidental pediatric exposure.

Despite the low compliance, difficulty of use, low penetration and other challenges associated with current therapies, in 2015, U.S. gross sales of branded and generic buprenorphine products were estimated to be approximately $2 billion. Reported 2015 U.S. net sales of Suboxone sublingual film were $807 million. We believe effective therapies can enhance compliance, lower treatment stigma, improve quality of life of patients and expand the addressable market.

Opioid addiction: our solutions

We intend to address the limitations of current treatment approaches for opioid addiction by replacing oral daily medications, including sublingual formulations, with a suite of complementary long-acting implantable and injectable medications. Our solutions are designed to establish a continuum of care for patients, providing personalized drug delivery that is optimized to help patients progress from treatment initiation through long-term maintenance. We believe that our product portfolio addresses several limitations of the current treatment pathway in opioid addiction as described below:

- **Enhanced medication compliance and clinical outcomes.** Patients frequently forget or choose not to take their oral daily medications as prescribed. This lack of compliance is one of the biggest barriers to achieving desired clinical outcomes. We believe that our long-acting treatments will provide patients and

healthcare providers with increased confidence that patients have received their required dose of medication, thereby leading to more successful clinical outcomes.

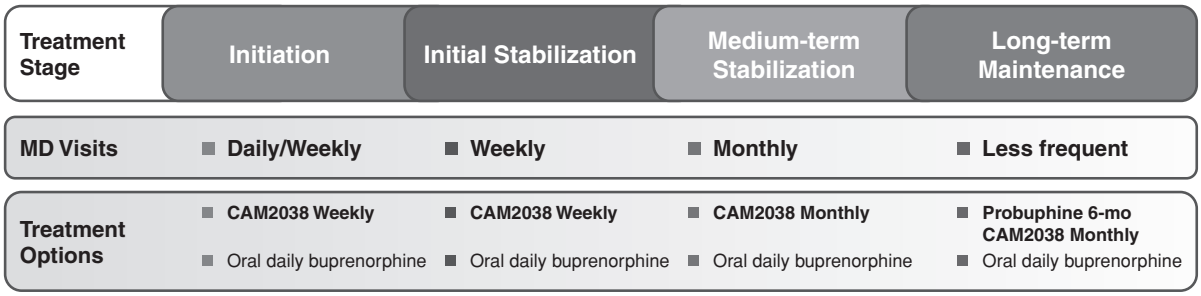
- **Improved quality of life for patients.** We believe that our long-acting treatments will relieve the burden of daily medication and daily reminders of the disease as well as reduce the stigma of opioid addiction for patients and their caregivers.
- **Improved social outcomes.** Chronic abuse of opioids can lead to impaired judgment, decision-making, learning, memory and behavior control, making it difficult for addicted patients to carry out normal daily activities. By reducing the risk of relapse and abuse, we believe our long-acting treatments will help patients take care of their families, fulfill their passions and lead more productive and rewarding lives.
- **Help manage a public health epidemic.** Oral medications find their way to streets, often through "pill mills" and other illegitimate channels, leading to drug abuse, addiction and overdose, as well as potentially life-threatening accidental pediatric exposure. Because our products are physician-administered, we believe that our long-acting treatments could help reduce these risks.

Our marketed product, Probuphine, was approved by the United States Food and Drug Administration, or FDA, in May 2016, and is the first and only implantable formulation of buprenorphine for the maintenance treatment of opioid addiction. Probuphine is administered by a healthcare provider who inserts four implants, each smaller than a one-inch matchstick, sub-dermally in the patient's upper arm during a short in-office procedure usually lasting less than 15 minutes. After insertion, Probuphine delivers buprenorphine continuously for six months. Thereafter, the implants can be removed and replaced with new Probuphine implants.

Our lead product candidates, weekly and monthly CAM2038, are subcutaneous injectable formulations of buprenorphine for the treatment of opioid addiction. We believe CAM2038 will expand our target patient population, including not only patients who have been successfully treated with buprenorphine but also patients new to buprenorphine therapy. In November 2016, we reported positive top-line results from a Phase 3 trial of weekly and monthly CAM2038 for opioid addiction. CAM2038 achieved non-inferiority compared to oral daily buprenorphine based on the primary endpoint and superiority to oral daily buprenorphine based on a secondary endpoint. Based on the successful results from this pivotal Phase 3 trial, we are working expeditiously to submit a New Drug Application, or NDA, for weekly and monthly CAM2038 in the first half of 2017. The FDA has granted fast track designation for weekly and monthly CAM2038 for the treatment of opioid addiction.

Probuphine and CAM2038 have the potential to transform and enhance the continuum of care for opioid addiction, as compared to current clinical practice which is limited to the use of oral daily buprenorphine. We believe a weekly buprenorphine injection would be an attractive option for beginning buprenorphine treatment where weekly medical visits to adjust dose is common practice. We believe a monthly injection would be an attractive option for early-stage maintenance treatment where a transition to monthly visits after finding a stable dose is common practice. For longer-term maintenance treatment, which may continue for years, or even indefinitely, we believe a six-month implant would be an attractive option.

Opioid addiction: Enhanced continuum of care aligned with clinical practice



The above graphic depicts the clinical practice for treating opioid addiction and shows how we believe our products, if approved, align with the various stages of treatment as compared to the current standard of care, oral daily buprenorphine.

In 2016, our post-approval commercialization efforts for Probuphine were focused on a medical affairs driven introduction, including training healthcare providers to prescribe and implant Probuphine, working with payors to ensure comprehensive reimbursement, and implementing our new specialty pharmacy distribution model. In the United States, approximately 6,000 physicians account for approximately 90% of buprenorphine prescriptions, and the top 100 payors account for approximately 85% of buprenorphine coverage. We have trained and certified approximately 2,500 healthcare providers to prescribe and implant Probuphine, and over 70 payors have indicated that they intend to cover Probuphine, including Humana and all regional Blue Cross Blue Shield plans, and certain larger payors, such as Aetna and Cigna, have indicated that they will not require prior authorization.

We are planning a full-scale commercial launch with our new fully-deployed field force of approximately 60 representatives in the first quarter of 2017 when we expect more payors to have released medical coverage policies for Probuphine. These commercialization efforts will also lay the groundwork for marketing CAM2038, which we expect will target the same prescribers. We intend to further expand our field force if and when we launch CAM2038.

Additional product candidates

Our investigational pipeline also includes late-stage programs in the therapeutic areas of pain and schizophrenia and an early-stage program in spasticity. We believe all of these conditions can also be more effectively managed using long-acting implantable or injectable medications. We believe that treating these diseases with long-acting therapies will have many of the benefits described above for opioid addiction, including enhanced compliance, improved clinical outcomes, improved quality of life for patients and reduced risk of diversion of controlled substances.

Because buprenorphine has also been approved for the treatment of chronic pain, we believe our long-acting medications, weekly and monthly CAM2038 and Probuphine, have the potential to provide a suite of therapeutic products across the continuum of care for pain. We believe our long-acting medications, if approved, will provide continuous around-the-clock therapy, resulting in improved pain relief, increased convenience and enhanced quality of life. Furthermore, we believe our long-acting pain medications can help address the root causes of the opioid abuse epidemic because they are implanted or injected directly by a healthcare provider, and therefore are not susceptible to the diversion and misuse that occurs with self-administered oral daily opioids.

We are also developing the following product candidates:

BB0817 is an implant that offers continuous, six-month delivery of risperidone, the most commonly prescribed medication for the treatment of schizophrenia. Schizophrenia requires life-long treatment, and positive outcomes are significantly dependent on medication compliance, making long-acting treatments especially effective. We believe BB0817 has the potential for unique positioning in the schizophrenia market with a treatment duration that at least doubles that of currently-marketed injectables, which range from two weeks to three months. This product candidate is currently in Phase 3 development, with expected clinical trial results in 2017.

BB0417 is a subcutaneous injectable formulation that offers three to five days of buprenorphine and granisetron, a widely used drug to treat nausea and vomiting, for the potential treatment of acute post-operative pain, nausea and vomiting. Effective acute post-operative pain management is an indispensable component of the continuum of care for the surgical patient, as inadequate pain control may result in delayed mobilization and recovery, pulmonary and cardiac complications and an increased likelihood of the development of neuropathic pain. In addition, post-operative vomiting and nausea are the most common causes of patient dissatisfaction after anesthesia, with approximately 30-50% of post-operative patients experiencing vomiting and nausea. We believe that BB0417 has the potential to improve the well-being of post-operative patients and reduce the need for other medications including oral opioid painkillers, which are taken home and self-administered by the patient. This product candidate is currently in Phase 1 development.

BB1216 is an implant that offers continuous, six-month delivery of tizanidine, a commonly prescribed muscle relaxant, for the treatment of moderate to severe spasticity. Spasticity is typically reported in patients with multiple sclerosis, traumatic brain injury, cerebral palsy and spinal cord injury. Current treatment options for spasticity include a variety of oral daily medications, and one common oral treatment is tizanidine. Another treatment option is surgical implantation of an intrathecal baclofen pump for disabling spasticity that does not respond to oral medications or where side effects limit treatment. We believe that BB1216 may provide effective relief with fewer side effects and enhanced clinical outcomes compared to oral medications and will be an attractive alternative to surgical implantation of an intrathecal pump. This product candidate is currently in animal testing of the formulation, and if this testing is successful, we expect that it will advance directly to Phase 3 development.

Intellectual property and barriers to entry

We believe our products are protected from generic entry by a range of intellectual property, trade secrets and know-how as well as a range of complex clinical and regulatory requirements. As a result of these barriers to entry, we believe our products will generate long-duration cash flows. These barriers to entry for our products include:

- **Strong patent protection.** For example, the U.S. patent estate for Probuphine is expected to extend through 2024, the U.S. patent estate for CAM2038 is expected to extend through 2027, the U.S. patent estate for BB0417 includes applications that, if issued, are expected to extend through 2036, the U.S. patent estate for BB0817 is expected to extend through 2029 and the U.S. patent estate for BB1216 is expected to extend through 2032.
- **Challenging formulation and manufacturing.** We believe that long-acting implantable and injectable formulations are particularly difficult to create or re-engineer, which is evidenced by the small number of long-acting implantable and injectable medications that have ever been approved. Manufacturing complexities include proprietary specifications for release rates that can be difficult to replicate, the

ability to produce pre-filled syringes under aseptic conditions and the ability to obtain adequate supplies of and work with the required complex raw materials, including controlled substances, which are only available from a limited number of suppliers.

- **Regulatory complexity.** We believe the regulatory pathway for generic versions of long-acting implantable and injectable medications will be more complex and costly than the relatively simple pharmacokinetic studies required for oral small molecule generics. We believe approval will require large and lengthy clinical trials which demonstrate not only equivalent efficacy and safety outcomes, but also equivalent drug release profiles. The regulatory requirement to certify healthcare providers under the REMS program for Probuphine and anticipated REMS program for CAM2038 will create additional barriers to entry for generics.

Competitive strengths

Focus on large and underserved specialty CNS markets. Our lead therapeutic area of focus is opioid addiction, which is widely recognized as an unprecedented public health epidemic in the United States. Treatment of opioid addiction is a multi-billion dollar market. In 2015, U.S. gross sales of branded and generic buprenorphine products were estimated to be approximately $2 billion. Further, buprenorphine sales have experienced double-digit growth year-over-year from 2009 to 2015, with an estimated compound annual growth rate, or CAGR, of 20% over this time period. We also have long-acting product candidates in development for chronic pain and schizophrenia, both of which are also fast-growing, multi-billion dollar markets with U.S. gross sales of all chronic pain products and schizophrenia products estimated at $15.1 billion and $3.5 billion, respectively in 2015. Our specialty CNS markets are characterized by concentrated prescriber audiences and strong patient advocacy efforts, which we believe will allow us to effectively commercialize products with a small, targeted sales force and enhance our ability to achieve comprehensive product reimbursement.

Differentiated products addressing high unmet medical needs. Our products utilize proprietary long-acting delivery mechanisms that are uniquely designed to provide novel solutions for our specialty CNS markets. Our products are designed to enhance compliance and lower treatment stigma and to reduce the potential for medication diversion and abuse. As a result, we believe our products will lead to better clinical and social outcomes. Oral daily medications for opioid addiction reinforce addictive behavior and societal stigma, and easily allow for ‘‘drug holidays’’ that can lead to relapse and potentially overdose. Opioid medications for chronic pain are overprescribed and physicians and public health organizations have been calling for new, safer and less addictive treatment alternatives. In addition, significant negative health and social consequences arise when compliance with schizophrenia therapy is inadequate.

Mitigated clinical and regulatory risk. Our current products apply novel delivery mechanisms to existing FDA-approved therapeutic molecules. Therefore, we may be able to leverage the proven safety and efficacy of these molecules to use the FDA’s section 505(b)(2) approval pathway. We believe this mitigates the clinical and regulatory risks associated with our products.

Long duration cashflows from products with high barriers to entry. Our products are covered by a range of intellectual property, trade secrets and know-how and are subject to a range of complex clinical and regulatory requirements. In addition, our supply chain is difficult to replicate as it involves the handling of controlled substances, which involves the need for special permits and licenses, and involves several single source suppliers. Patents on our products are expected to extend through the mid-2020s through mid-2030s. Long-acting implantable and injectable formulations are particularly difficult to create or re-engineer, due to trade secrets and proprietary know-how around complexities working with

undisclosed and difficult to source raw materials. We believe the generic regulatory pathway will be complex and costly, requiring clinical trials which demonstrate high standards of equivalent efficacy, safety and drug release profiles. Certification under controlled substance REMS programs will create additional barriers.

Platform for organic growth and expansion. Our business model is driven by seeking out, in-licensing and developing the best long-acting therapies in order to improve patient outcomes and reduce costs to the healthcare system and society. Our product development expertise, and the investments we are making in our commercial and manufacturing infrastructure, can be leveraged across our diversified product portfolio and we believe will provide operating leverage as we continue to bring products to market. We intend to leverage our existing technology platforms as well as business development efforts to complement our organic growth and support sustainable long-term growth.

Proven, experienced management team. Our management team has an established track record of developing successful clinical and commercial organizations. Over the course of more than 25 years in the pharmaceutical industry, our CEO Behshad Sheldon drove the success of multiple blockbuster pharmaceuticals, including Abilify for schizophrenia, bipolar disorder and depression; Glucophage for type 2 diabetes; and Plavix for the prevention of stroke and heart attack. Other key members of our management team were also part of the teams responsible for these and other blockbuster drugs, have reimbursement experience including for buprenorphine products for treatment of opioid addiction, or have experience in government agencies including as Commissioner of the FDA.

Our growth strategies

Grow sales of our recently approved product Probuphine for opioid addiction. We intend to drive strong adoption of Probuphine by targeting physicians, physician practices, integrated health systems, correctional facilities and other institutional providers who are likely to have substantial numbers of patients suitable for Probuphine treatment, and the top 100 payors who account for approximately 85% of U.S. buprenorphine coverage. To date, our post-approval commercialization efforts for Probuphine have focused on a medical affairs driven introduction, including training healthcare providers to implant and prescribe Probuphine and working with payors to ensure comprehensive reimbursement. We have trained and certified approximately 2,500 healthcare providers to prescribe and implant Probuphine, and over 70 payors have indicated that they intend to cover Probuphine, including Humana and all regional Blue Cross Blue Shield plans, and certain larger payors, such as Aetna and Cigna, have indicated that they will not require prior authorization. We are planning a full-scale commercial launch with our new fully-deployed field force of approximately 60 representatives in the first quarter of 2017 when we expect more payors to have released medical coverage policies for Probuphine and when we will have implemented our specialty pharmacy distribution model. These commercialization efforts will also lay the groundwork for marketing CAM2038 which we expect will target the same prescribers.

Advance our lead product candidates, weekly and monthly CAM2038 for opioid addiction, and the rest of our specialty CNS pipeline, to establish a diversified portfolio of commercial products. If weekly and monthly CAM2038 is approved, we will market a comprehensive suite of opioid addiction products that we believe will allow healthcare providers to treat patients throughout the continuum of care as they progress from treatment initiation through long-term maintenance. We expect a number of key milestones over the course of 2017, including submitting an NDA for weekly and monthly CAM2038 in the first half of 2017. Our development pipeline has the potential to launch eight products over the next four years, and this diversified portfolio will leverage our specialty CNS commercial infrastructure.

Leverage differentiated product profiles to establish leadership positions in underserved markets. We intend to establish our products as new standards of care in the therapeutic markets in which we operate. In both opioid addiction and chronic pain, we have the potential to be the only company that offers a comprehensive portfolio of long-acting medications including once weekly, once monthly and six-month formulations. BB0817, our long-acting risperidone for schizophrenia, has the potential to be the first and only implantable risperidone in a market which has been transitioning towards long-acting formulations given the significant consequences associated with inadequate compliance. We believe our products will be differentiated both by their inherent attributes and their potential to offer improved clinical outcomes and quality of life for patients.

Expand our markets by addressing unmet needs and providing access to innovative therapies. Our novel long-acting medications are differentiated from current standards of care, and are designed to address high unmet needs in the large and growing markets of opioid addiction, pain and schizophrenia. We believe our innovative therapies will enhance compliance and lower treatment stigma, and therefore will improve patient outcomes and quality of life. In addition, our long-acting medications reduce the potential for medication diversion and abuse, which is important for both the pain and opioid addiction markets. By addressing currently unmet medical needs, we believe our portfolio will allow healthcare providers to expand the population of patients they are able to effectively treat.

Pursue additional product development opportunities via targeted business development. Over time, we intend to leverage our commercial infrastructure to become the leading pharmaceutical company focused on specialty CNS therapeutic areas. As such, we believe we will become the partner of choice for development and commercialization in specialty CNS which will provide opportunities to expand our pipeline of long-acting product candidates. We believe that the concentrated and targeted nature of the specialty CNS sector will allow us to benefit from meaningful operating leverage as we further expand our product portfolio.

Our technology approach

Our approach to developing long-acting medications is to identify the best possible therapeutic solution for a targeted indication and then to license or acquire delivery technologies that enable us to offer this solution. As a result of this approach we are not limited to specific technologies or platforms.

Our long-acting six-month implantable medications, Probuphine, BB0817 and BB1216 are the only long-acting implantable medications either approved or in development for their targeted indications.

Our long-acting injectable medications have inherent attributes that we believe make them uniquely suited to the development of more convenient and attractive therapeutic alternatives as described below:

- **Multiple duration forms.** We are able to formulate injectables in both once weekly and once monthly forms. This will allow us to align our products with the prevailing clinical practices across certain therapeutics areas that we intend to serve.
- **Multiple dosages.** For each injectable, we are able to provide a wide range of different dosages. This enables healthcare providers to prescribe personalized care for each patient across a complex patient base having diverse therapeutic needs.
- **Small, low-viscosity volumes.** Our injectables require a small dosage volume of only 0.6 ml. We believe this small volume and the low viscosity of the liquid solution will minimize discomfort for patients, leading to enhanced patient and physician acceptance.

- **Small needle size.** Our injectables require a small 23 gauge needle for administration, similar to the needle size used for patient self-administered insulin injections or seasonal flu shots. We believe this small needle size will minimize discomfort and make the injection process less frightening for patients, leading to enhanced patient and physician acceptance.
- **No refrigeration required.** While the current formulations of buprenorphine require refrigerated storage, which most healthcare provider offices do not have, our injectables do not require refrigerated storage. This enables healthcare providers to store and administer our injectables with greater convenience.
- **No reconstitution required.** Our injectables come in ready-to-use pre-loaded syringes, which do not require extra time spent in mixing and preparation prior to use, adding to the convenience for healthcare providers.

Our current product portfolio combines three primary delivery technologies with FDA-approved compounds for the treatment of opioid addiction, pain, schizophrenia and spasticity:

ProNeura implantable drug delivery technology This long-acting implantable technology offers continuous buprenorphine delivery for up to six months, and consists of a small, solid implant, smaller than the size of a one-inch matchstick, made from a mixture of ethylene-vinyl acetate, or EVA, and the drug substance. The resulting product is a solid matrix that is placed sub-dermally, normally in the inner part of the upper arm in a short in-office procedure usually lasting less than 15 minutes. After insertion, Probuphine delivers buprenorphine continuously for six months. Thereafter, the implants can be removed and replaced with new Probuphine implants.

FluidCrystal injectable drug delivery platform This long-acting injectable technology offers continuous buprenorphine delivery from one week to one month, and consists of a liquid lipid solution which on contact with the body transforms to a liquid crystalline gel. This gel depot effectively encapsulates the drug compound which is slowly and steadily released as the depot biodegrades. The technology also allows for a high drug load in a smaller injection volume.

MedLaunch implant platform This implant platform technology enables subcutaneous insertion of a cylindrical, non-biodegradable, flexible polymer that can be used to deliver long-acting formulations of daily, oral drugs, such as risperidone or tizanidine. This polymer membrane controls the rate of diffusion of the drug substance thereby providing immediate release while improving drug delivery via controlled release over a period of six months and up to one year.

Our markets and product portfolio

The table below summarizes our current product portfolio:

Product	Indication	Substance	Form	Phase of Development	Braeburn Commercialization Rights
Probuphine	Opioid addiction	Buprenorphine	6-month implant	Marketed(1)	United States, Canada(2)
CAM2038 Weekly	Opioid addiction	Buprenorphine	Weekly injectable	Phase 3	North America; Asia option rights(3)
CAM2038 Monthly	Opioid addiction	Buprenorphine	Monthly injectable	Phase 3	North America; Asia option rights(3)
CAM2038 Weekly	Chronic pain	Buprenorphine	Weekly injectable	Phase 3	North America; Asia option rights(3)
CAM2038 Monthly	Chronic pain	Buprenorphine	Monthly injectable	Phase 3	North America; Asia option rights(3)
Probuphine	Chronic pain	Buprenorphine	6-month implant	Phase 3	United States, Canada(2)
BB0817	Schizophrenia	Risperidone	6-month implant	Phase 3	Worldwide
BB0417	Acute post-operative pain	Buprenorphine and Granisetron	3 to 5 day injectable	Phase 1	North America; Asia option rights(3)
BB1216	Spasticity	Tizanidine	6-month implant	Clinic ready(4)	Worldwide

(1) The FDA has required that we conduct four post-approval clinical trials to assess the insertion, localization and removal related serious adverse events of Probuphine, the risk of the QT interval in the heart's electrical cycle during treatment with Probuphine, the effect of scarring or inflammation related to a prior implant on the safety of re-implantation / re-insertion, the potential for implant migration, and the bioavailability of Probuphine into the same insertion site, and the safety, feasibility and pharmacokinetics of Probuphine implantation at alternate body sites.

(2) We have exclusively sub-licensed commercialization rights in Canada to Knight Therapeutics, Inc.

(3) We have option rights for China, Japan, South Korea and Taiwan.

(4) If current formulation and testing are successful, we expect BB1216 will advance directly to Phase 3 development.

Opioid addiction

Overview

Prescription opioids, such as oxycodone and fentanyl, as well as illicit opioids, such as heroin, can be physically and psychologically addictive. They are full (not partial) opioid agonists that cause the release of dopamine, a brain chemical that regulates emotion and feelings of pleasure, resulting in a euphoric effect, or "high," which strongly reinforces substance abuse. After chronic abuse of opioids, people develop tolerance, feel fewer euphoric effects and develop stronger symptoms of withdrawal if they stop taking opioids. Greater amounts of opioids are required to overcome tolerance to the desired effects even as they may be less pronounced or even non-existent. Chronic abuse of opioids can lead to impaired judgment, decision-making, learning, memory and behavior control.

The U.S. government has declared opioid abuse an unprecedented public health epidemic, with more than 60% of drug overdose deaths involving an opioid. The epidemic is driven by opioid medications prescribed for pain. Between 2000 and 2014, nearly half a million Americans died from drug overdoses and the number of overdose deaths related to opioids quadrupled, closely tracking the increase in prescriptions dispensed for opioids. In 2015, healthcare providers wrote 228 million prescriptions for opioids, more than the number of American adults. Misuse of prescription painkillers often leads to heroin use as a cheaper alternative to prescription drugs, and accounts for four out of five new heroin users. On a daily basis, more than 650,000 opioid prescriptions are dispensed, 3,900 people begin to abuse or misuse prescription

opioids, and 580 people begin to use heroin. Every day approximately 2,000 people are hospitalized and 78 people die from overdose involving opioids, resulting in approximately 30,000 opioid overdose deaths per year.

Today, less than half of the estimated 2.6 million people who have been diagnosed with opioid addiction in the United States are receiving medication. Left untreated, opioid addiction is associated with spread of HIV and hepatitis C, criminal activity, accidents and trauma related to drug-seeking behaviors and fatal overdose. Consequently, the opioid addiction epidemic has major social and economic impacts. In 2013, prescription opioid abuse accounted for approximately an estimated $80 billion in U.S. health and social costs.

Current treatment options

In 2015, approximately 12.5 million people misused opioid pain relievers and over 800,000 people used heroin in the United States. Opioid addiction can be effectively treated with a combination of medication and psychosocial therapy. Society saves up to an estimated $12 for every $1 spent on treatment for opioid addiction. The current standard of care for the outpatient treatment of opioid addiction is oral daily buprenorphine, which is a partial (not full) opioid agonist that was first approved by the FDA in 2002. Buprenorphine is an opioid, but it is recognized as safer than other opioids because it has a ''ceiling effect,'' meaning that its euphoric effects only increase with its increasing dosage up to a ceiling point, after which taking higher doses has minimal or no increase in effect. This means buprenorphine is less addictive than full agonists, with lower potential for misuse. The ceiling effect also reduces the risk of respiratory failure associated with high doses of opioids, which is the primary cause of fatality related to opioid overdose.

In 2015, U.S. gross sales of all marketed branded and generic buprenorphine products was estimated to be approximately $2 billion. The largest branded oral daily buprenorphine product in the United States is Suboxone sublingual film, which must be held under the tongue for up to 15 minutes without swallowing in order to receive the full dose. The HHS regulates the number of patients that physicians can treat with buprenorphine for opioid addiction and recently increased this number from a maximum of 100 patients to 275 patients for qualified physicians.

Patients treated with buprenorphine are more likely to maintain abstinence compared with those who receive psychosocial intervention alone, leading to a reduction in rates of death and secondary disease. Treatment with buprenorphine has been shown to decrease not only illicit opioid abuse, but also transmission of infectious diseases associated with needle sharing, drug-related crime and fatal overdose. According to a 2015 study by the Legal Action Center, patients receiving medication, such as buprenorphine, as part of their treatment were 75% less likely to die from a drug overdose than patients without medication.

Although oral buprenorphine is an effective treatment for opioid addiction, the burden of daily medication coupled with the inconvenience of the sublingual formulation contributes to low patient compliance and suboptimal medical outcomes. Despite being a chronic condition where relapse can have dire consequences, patients are taking medication on average only 33% of the time that they need it. Each day a patient is off medication, the odds of relapse increase significantly, and consequently a patient is in significant danger of potential overdose and death.

When dispensed to patients for self-administration, buprenorphine becomes susceptible to diversion, misuse, abuse and accidental pediatric exposure. With buprenorphine, patients are faced with the choice of

continuing their medication, or using illicit opioids. A common practice is known as taking a ‘‘drug holiday,’’ which means using oral buprenorphine to control withdrawal symptoms in between using illicit opioids for euphoric effect. When a patient is actively using illicit opioids their brain adapts to the exposure of the opioid, and when a patient is on buprenorphine the brain begins to heal and starts moving to a more normal state. As a result, if a person decides not to take their medication and use illicit opioids the potential for an overdose increases because they no longer have the same tolerance level.

Our products for opioid addiction

Our marketed product, Probuphine, is a six-month buprenorphine implant for the maintenance treatment of opioid addiction in patients who have achieved and sustained prolonged clinical stability on a dose of up to 8 mg per day of oral buprenorphine, which represents approximately twenty-five percent of oral buprenorphine prescriptions. Probuphine uses the proprietary ProNeura drug delivery technology whereby buprenorphine hydrochloride is uniformly distributed throughout a polymer implant made out of EVA. Treatment with Probuphine requires a healthcare provider to insert a set of four implants, each smaller than a one-inch matchstick, sub-dermally in the patient’s upper arm during a short in-office procedure lasting less than 15 minutes. After insertion, Probuphine delivers buprenorphine continuously for six months. Thereafter, the implants can be removed and replaced with new Probuphine implants.

Our lead product candidates, weekly and monthly CAM2038, are subcutaneous injectable formulations of buprenorphine for the treatment of opioid addiction. CAM2038 uses the proprietary FluidCrystal delivery system. After injection, CAM2038 absorbs body fluids to create a gel-like encapsulation of buprenorphine under the skin. This results in an initial immediate release of buprenorphine followed by a slow and consistent release of the drug over a weekly or monthly treatment period. Weekly and monthly CAM2038 each come in multiple doses to match the range of effective buprenorphine doses. Each finished product candidate comes as a ready-to-use, low-volume, thin-needle, pre-filled syringe, which is stable at room temperature and therefore does not require refrigeration.

We believe CAM2038 will expand our target patient population, including not only patients who have been successfully treated with buprenorphine but also patients new to buprenorphine therapy. We believe a weekly buprenorphine injection, if approved, available in a range of therapeutic dose options would be an attractive option for beginning buprenorphine treatment where weekly medical visits to adjust dose is common practice. We believe a monthly injection available in a range of therapeutic dose options that match our weekly injection doses would be an attractive option for early-stage maintenance treatment where a transition to monthly visits after finding a stable dose is common practice. For longer-term maintenance treatment, we believe a Probuphine six-month implant would be an attractive option.

In November 2016, we reported positive top-line results from a Phase 3 trial of weekly and monthly CAM2038 for opioid addiction. CAM2038 achieved non-inferiority compared to oral daily buprenorphine based on the primary endpoint and superiority to oral daily buprenorphine based on a secondary endpoint. Based on the successful results from this pivotal Phase 3 trial, we are working to submit an NDA for weekly and monthly CAM2038 in the first half of 2017. The FDA has granted fast track designation for weekly and monthly CAM2038 for the treatment of opioid addiction. Other ongoing supportive trials for CAM2038 include a customary one year safety trial and a Phase 2 injection site trial to determine if CAM2038 can produce similar buprenorphine levels at injection sites in the buttocks, abdomen, arm and thigh.

We believe that weekly and monthly CAM2038, together with six-month Probuphine, address the limitations of current treatment approaches for opioid addiction by providing a suite of complementary long-acting

implantable and injectable medications. Our products will allow healthcare providers to treat patients throughout the continuum of care as they progress from treatment initiation through long-term maintenance.

Pain

Overview

Chronic pain, or pain lasting for more than 12 weeks, is a large and growing market. According to the National Institute on Drug Abuse, or NIDA, over 100 million people suffer from chronic pain in the United States, with 23 million patients reporting a significant level of pain. Common chronic pain complaints include headache, lower back pain, cancer pain, arthritis pain and neurogenic pain, or pain resulting from damage to the nervous system. In United States, the total annual incremental cost of health care due to chronic pain in 2010 was up to $635 billion, which combines the medical costs of pain care and the economic costs related to lost wages and productivity. Acute pain, usually following a specific event such as surgery or injury, generally lasts less than 12 weeks but can often transition to chronic pain and, if treated with opioids, can lead to dependence and addiction.

Current treatment options

Opioids (e.g., morphine, oxycodone, hydrocodone and fentanyl), have consistently been shown to be effective in treating pain, and roughly one in five patients seen by healthcare providers for non-cancer pain symptoms are prescribed opioids, accounting for approximately 228 million prescriptions written for opioids in 2015. According to the NIDA over 48 million people use opioid analgesics to treat their pain. However, the rapid rise in the opioid abuse epidemic has heightened scrutiny of the use of opioid painkillers and led the Centers for Disease Control and Prevention, or CDC, to issue new guidelines about their use. These guidelines caution healthcare providers to be selective in prescribing opioids, to start with low doses, to weigh risks and benefits when prescribing opioids for chronic pain, and to prescribe high doses only after a careful risk assessment. The guidelines also recommend that patients being treated with opioids for chronic pain who are suspected of a potential opioid addiction should be transitioned to treatment with methadone or buprenorphine. In 2015, approximately 3 million prescriptions were written for methadone and 6.7 million prescriptions for buprenorphine.

Buprenorphine is an attractive treatment alternative for patients with pain, due to the fact that it is powerful, with a potency 25 to 50 times that of morphine. However, buprenorphine has a ceiling effect with respect to euphoric effects, which means there is a reduced risk of addiction, and a reduced risk of respiratory failure associated with high doses of opioids, which is the primary cause of death related to opioid overdose. Clinical trials, including those evaluating the treatment outcomes of patients treated with high doses of opioids (as much as 400 mg/day or more of morphine) who were transitioned to oral buprenorphine at doses ranging from 8-32 mg/day, have shown that buprenorphine is useful in treating pain. The FDA has approved two buprenorphine drug products for treatment of chronic pain, a transdermal patch marketed as Butrans and a buccal film marketed as Belbuca.

However, Butrans and Belbuca are only available in low doses of buprenorphine, comparable to roughly 1 mg/day or less of oral buprenorphine. While Butrans and Belbuca may be effective for some chronic pain patients, a survey of existing clinical practices suggests that many patients have improved outcomes at higher doses. Butrans and Belbuca also carry risks of diversion, abuse, misuse and accidental pediatric exposure. A transdermal patch may be swallowed or the buprenorphine may be extracted from the patches and injected or ingested, including from improperly disposed patches. None of the higher-dose oral

buprenorphine products approved for opioid addiction have been approved for the treatment of chronic pain.

Our product candidates

We believe our long-acting medications, six-month Probuphine and weekly and monthly CAM2038, have the potential to provide a suite of therapeutic products across the continuum of care for pain. We believe our long-acting medications, if approved, will provide continuous around-the-clock therapy, resulting in improved pain relief, increased convenience and enhanced patient quality of life. In addition, we believe that our product candidates will reduce the risk of diversion, abuse, misuse and accidental pediatric exposure associated with the daily administration of oral opioids to treat pain. Like opioid addiction, chronic pain is a long-term condition and therefore we expect that our products would be used by patients for as long as required.

Our current development efforts focus on indications for transferring chronic pain patients, who are being treated with opioid painkillers at a dose equivalent to 80 mg/day or more of morphine, to buprenorphine. We are currently conducting a Phase 3 clinical trial of weekly and monthly CAM2038 in the treatment of patients with moderate to severe chronic lower back pain, and anticipate announcing the results of this trial in the second half of 2017. We plan to enroll an estimated 350 patients in a Phase 3 clinical trial of Probuphine in the treatment of patients with moderate to severe chronic lower back pain and enrollment began in the fourth quarter of 2016.

Based on a 2016 market research survey of 196 physicians that we commissioned, approximately 82% of all physicians, and 94% of physicians with a high volume of patients, would possibly, probably, or definitely, prescribe a buprenorphine injection, such as CAM2038, for the treatment of chronic pain if approved, and approximately 82% of such physicians, would possibly, probably, or definitely, prescribe a buprenorphine implant, such as Probuphine, for the treatment of chronic pain if approved. These same physicians predicted that they would prescribe a buprenorphine injection to approximately 9% of their chronic pain patients and a buprenorphine implant to approximately 7% of their chronic pain patients. The key reasons cited for adoption of a buprenorphine injection or implant were less abuse, less diversion, steadier dose, limiting opioid dependence and convenience.

We are also developing BB0417, a subcutaneous injectable formulation that offers three to five days of buprenorphine and granisetron, a widely used drug to treat nausea and vomiting, for the potential treatment of acute post-operative pain, nausea and vomiting. Effective acute post-operative pain management is an indispensable component of the continuum of care for the surgical patient, as inadequate pain control may result in delayed mobilization and recovery, pulmonary and cardiac complications and an increased likelihood of the development of neuropathic pain. In addition, post-operative vomiting and nausea are the most common causes of patient dissatisfaction after anesthesia, with approximately 30-50% of post-operative patients experiencing vomiting and nausea. We believe that BB0417 has the potential to improve the well-being of post-operative patients and reduce the need for other medications including oral opioid painkillers, which are taken home and self-administered by the patient. BB0417 is currently in Phase 1 development.

Schizophrenia

Overview

Schizophrenia is a debilitating mental illness estimated to affect up to approximately 1% of the U.S. population, or approximately 2.4 million individuals, and accounts for 20% of all hospital bed-days in the

United States. Schizophrenia is characterized by positive and negative symptoms as well as disorganized thoughts which are manifested in a patient's speech and behaviors. Positive symptoms include hallucinations, voices that converse with, or about the patient and delusions. Negative symptoms include lack of emotion, loss of will or drive and social withdrawal. Disorganized behaviors may lead to difficulty for patients to live normal lives, which includes preparing meals, maintaining employment, or interacting with friends, family and colleagues.

Schizophrenia is a life-long illness and the current standard of care is a combination of medication and psychosocial therapy. The aim of long-term treatment is to maintain symptom stability, adequately treat any increases in symptoms, maintain or improve daily functioning and quality of life and to prevent relapse. Patients with schizophrenia generally have impaired insight and do not recognize that they have the illness. This lack of insight leads to poor or partial compliance with prescribed medication, which in turn results in reduced treatment efficacy, earlier relapses, higher psychiatric admissions, reduced quality of life, increased suicide rates and a shortened life expectancy. These factors make schizophrenia one of the leading causes of disability in the United States, and in 2013, cost the United States approximately $156 billion in direct and indirect expenses.

Current treatment options

Treatment of schizophrenia is a $6.5 billion market in the United States, with roughly a dozen different pharmacotherapies available in multiple dosage forms. The most commonly used medications are atypical antipsychotics, a new generation of medicine that are highly effective and designed to have less undesirable side effects than those associated with the first generation, or typical, antipsychotics. In 2015, U.S. sales of all antipsychotics were approximately $21.2 billion across all indications. As of 2014, the most commonly prescribed chemical compounds for schizophrenia were risperidone, olanzapine, quetiapine and aripiprazole, all available in oral dosage form requiring daily administration. In 2015, healthcare providers wrote over 9.3 million prescriptions for risperidone.

Due to the life-long nature of schizophrenia and importance of adhering to a medication treatment plan over a patient's lifetime, long-acting medications represent a growing share of the schizophrenia market. In 2015, risperidone accounted for $3.6 billion in U.S. sales and long-acting schizophrenia medications have experienced double-digit growth in market share over the past two years. In 2007, the last year of exclusivity for risperidone, U.S. sales were $3.0 billion and represented approximately 27% of prescriptions across all indications in 2007. As of 2015, an estimated 23% of the schizophrenia patient population is treated with a long-acting medication, and continued growth in the market share is expected over the next five years. The success of long-acting medications despite the widespread availability of generic oral alternatives suggests that there is significant unmet need in treatment of schizophrenia. Several studies have also demonstrated that treatment of schizophrenia with long-acting medications compared to oral medications reduces hospital readmission rates.

Our product candidate

Our product candidate BBO817 is a six-month risperidone implant based on the MedLaunch platform technology, whereby the risperidone drug substance is enclosed within a sealed, cylindrical polymer membrane. This polymer membrane controls the rate of diffusion of the drug substance thereby providing immediate release while improving drug delivery via controlled release over a period of six months. We believe BBO817 has the potential for unique positioning in the schizophrenia market with a treatment duration that at least doubles that of currently-marketed injectables, which range from two weeks to three

months. As schizophrenia is a life-long condition, we expect that BBO817 would be used by patients indefinitely.

Our BBO817 development program focuses on demonstrating that BBO817 delivers an efficacious dose of risperidone and showing that our delivery device is safe and well-tolerated. We believe that the unique drug-release profile of BBO817 may make it possible to demonstrate effectiveness of BBO817 by bridging to the pharmacokinetics of oral risperidone without conducting a traditional Phase 3 clinical efficacy trial. BBO817 is currently in Phase 3 development, with expected clinical trial results in 2017.

Spasticity

Overview

Spasticity, which refers to feelings of stiffness and a wide range of involuntary muscle spasms, is typically reported in patients with multiple sclerosis, stroke, traumatic brain injury, cerebral palsy and spinal cord injury. Medical treatment is reserved for spasticity that causes pain, interferes with activities of daily living or results in functional disability. We estimate that there are approximately 350,000 patients in the United States with moderate to severe spasticity who are eligible for medical treatment, out of the approximately 1 million patients with spasticity in the United States (312,000 with multiple sclerosis, 245,000 with ischemic stroke, 125,000 with traumatic brain injury, 270,000 with cerebral palsy and 80,000 with spinal cord injury).

Current treatment options

Current treatment options for spasticity include a variety of oral daily medications, and one common oral treatment is tizanidine, which is taken at least four times per day. Another treatment is surgical implantation of an intrathecal baclofen pump for disabling spasticity that does not respond to oral medications or where side effects limit treatment. In 2015, U.S. gross sales of all marketed branded and generic tizanidine and baclofen were $186 million and $141 million, respectively.

Our product candidate

Our product candidate BB1216 is a six-month tizanidine implant based on the MedLaunch platform technology, whereby the tizanidine drug substance is enclosed within a sealed, cylindrical polymer membrane. This polymer membrane controls the rate of diffusion of the drug substance, thereby providing immediate release while improving drug delivery via controlled release over a period of six months. We believe that BB1216 may provide effective pain relief with fewer side effects and enhanced clinical outcomes compared to oral medications and will be more convenient for patients. We also believe that BB1216 will be an attractive alternative to surgical implantation of an intrathecal baclofen pump, as the surgical procedure to implant BB1216 is simpler and safer. BB1216 is currently in animal testing of the formulation and if this testing is successful, we expect that it will advance directly to Phase 3 development.

Clinical trials

Opioid addiction

Probuphine

Completed Phase 3 Trial

The safety and effectiveness of Probuphine in adult patients with opioid addiction who were clinically stable on 8 mg/day or less of sublingual buprenorphine was studied in a Phase 3 clinical trial. The trial

enrolled 177 patients in two treatment arms, with 87 patients receiving Probuphine and placebo sublingual tablets and 89 patients receiving sublingual buprenorphine/naloxone tablets and placebo implants. The mean age of all patients was 39 and patients across both treatment arms were 59.1% male and 40.9% female. The primary objective of the trial was to demonstrate that Probuphine was not inferior to sublingual buprenorphine The treatment phase of the trial lasted 24 weeks. Patients were scheduled for six monthly office visits that included psychosocial counseling and were asked to make four random, unscheduled office visits. Urine toxicology samples were collected at each scheduled monthly office and each random office visit. The pre-specified primary efficacy analysis compared the proportion of responders in each treatment arm. Based on the FDA's analysis, a responder was defined as a subject with six months without any evidence of illicit opioid use, which meant no positive urine toxicology test (or missing urine test, as such was imputed positive in the Probuphine arm), no self-report of illicit opioid use and no supplemental buprenorphine use in the Probuphine arm. The results demonstrated that Probuphine was not inferior to oral buprenorphine, as a total of 55 subjects (or 63%) in the Probuphine arm were responders compared with 57 subjects (or 64%) in the sublingual buprenorphine arm. Although a response rate for the Probuphine arm was a single percentage point lower than the sublingual buprenorphine arm, non-inferiority of Probuphine was still established. In this Phase 3 trial, five subjects experienced at least one serious adverse event, or SAE, three in the sublingual buprenorphine arm: biliary colic, chronic cholecystitis, and bronchitis and two in the Probuphine arm: convulsion and bipolar I disorder, but none of the SAEs occurred at the implant site or were related to Probuphine or implant insertion/removal.

Ongoing Trials

The FDA has required that we conduct four post-approval clinical trials to assess the insertion, localization and removal related serious adverse events of Probuphine, the risk of the QT interval in the heart's electrical cycle during treatment with Probuphine, the effect of scarring or inflammation related to a prior implant on the safety of re-implantation / re-insertion, the potential for implant migration, and the bioavailability of Probuphine into the same insertion site, and the safety, feasibility and pharmacokinetics of Probuphine implantation at alternate body sites. The Probuphine registry to assess risks associated with insertion, localization and removal will be a long-term study. The FDA has provided a deadline of May 2021 for completion of the study with the final report due November 2021. The thorough QT prolongation study protocol has been completed and will be submitted to the FDA in December 2016. Once approved, the study is anticipated to start in the first quarter of 2017 and finish in the fourth quarter of 2017. The alternate site / same site insertion study protocol has been submitted to the FDA. The study will be initiated in the first quarter of 2017, and if the FDA agrees with our rationale for a shorter duration for the study, the final report can be expected by the end of the third quarter of 2017. However, if a full six months of pharmokinetics are required, the study report can be expected in the fourth quarter of 2017.

CAM2038

We are evaluating weekly CAM2038 at doses of 8, 16, 24 and 32 mg and monthly CAM2038 at doses of 64, 96, 128 and 160 mg. Each of the three highest weekly CAM2038 doses and the three lowest monthly CAM2038 doses are designed to be interchangeable with each other and as alternatives to oral buprenorphine at doses of 8, 16 and 24 mg/day, respectively. For example, we expect 8 mg/day sublingual buprenorphine, 16 mg weekly CAM2038 and 64 mg monthly CAM2038 to be comparable in therapeutic effect.

Completed Trials

CAM2038 was studied in a pivotal Phase 3 clinical trial evaluating the safety and efficacy of CAM2038 among adult patients with opioid addiction and using sublingual buprenorphine as an active comparator. A

total of 428 patients who had not been treated with medication for opioid addiction for at least 60 days prior to starting in the trial were enrolled.

This trial had two, 12-week treatment phases. During the first phase, patients initiated treatment with buprenorphine using either sublingual buprenorphine tablets or weekly CAM2038 injections (along with the corresponding placebo treatment) and participated in weekly clinic visits. During the second phase, patients continued treatment with monthly treatment with daily sublingual buprenorphine or were transferred from weekly CAM2038 injections to monthly CAM2038 injections (along with the corresponding placebo treatment). Urine toxicology samples were collected during 12 scheduled weekly visits, three scheduled monthly visits and three random visits.

The primary objective of this trial was to demonstrate the non-inferiority of CAM2038 compared with sublingual buprenorphine among adult patients with opioid addiction. The primary efficacy variable used for FDA was the responder rate in both Phase 1 and 2 of the trial. To be a responder for Phase 1, the patient must have had no evidence of illicit opioid use at Week 13 and have no evidence of illicit opioid use for at least two out of the three weeks from Week 10 to Week 12, inclusive. To be a responder for Phase 2, the patient must have demonstrated no evidence of illicit opioid use at Month 6 and no evidence of illicit opioid use in five out of the six illicit opioid use assessments in Phase 2. To meet the definition of a responder for the full trial, participants needed to meet responder criteria for both Phases 1 and 2. The primary efficacy variable used for EMA was mean percent of urines negative for opioids. The trial's key secondary efficacy endpoint was a superiority testing of the cumulative distribution function of urine samples negative for illicit opioids, verified with self-report.

CAM2038 achieved non-inferiority compared to the active comparator of sublingual buprenorphine for both the FDA and the EMA specified primary endpoints of responder rate and percent negative urine samples for opioids. While the Phase 3 trial was designed and powered for assessing non-inferiority, the protocol also planned to test superiority against sublingual buprenorphine based on the pre-defined secondary endpoint of cumulative distribution function of the percent urines negative for opioids combined with self-reports for weeks 5 through 25. The superiority of CAM2038 over sublingual buprenorphine was established.

The retention rate in the trial was approximately 57.5% and, as expected, was similar across both treatment arms. The overall safety profile was comparable between the two treatment groups, with few serious adverse events reported for both CAM2038 and sublingual buprenorphine (3.2% vs 6%, respectively). There were a total of 18 patients who experienced one or more SAEs in the Phase 3 trial of CAM2038 for opioid addiction, with 13 patients in the sublingual buprenorphine group and five patients in the CAM2038 group experiencing at least one SAE. The reported SAEs in the sublingual buprenorphine group were haemophilia, abscess limb, acute hepatitis C, cellulitis, localised infection, osteomyelitis, pneumonia, sepsis, subcutaneous abscess, accidental overdose, intentional overdose, seizure, bipolar disorder, substance-induced mood disorder, suicidal ideation, and chronic obstructive pulmonary disease and in the CAM2038 group, the SAEs were vomiting, non-cardiac chest pain, road traffic accident, abortion spontaneous, and suicidal ideation. There was only one SAE that was possibly related to the drug, which was vomiting in the CAM2038 group. The rest of the SAEs in the trial were unrelated to the treatment drug. To make the determination of relatedness, the principal investigator used progress notes, laboratory results, hospital admissions/discharge notes, death certificate, and imaging results, in each case, as applicable. The principal investigator determines the relatedness to the treatment drug and procedure as not related, unlikely, possibly, probably and definitely related. We have the right to review all the relatedness determinations and question the results. For the SAEs for the Phase 3 trial of CAM2038 for opioid addiction, we did not question any of the relatedness determinations. There were no reported

overdoses on CAM2038, compared to four overdoses on sublingual buprenorphine. There was one death due to a traffic accident in the CAM2038 arm.

The degree and duration of action of two doses of weekly CAM2038 in blocking the effects of hydromorphone, a powerful opioid used to treat pain, was studied in a Phase 2 trial of patients with moderate to severe opioid addiction. A total of 47 patients participated in this trial. The mean age of all patients was 35.8 and patients across both treatment arms were 74.5% male and 25.5% female.

After a baseline assessment while treated with morphine, patients were randomized to two treatment groups to evaluate the effects of hydromorphone challenges while being treated with weekly CAM2038 doses of either 24 mg or 32 mg. Specifically, patients in each treatment arm were assessed for how much they liked the effects of a placebo dose, a 6 mg hydromorphone dose and an 18 mg hydromorphone dose, each of which were presented randomly. The 24 and 32 mg doses of weekly CAM2038 performed equally well in the trial in achieving the desired level of blocking effect.

Ongoing Clinical Trials

We have two additional ongoing clinical trials of CAM2038 in opioid addiction, a one-year safety trial of weekly and monthly CAM2038 that is being conducted in the United States, Australia and Europe, and a Phase 2 trial to evaluate whether weekly and monthly CAM2038 can be expected to produce similar buprenorphine blood levels following administration at injection sites in the buttocks, abdomen, arm and thigh.

Pain

CAM2038

We are currently conducting a Phase 3 clinical trial to evaluate the efficacy and safety of weekly and monthly CAM2038 in patients with a recent history of moderate to severe chronic lower back pain, or CLBP. An estimated 340 patients will be enrolled in the trial. Patients will be men and women aged 18-75 who have had a recent history of moderate to severe CLBP for at least three months prior to screening and who have been on a stable dose of opioid pain medication equivalent to 80 mg per day or more morphine. Enrollment began in the third quarter of 2016.

The trial design includes an open-label, 10-week treatment phase during which patients will be titrated to a stable dose of 8, 12, 16, 24 or 32 mg weekly CAM2038. During a subsequent 12-week treatment phase, one group of patients will continue treatment with weekly CAM2038 (if stabilized on 8 or 12 mg weekly CAM2038) or be transitioned to treatment with monthly CAM2038 (if stabilized on 16, 24 or 32 mg weekly CAM2038), and a second group will be transitioned to placebo injections. The primary efficacy measure will be a comparison in the change in worst pain intensity from baseline according to patient-reported pain intensity collected daily in an electronic diary.

We anticipate reporting the results of this trial in the second half of 2017. If the results of this trial are positive, we plan to submit an NDA for monthly and weekly CAM2038 for the treatment of chronic pain.

Probuphine

We are conducting a single Phase 3 clinical trial to evaluate the efficacy and safety of two doses of Probuphine, two implants and four implants, as a treatment for moderate to severe CLBP. Patients will be men and women aged 18-75 who have had a recent history of moderate to severe CLBP for at least three months prior to screening and who have been on a stable dose of opioid pain medication equivalent to 80 mg per day or more morphine. We plan to enroll an estimated 350 patients under a trial design similar

to the Phase 3 clinical trial of weekly and month CAM2038 for chronic pain and enrollment began in the fourth quarter of 2016.

BBO417

BBO417 has completed formulation development and nonclinical evaluation and is being transferred to clinical development during the fourth quarter of 2016, initially being studied for the prevention and treatment of postoperative pain, nausea and vomiting. Camurus will lead the Phase I clinical trial for BBO417.

Schizophrenia

BBO817

We believe the unique drug-release profile of BBO817 may make it possible to demonstrate effectiveness of BBO817 by bridging to the pharmacokinetics of oral risperidone without conducting a traditional Phase 3 clinical efficacy trial.

Phase 2 clinical trial

We are currently conducting a Phase 2 trial evaluating the safety, tolerability and pharmacokinetics of risperidone and 9-OH-risperidone, a risperidone byproduct, following implantation of BBO817. 56 patients who were diagnosed with schizophrenia or schizoaffective disorder and were stable on 4 mg per day of oral risperidone for at least eight weeks were enrolled in the trial. The primary objective of this trial is to demonstrate that three 300 mg BBO817 implants (total risperidone dose of 900 mg) will maintain risperidone/9-OH risperidone concentrations within the minimum and maximum steady-state concentrations of 4 mg per day of oral risperidone. The secondary objective is to explore the safety and efficacy of the BBO817 implants as assessed by the Positive and Negative Syndrome Scale, or PANSS, a common measure to evaluate symptoms associated with schizophrenia. We expect to report the results of this trial in the second half of 2017.

Open-label clinical trial

This is a one year, open-label, trial to evaluate the safety and tolerability of BBO817 as a maintenance treatment in patients with schizophrenia. An estimated 140 patients will be enrolled in the trial. The primary objective of this trial is to evaluate the 48-week safety and tolerability of BBO817 as maintenance therapy in patients with schizophrenia. Enrollment of the trial began in April 2016 and is expected to be completed in the first half of 2017. We expect to report the results of this trial in 2017.

Sales, marketing and distribution

As a condition to the FDA's approval of Probuphine, we were required to put into place the Probuphine REMS program, to mitigate the risk of complications of migration, protrusion, expulsion and nerve damage associated with the improper insertion and removal of Probuphine, and the risks of accidental overdose, misuse and abuse. The Probuphine REMS requires training for healthcare providers who prescribe and insert Probuphine implants and patient counseling, and Probuphine distribution is restricted to those healthcare providers who have completed training and received certification under the Probuphine REMS.

To date, our post-approval commercialization efforts for Probuphine have focused on a medical affairs driven introduction, including training healthcare providers to implant and prescribe Probuphine and working with payors to ensure comprehensive reimbursement. Approximately 6,000 physicians account for approximately 90% of buprenorphine prescriptions, and the top 100 payors account for approximately 85% of buprenorphine coverage. We have trained and certified approximately 2,500 healthcare providers to prescribe and implant Probuphine, and over 70 payors have indicated that they intend to cover Probuphine, including Humana and all regional Blue Cross Blue Shield plans, and certain larger payors, such as Aetna and Cigna, have indicated that they will not require prior authorization.

Reimbursement for injectable and implantable medications that are administered by a healthcare provider generally require a J-Code, or code for the drug itself. We submitted our application for a permanent J-Code for Probuphine in June 2016. On November 1, 2016, the U.S. Centers for Medicare & Medicaid Services, or CMS, released a final rule that assigned a specific J-Code for Probuphine beginning January 1, 2017. Separate reimbursement codes are required for the Probuphine insertion and removal procedures. Our initial request for interim "G" fee codes to cover reimbursement for the insertion and removal procedures was declined. In order to address the reimbursement for the multiple implant insertion and removal pertaining to Probuphine, several strategies are currently being pursued. In the interim, the code 17999 or codes 11981-11983 along with a modifier can be utilized to bill for reasonable and customary charges related to the implantation and removal of Probuphine. The primary strategies to address the procedural reimbursement are to petition CMS for the establishment a set of G fee codes with a specified reimbursement amount that can be utilized or referenced by both commercial and government payors. The timeline to the creation of the various procedural reimbursement pathways will vary based on the required governmental process or market needs for accurately tracking and reimbursing for the delivery of Probuphine and related procedural services.

As of September 30, 2016, we have built a team of 27 highly-qualified clinical educators, or CEs, who are organized under five regional CE directors to support the commercialization of Probuphine. CEs are responsible for training, certification and on-going in-market technical support to assist doctors in developing expertise with the Probuphine insertion and removal procedures. The CE field force also works closely with the reimbursement support personnel to help ensure that all information required to place Probuphine orders and to complete benefits investigations is provided on a timely basis.

Our Probuphine distribution was initially restricted by the Federal government to a "buy-and-bill" payment method, where prescribers are required to buy Probuphine inventory themselves and then bill patients or payors following the procedure. This means that prescribers have to assume the financial risk of payment or reimbursement, and requires them to invest in working capital to cover a large upfront cost of the Probuphine implant, which provides a 6-month supply of buprenorphine, as opposed to a distributed cost that results in a lower upfront payment associated with a weekly or monthly purchase of oral buprenorphine. In July 2016, the DEA approved our written request to supplement this "buy-and-bill" distribution model with a specialty pharmacy, which carries inventory and ships it to healthcare providers as requested and prescribed, and directly handles the subsequent billing and payment process with payors. This will remove healthcare providers from the inventory and reimbursement chain and its associated financial risks. We have contracted with Avella of Deer Valley, Inc., or Avella, to serve as the specialty pharmacy for Probuphine. We expect that a majority of our sales of Probuphine will be through this specialty pharmacy distribution model, with the remainder through the "buy-and-bill" system.

We are planning a full-scale commercial launch of Probuphine with our new fully-deployed field force of approximately 60 representatives in the first quarter of 2017 when we expect more payors to have

released medical coverage policies for Probuphine and when Avella will be in place as our specialty pharmacy distributor to supplement the current "buy-and-bill" system. These commercialization efforts will also lay the groundwork for marketing weekly and monthly CAM2038, which we expect will target the same prescribers. If CAM2038 is approved, we plan to further expand our CE market access and sales organization.

We plan to build a separate sales and marketing organization to support commercialization of Probuphine and CAM2038 for pain as well as BBO817 for schizophrenia. The Probuphine REMS training infrastructure will be leveraged for training on insertion and removal of BBO817.

Research and development

Our Research & Development capabilities are led by Frank E. Young, MD, PhD, Executive Vice President, Regulatory and Medical, and Sonnie Kim, PharmD, Senior Vice President, Clinical Development & Medical Affairs, who oversee a team of six full-time employees dedicated to the development of our investigational product pipeline with support from our personnel in related functional areas, including manufacturing, clinical supplies and quality management. We rely principally on clinical research organizations and other vendors to conduct our research and development functions, with each vendor carefully-selected and closely-managed by our full-time personnel.

Manufacturing and supply

We contract with third parties for the manufacture of Probuphine, CAM2038, BBO817 and our other product candidates. We plan to continue contracting with third parties in the future but are in the early stages of building our own manufacturing facility in North Carolina, initially as a secondary source and potentially as the primary source of all finished clinical and commercial drug products. Our personnel have extensive experience in managing on-site and contract manufacturing and quality control and expect to build the necessary internal capacity to bring our own manufacturing facility on line, subject to the outcome of our commercialization efforts for Probuphine and the regulatory progress with CAM2038.

We have a supply agreement with Titan Pharmaceuticals, Inc., or Titan, for clinical and commercial supply of Probuphine implants, which currently expires in February 2017 but which we anticipate amending to extend through February 2018. Titan has contracted with DPT Laboratories, Ltd., or DPT, to manufacture Probuphine implants. We anticipate that our supply agreement with Titan will enable us to continue to manufacture Probuphine at DPT by placing orders through Titan until our own manufacturing facility is operational. DPT's manufacturing of Probuphine implants depends on delivery to DPT of the active ingredient buprenorphine hydrochloride and milled EVA.

Titan currently sources the active ingredient from Teva Pharmaceuticals and milled EVA from Southwest Research Institute, or SwRI. Approximately 15 kg of unmilled EVA is allocated for Probuphine and being stored at SwRI. The current supplier of EVA (supplied by Aldrich Chemical Company and manufactured by Equistar) is no longer supplying GMP grade for pharmaceutical use. A new supplier Celanese Corporation is in the process of being qualified with an expected FDA prior-approval supplement, or PAS, approval by the end of 2017. SwRI will continue to store and mill EVA for both sources. We estimate that our current source of EVA is sufficient to meet our needs for the next two years.

The Probuphine applicator is manufactured by Manan Medical Products, Inc., or Manan. We currently purchase Probuphine applicators directly from Manan and anticipate entering into a supply agreement with Manan that will govern all past and future orders of Probuphine applicators.

Probuphine implants and Probuphine applicators are shipped to Sharp Corporation, or Sharp, for packaging and labeling of commercial Probuphine kits at Sharp's facilities. We are currently purchasing finished commercial kits from Sharp and have entered into a packaging and supply agreement with Sharp that governs all past and future orders for packaging and labeling Probuphine kits.

We source commercial supplies of weekly and monthly CAM2038 buprenorphine injection depots through our licensor, Camurus. We plan to manufacture clinical and commercial supplies of CAM2038 at our Morrisville, North Carolina facility once it is cGMP qualified and batches are validated and subject to regulatory approval.

We source clinical supplies of BBO817 from Xcelience, LLC. The constituent parts of BBO817 finished product are the polymer tubing and the active ingredient. In September 2010, we entered into a long-term, exclusive supply agreement with Lubrizol Advanced Materials, Inc, or Lubrizol, for supply of polymer tubing. We currently acquire the active ingredient, risperidone USP, indirectly through Teva Pharmaceuticals. We are currently in early-stage negotiations for a long-term supply agreement to source risperidone USP for use in clinical and commercial supply of BBO817. We plan to manufacture clinical and commercial supplies of BBO817 at our Morrisville, North Carolina facility once it is cGMP qualified and batches are validated and subject to regulatory approval.

We presently expect that completion of construction of our manufacturing facility located in Morrisville, North Carolina will occur in the first half of 2018, and that commercial grade production will be available no earlier than the end of 2018, subject to regulatory approvals and commercial developments with Probuphine and our product candidates. In connection with manufacture at our North Carolina facility, we plan to enter into supply agreements with one or more suppliers of the Probuphine active ingredient, buprenorphine hydrochloride, and a single supply agreement with the EVA manufacturer currently undergoing the qualification process. Probuphine applicators will continue to be manufactured by Manan.

Intellectual property

We strive to protect the proprietary technologies, inventions and improvements that are commercially important to the development of our business, including by seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also rely on trade secrets and know-how relating to our proprietary technology platform, on continuing technological innovation and on in-licensing opportunities to develop, strengthen and maintain the strength of our position in the fields of opioid addiction, pain, schizophrenia and spasticity that may be important for the development of our business.

Our commercial success may depend in part on our ability to obtain and maintain patent, trade secret and other intellectual property and proprietary protections for our commercially important technology, current and future products and product candidates and methods used to develop and manufacture them, as well as operate without infringing the valid, enforceable patents and intellectual property rights of third parties. Our ability to stop third parties from making, having made, using, selling, offering to sell or importing our current and future products may also depend on the extent to which we have rights under valid and enforceable licenses to patents or trade secrets that cover these activities. In some cases, these rights may need to be enforced by third party licensors. With respect to both our licensed and owned intellectual property, we cannot be sure that patents will be granted with respect to any pending patent applications or with respect to any patent applications filed by us or our licensors in the future, nor can we be sure that any of our or our licensors' existing patents or any patents that may be granted to us or our licensors in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same or will not be challenged, invalidated or circumvented. For more information

regarding the risks related to our intellectual property, please see "Risk Factors—Risks Related to Intellectual Property."

Patent protection

We have in-licensed or acquired patent portfolios from third parties to protect Probuphine and our product candidates. Our policy is to file additional patent applications to protect our products and product candidates and other technology, inventions and improvements to inventions that are commercially important to the development of our business.

Probuphine

As of December 31, 2016, we have exclusively licensed from Titan one issued U.S. patent and one issued Canadian patent directed to methods of using the ProNeura implant formulation for Probuphine to treat opioid addiction. As discussed herein, we have not licensed any patents related to Probuphine outside of the United States and Canada. The issued U.S. patent is expected to expire in 2024, which takes into account a patent term adjustment granted by the PTO. The issued Canadian patent is expected to expire in 2023.

CAM2038

As of December 31, 2016, we have exclusively licensed from Camurus two issued U.S. patents directed to the weekly buprenorphine FluidCrystal injection formulation of our product candidate CAM2038, one issued U.S. patent directed to the monthly buprenorphine FluidCrystal injection formulation of our product candidate CAM2038, three pending U.S. patent applications directed to both weekly and monthly CAM2038, and one pending U.S. patent application directed to monthly CAM2038. We have also licensed or have the option to license from Camurus related patents in China, Japan, South Korea, Mexico and Canada. As discussed herein, we have not licensed or obtained any option to license any patents related to CAM2038 outside of these jurisdictions. The U.S. issued patents are expected to expire between 2025 and 2027, which takes into account patent term adjustments granted by the PTO.

BB0417

As of December 31, 2016, we have exclusively licensed from Camurus the U.S., Canadian and Mexican patent rights under one pending international PCT patent application directed to the buprenorphine/granisetron FluidCrystal injection formulation of our product candidate BB0417. We also have the option to license from Camurus related patent rights under this international PCT application in China, Japan and South Korea and a counterpart patent application in Taiwan. Patents that issue from national counterparts of this international PCT patent application are generally expected to expire in 2036, excluding any additional term for patent term adjustment.

As of December 31, 2016, we have also exclusively licensed from Camurus two issued U.S. patents and four pending U.S. patent applications which generally cover the buprenorphine/granisetron FluidCrystal injection formulation of our product candidate BB0417. The U.S. issued patents are expected to expire between 2026 and 2027 which takes into account patent term adjustments granted by the PTO. We have also licensed or have the option to license from Camurus patent rights corresponding to these U.S. patents and patent application in China, Japan, South Korea, Mexico and Canada.

As discussed herein, we have not licensed or obtained any option to license any patents related to BB0417 outside of these jurisdictions.

BB0817

As of December 31, 2016, we own one formulation patent family specific to BB0817 for the release of risperidone with the MedLaunch implant delivery system. This includes one issued U.S. patent, one pending U.S. pending patent application and five issued patents and 10 pending patent applications in countries outside of the United States. Patents that issue from this patent family are generally expected to expire in 2029, excluding any additional term for patent term adjustment.

BB1216

As of December 31, 2016, we own one formulation patent family specific to BB1216 for the release of tizanidine free base with the MedLaunch implant delivery system. This includes two issued U.S. patents and four pending patent applications in countries outside of the United States. The U.S. issued patents are expected to expire in 2032.

Other MedLaunch platform patents

As of December 31, 2016, we also own two formulation patent families that support a range of applications of the MedLaunch implant delivery system, including BB0817 and BB1216. One patent family includes five issued U.S. patents and 37 issued patents (including 25 European validations) and two pending patent applications in countries outside of the United States. The second patent family includes four issued U.S. patents and nine issued patents and seven pending patent applications in countries outside of the United States. Patents that issue from these two patent families are generally expected to expire between 2023 and 2029, excluding any additional term for patent term adjustment or patent term extension. We further own six additional patent families with 14 issued patents and 20 pending patent applications in the United States and outside the United States, which are related in part to applications of the MedLaunch platform to other specific drug substances.

Trademark protection

As of December 31, 2016, we exclusively licensed the right to use the PROBUPHINE trademark in the U.S. and Canada including a U.S. registered trademark for PROBUPHINE, two pending U.S. trademark applications for the PROBUPHINE logo, and one pending Canadian trademark application for PROBUPHINE.

Trade secret protection

We also rely, in some circumstances, on trade secrets and know-how to protect our technology including our proprietary technology platform. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. 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. Notwithstanding these measures, these agreements and security measures may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, scientific advisors, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For more information regarding the risks related to our intellectual property, please see "Risk Factors—Risks Related to Intellectual Property."

Third party agreements

Titan in-licensed intellectual property

In December 2012 we entered into a license agreement with Titan. This agreement was amended in each of May 2013, July 2013 and November 2013, and the agreement as amended is referred to as the Titan Agreement. Pursuant to the Titan Agreement, Titan granted us an exclusive and sublicensable license to certain of Titan's patents and know-how to commercialize Probuphine in the United States and its territories, including Puerto Rico, and Canada, or collectively, the Territory. Titan also granted us an exclusive license to use its logo and the PROBUPHINE trademark in connection with the commercialization of Probuphine in the Territory subject to certain review rights of Titan. We are obligated to use commercially reasonable efforts to commercialize and market Probuphine in the Territory, including in accordance with a specified plan.

In consideration of the rights granted to us by Titan under the Titan Agreement, we paid Titan an upfront, non-refundable license fee of $15.75 million and agreed to pay Titan tiered royalties on a percentage of net sales of Probuphine, ranging from the mid-teens to the low twenties. In June 13, 2016, we paid Titan a $15 million payment following FDA approval of the Probuphine NDA in conjunction with Titan's transfer and our acceptance of all rights, obligations, and responsibilities related to the Probuphine NDA. We are required to pay Titan up to $165 million upon achievement of specified sales milestones and $35 million upon achievement of specified regulatory milestones. In addition, if we or our affiliates commercialize a product that entails continuous delivery of more than ten days of a therapeutic agent for the treatment of opioid addition in the Territory, we are required to pay a low single digit percentage royalty on sales of such product up to an aggregate royalty of $50 million. Furthermore, if we or our affiliates market or sell any other product (other than Probuphine or the product described in the immediately preceding sentence) that entails the continuous delivery of a therapeutic agent for the treatment of any substance addiction, Titan may, in its sole discretion, irrevocably elect to reduce the royalty rate we pay on net sales of Probuphine and receive a low single-digit royalty on net sales of such product, up to aggregate of $50 million. Pursuant to the Titan Agreement, we have engaged with Titan to effect the transfer of Probuphine manufacturing and supply from Titan to us, which we anticipate will be completed by early 2017.

Pursuant to the Titan Agreement, Titan retains control over the prosecution and maintenance of the licensed patents and know-how, except that we will control the prosecution and maintenance over certain specified licensed patents, subject to certain rights of Titan to review and comment on such prosecution. Further, Titan and we will co-own any inventions related to Probuphine that are jointly developed by us, Titan will own any inventions related to Probuphine that are solely developed by Titan, and we will own any inventions related to Probuphine that are solely developed by us.

Unless earlier terminated, the Titan Agreement will expire on the later of (i) the 15th anniversary of the date of the last product launch in the Territory or (ii) the expiration of the last-to-expire patent in the Territory included in the Titan Agreement. Either party may terminate the Titan Agreement in the event that the other party has materially breached the agreement and has not cured such breach within a specified time period and in the event the other party is subject to insolvency or other similar events. In addition, we may terminate the Titan Agreement in the event that we, notwithstanding good faith efforts to do so, are unable to enter into an agreement for the supply of ethylene vinyl acetate, or EVA; such a supply agreement is terminated by material breach of the supplier; or the supplier fails to provide EVA for a period of at least three months. We may also terminate the Titan Agreement (i) on a country-by-country basis upon six months' notice following the entry of any generic of Probuphine that results in a certain reduction in sales of Probuphine; or, (ii) immediately upon notice if we determine, in good faith, that it is

inadvisable to continue commercialization as a result of any actual or perceived safety issues. Titan may terminate the Titan Agreement if, for reasons other than force majeure, regulatory, safety, manufacturing or product quality issues, we discontinue commercial sale of Probuphine and fail to resume sales within 30 days following notice or in the event we or any of our affiliates or sub-licensees commences any legal proceeding seeking to challenge or dispute the validity or ownership of the licensed patents.

Upon expiration of the Titan Agreement, all rights and licenses granted to us under the agreement will be fully paid up and we will be relieved of any obligation to pay Titan any royalties or fees in excess of any undisputed fees that accrued prior to the date of expiration. In the event that we or Titan terminate the Titan Agreement, we will have the right to sell, or otherwise dispose of, any remaining stock of Probuphine at the time of termination and at Titan's request, we will return to Titan any remaining stock of Probuphine that has not been sold or used within six months of the date of termination. In the event that Titan terminates the Titan Agreement, we must transfer and assign the Probuphine NDA back to Titan.

Camurus AB in-licensed intellectual property

In November 2014, we entered into a license agreement, or the Camurus Agreement, with Camurus AB, or Camurus. Pursuant to the Camurus Agreement, Camurus granted us an exclusive license to certain of its patents and other intellectual property to develop and commercialize buprenorphine FluidCrystal injection formulations, including CAM2038, for any and all uses in the United States, Canada and Mexico, or the Licensed Territory. In October 2016, we entered into an amendment to the Camurus Agreement to, among other things, add BBO417 to the exclusive license. Camurus also granted us an exclusive option, on a country-by-country and product-by-product basis, to include Japan, Taiwan, South Korea and China in the Licensed Territory and a right of first negotiation to include other countries outside the European Union in the Licensed Territory, subject to certain conditions. We granted Camurus an exclusive license to certain of our patents and other intellectual property to commercialize certain products in all countries in the world, other than the Licensed Territory.

For a period beginning on the effective date of the Camurus Agreement and ending on the tenth anniversary of the first commercial sale of the first licensed product, on a country-by-country basis, we may not commercialize in the Licensed Territory any other long acting injectable product containing buprenorphine as an active ingredient for any indication, other than the licensed products. We must also use commercially reasonable efforts to develop, obtain regulatory approval for, commercialize, market and prolong the life cycle of the licensed products in accordance with the Camurus Agreement, a specified development plan and a specified commercialization plan. Camurus will use commercially reasonable efforts to provide certain services specified in the development plan and we will reimburse Camurus for any reasonable costs associated with such services.

We paid Camurus a non-refundable and non-creditable upfront signing fee of $20 million upon execution of the Camurus Agreement. In addition, we agreed to reimburse Camurus up to $2.75 million for certain clinical trial costs. We are required to pay Camurus up to $63 million in one-time, non-refundable development and commercialization milestones and on a product-by-product basis, up to $75 million in one-time, non-refundable sales milestones. We are also required to pay to Camurus mid-teen percentage royalties on net sales of licensed products on a licensed product-by-licensed product and country-by-country basis until the later of (i) 12 years after the date of first commercial sale of such licensed product in such country; or (ii) the expiration of the last-to-expire valid claim of all licensed patent rights in such country covering such licensed product, subject to certain reductions for generic entry.

Camurus will solely own all inventions developed by either party that solely relate to Camurus' FluidCrystal injection depot technology or Camurus' other proprietary formulations for injection that have an effective extended release duration of more than 24 hours. The parties will jointly own any other inventions developed under the Camurus Agreement by both parties. Camurus controls the prosecution and maintenance of certain specified licensed patents, which relate to Camurus' FluidCrystal injection depot technology or Camurus' other proprietary formulations for injection which have an effective extended release duration of more than 24 hours. We control the prosecution and maintenance of certain specified licensed patents that relate solely to the licensed products.

Unless earlier terminated, the Camurus Agreement remains in force until we no longer have any obligations to pay royalties to Camurus for the licensed products. Upon expiration of the Camurus Agreement, the licenses become fully paid and irrevocable and we will have all rights to the licensed products in the countries in which we have obtained such licenses. We may terminate the Camurus Agreement on a product-by-product basis or in its entirety at any time by giving (i) if the Camurus Agreement is terminated in its entirety prior to the first NDA approval of the first licensed product, 90 days' prior written notice, (ii) if the Camurus Agreement is terminated with respect to a specific licensed product, prior to the NDA approval of such product, 90 days' prior written notice, or (iii) 180 days' prior written notice in all other cases. In addition, we or Camurus may terminate the Camurus Agreement in the event (i) that the other party has materially breached the agreement and has not cured such breach within a specified time period, (ii) that the other party has become bankrupt, or (iii) that we or any of our affiliates or sublicensees commence any legal proceedings seeking to challenge the validity of any of patents licensed from Camurus related to the products that are subject to the Camurus Agreement.

In the event that we terminate the Camurus Agreement for convenience or if Camurus terminates the Camurus Agreement for our material breach, bankruptcy or filing of a legal proceeding to challenge the validity of the patents licensed from Camurus or a force majeure event, among other things, all licenses granted to us by Camurus will terminate, the license we granted to Camurus will continue and we will assign all of our intellectual property related solely to the licensed products and all regulatory filings and approvals related to the licensed products to Camurus. If, however, we terminate the Camurus Agreement due to a material breach by Camurus, its bankruptcy or a force majeure event, among other things, all licenses granted by us to Camurus will terminate and at our option, all licenses granted to us by Camurus will continue in full force and effect subject to our continuing obligations to make royalty and milestone payments to Camurus, unless such termination was due to Camurus' bankruptcy.

FX/Endo Pharmaceuticals

In October 2014, we entered into an agreement, or the FX Agreement, with FX Therapeutics, Inc., or FX, under which we paid $8 million to acquire all right, title and interest in an option agreement, or the Option Agreement, which granted an option, or the Option, to purchase certain assets from Endo Pharmaceuticals, Inc., or Endo, relating to the MedLaunch Implant Program, or MedLaunch, under an asset purchase agreement. MedLaunch is a platform implant technology that encloses a drug substance within a sealed, cylindrical polymer membrane made of Tecoflex EG-80A, which controls the rate of release of a drug substance through the polymer membrane. On the same day as the execution of the FX Agreement, FX entered into an amendment to the Option Agreement under which FX exercised its Option to acquire MedLaunch and assigned the Option Agreement to us.

In November 2014, pursuant to the FX Agreement, we entered into an asset purchase agreement with Endo, or the Endo Purchase Agreement, to acquire MedLaunch for $1.2 million. Under the Endo Purchase Agreement, we acquired global rights to BB0817 and BB1216 along with issued patents and pending patent applications covering all MedLaunch applications. Pursuant to the Endo Purchase Agreement, we granted

Endo a worldwide, exclusive license under the intellectual property we purchased from Endo to commercialize pharmaceutical products containing histrelin or octreotide, or tools for implanting or explanting a product containing histrelin, in each case covered by the purchased intellectual property. In addition, Endo has the first right to enforce the purchased intellectual property against any infringement based on a product containing histrelin or octreotide. Under the Endo Purchase Agreement, we agreed to pay Endo $2 million in milestone payments upon the first commercial sale of any FDA approved MedLaunch product in the United States. In addition, we are required to pay Endo low single-digit percentage royalties on worldwide net sales of any MedLaunch product until the later of (i) the tenth anniversary of the closing of our acquisition of MedLaunch or (ii) until such product is no longer covered by a valid claim in the patents we acquired from Endo.

Knight Therapeutics Inc. distribution and sublicense agreement

In February 2016, we entered into a Distribution and Sublicense Agreement, or Knight Agreement, with Knight Therapeutics Inc., or Knight, in which we appointed Knight as our exclusive distributor of Probuphine in Canada. Pursuant to the Knight Agreement, we granted Knight an exclusive license to (i) certain patents and know-how controlled by us and (ii) certain trademarks owned by us and the PROBUPHINE trademark we licensed from Titan to commercialize Probuphine in Canada. We retained the right to commercialize Probuphine in the United States and its territories, including Puerto Rico. We also granted to Knight a right of first negotiation in the event we intend to license our right to commercialize any of our other products in Canada. During the term of the Knight Agreement, we may not commercialize any product containing buprenorphine that is intended for a treatment duration of six months or more in Canada.

Pursuant to the Knight Agreement, Knight must use commercially reasonable efforts to commercialize Probuphine in Canada. We are entitled to receive royalty payments from Knight on net sales of Probuphine in Canada with four tiers of royalty rates ranging from low double-digit percentages to percentages in the mid-thirties. In addition, we will be the exclusive supplier of Probuphine to Knight subject to a supply agreement to be negotiated between us and Knight.

Unless earlier terminated, the initial term of the Knight Agreement will expire on the 15th anniversary of the date of the first commercial sale of Probuphine for opioid addiction in Canada. If Probuphine is approved for another indication in Canada after the fifth anniversary of the first commercial sale of Probuphine for opioid addiction in Canada, we must negotiate in good faith whether to extend the initial term. After the initial term, the Knight Agreement will automatically renew for two-year periods until either party provides the other party with written notice of its intent not to renew at least 180 days prior to the expiration of the initial term or then-current term. We or Knight may terminate the Knight Agreement in the event that (i) the NDA for Probuphine has not been transferred to us by Titan within six months of the date of the Knight Agreement, (ii) either party determines in good faith that it is not advisable for Knight to continue to commercialize Probuphine in Canada as a result of a bona fide safety issue, (iii) the other party has filed for bankruptcy, reorganization, liquidation or receivership proceedings, or (iv) the other party materially breached the agreement and has not cured such breach within a specified time period. In addition, subject to certain exceptions and requirements, we may terminate the Knight Agreement (i) if Knight discontinues the commercial sale of Probuphine for a period of at least three months and fails to resume sales within the specified cure period, (ii) in the event that Knight commences any legal proceedings seeking to challenge the validity or ownership of any of our patents related to Probuphine, or (iii) if we determine, in our sole discretion to terminate the Titan Agreement.

In the event of termination, among other things, Knight shall (i) cease commercialization of Probuphine in Canada, (ii) transfer title to all current and pending regulatory submissions and regulatory approvals for Probuphine to us and (iii) pay any royalty payments generated by Knight's sales of Probuphine in Canada due to us.

Lubrizol Advanced Materials, Inc. supply agreement

In September 2015, we entered into an exclusive supply agreement, or the Lubrizol Agreement, with Lubrizol Advanced Materials, Inc., or Lubrizol, pursuant to which we have the exclusive right to purchase Lubrizol's implantable thermoplastic polyurethane resin and tubing product, the Product, as an excipient in our MedLaunch implant. Pursuant to the Lubrizol Agreement, we paid Lubrizol a non-refundable, non-creditable upfront fee of $108,000 upon signing.

Under the Lubrizol Agreement, we have the right to purchase the Product, in both GMP and non-GMP forms, at a pre-determined, fixed price for the first eight years of the term. In addition to the upfront payment, we also agreed to pay to Lubrizol up to $217,000 in milestone payments related to certain regulatory successes. In addition, we will pay Lubrizol a royalty of 0.5% of net sales of any commercial product utilizing the Product, beginning on first commercial sale of the product and ending on the earlier of: (a) the later of: (i) the expiration of the last valid claim in an issued patent owned or controlled by us, and (ii) the expiration of the last marketing exclusivity covering the product granted a regulatory authority; or (b) the approval by a regulatory authority of an abbreviated new drug application for any product using our product as reference.

The Lubrizol Agreement will expire 20 years from the effective date, however, we have the option to extend the term for additional 5-year terms, provided we notify Lubrizol at least six months before the expiration date of each term. In the event that we extend the term of the Lubrizol Agreement, Lubrizol may adjust the price of the Product.

We may terminate the Lubrizol Agreement (i) upon 180 days written notice if we discontinue development and commercialization of all MedLaunch implants or (ii) upon 60 days written notice if Lubrizol undergoes a change in control and Lubrizol has not provided an alternative arrangement to supply the Product on terms and conditions that are consistent in all material respects with the terms and conditions of the Lubrizol Agreement. In addition, we or Lubrizol may terminate the Lubrizol Agreement in the event (i) that the other party has materially breached the agreement and has not cured such breach within a specified time period or (ii) that the other party has filed for bankruptcy. Lubrizol may also terminate the Lubrizol Agreement if they do not receive the agreed upon royalty payments from us for two consecutive calendar quarters.

Upon expiration or termination of the Lubrizol Agreement for any reason other than a material breach, Lubrizol will fulfill all of our outstanding purchase orders as of the date of termination or expiration and we will take delivery of and pay for the Products under such purchase orders.

Avella product purchase and pharmacy services agreement

In September 2016, we entered into a Product Purchase and Pharmacy Services Agreement, or the Pharmacy Services Agreement, with Avella, a National Accredited Specialty Pharmacy, in which we granted Avella the exclusive, non-transferable, non-sublicensable, revocable right to purchase certain of our products and Avella agreed to perform certain pharmacy services related to such products. Under the terms of the Pharmacy Services Agreement, Avella has agreed to purchase certain of our products at the applicable Wholesale Acquisition Cost, or WAC, subject to certain adjustments and discounts, and will order such products through a distributor designated by us. In addition, Avella will provide pharmacy services with respect to such products, in accordance with applicable laws and regulations as well as specific REMS requirements imposed by the REMS Program as directed by us. Services provided by Avella will be paid in accordance with the fee schedule set forth in the Pharmacy Services Agreement. Additionally, Avella is required to maintain general liability insurance of at least $2.0 million per occurrence.

The Pharmacy Services Agreement expires on September 1, 2018 and will automatically renew for a period of one (1) year unless either party provides at least sixty (60) days prior notice of its intent not to renew. Either party may terminate the Pharmacy Services Agreement without cause with sixty (60) days prior written notice to the other party. In addition, either party may terminate the Pharmacy Services Agreement if (i) the other party materially breached the agreement and has not cured such breach within a specified time period; or (ii) the other party has filed for bankruptcy, reorganization, liquidation or admits in writing its inability to pay its debts as they become due.

Upon expiration or termination of the Pharmacy Services Agreement, both parties will return all equipment and materials belonging to the other party. In addition, Avella has agreed to assist us with the decommissioning or transition of the pharmacy services and will provide reasonable access to relevant records for a period of one (1) year following such termination provided there are no undisputed invoices due or outstanding.

Competition

The biopharmaceutical industry is characterized by intense and dynamic competition to develop new technologies and proprietary therapies. Our marketed product and any product candidates, that are approved and commercialized, compete with existing therapies and new therapies that may become available in the future. We face potential competition from various sources, including larger and better-funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as from academic institutions, governmental agencies and public and private research institutions.

Our principal competition in the opioid addiction market comes from manufacturers of oral buprenorphine products, including Indivior Plc, or Indivior, which markets the Suboxone and Subutex brands. We may also face additional competition in the long-acting buprenorphine market from Indivior if its product candidate RBP-6000, a monthly buprenorphine injection in Phase 3 development, is approved for U.S. marketing. We are not aware of any injectable or implantable buprenorphine products in clinical-stage development besides Indivior's.

We anticipate that our primary competitors for CAM2038 and Probuphine for chronic pain, will be manufacturers of opioid analgesics such as oxycodone that are available at doses equivalent to 80 mg per day of morphine. We are not aware of any implantable or injectable opioid products, including buprenorphine products, in clinical-stage development for pain indications.

We expect our primary competitor for BBO817 will be Janssen Pharmaceuticals, the manufacturer of long-acting injectable formulations of risperidone, marketing bi-weekly and monthly injectable formulations of risperidone or compounds resembling risperidone under the brand names Consta and Sustenna. Indivior is in late-clinical-stage development of RBP-7000, a monthly risperidone injection based on the same injection technology as used in its RBP-6000 buprenorphine injection. We expect to have secondary competitors in the manufacturers of injectable formulations of aripiprazole, another atypical antipsychotic. These include Otsuka Pharmaceutical Co., which markets a monthly injectable formulation of aripiprazole under the brand name Abilify Maintena and Alkermes Inc., which manufactures a monthly injectable formulation of the closely-related molecule aripiprazole lauroxil under the brand name Aristada.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of product candidates and commercializing those product candidates.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We anticipate that we will face intense and increasing competition as new product candidates enter the market and advanced technologies become available. We expect any product candidates that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Government regulation

Government authorities in the United States at the federal, state and local level and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug products. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. drug development

In the United States, the FDA regulates drugs and devices under the FDCA, and its implementing regulations. Drugs and devices are also subject to other federal, state and local statutes and regulations. Products composed of both a drug product and device product are combination products. If marketed individually, each component would be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its regulation based on a determination of the combination product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of some of our product candidates, we expect the primary mode of action to be attributable to the drug component of the product, which means that the FDA's Center for Drug Evaluation and Research would have primary jurisdiction over the premarket development, review and approval. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution,

disgorgement, or civil or criminal penalties. Additionally, a manufacturer may need to recall a product from the market. Any agency or judicial enforcement action could have a material adverse effect on us.

- Our product candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States. The process required by the FDA before a drug may be marketed in the United States generally involves the following:
    - Completion of extensive nonclinical laboratory tests, animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations;
    - Submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
    - Approval by an independent institutional review board, or IRB, or ethics committee at each clinical trial site before each trial may be initiated;
    - Performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical trial-related regulations, referred to as good clinical practices, or GCPs, to establish the safety and efficacy of the proposed drug for each proposed indication;
    - Submission to the FDA of an NDA for a new drug;
    - A determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
    - Satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
    - Potential FDA audit of the nonclinical study and/or clinical trial sites that generated the data in support of the NDA; and
    - FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States.

The nonclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

The data required to support an NDA is generated in two distinct development stages: nonclinical and clinical. For new chemical entities, the nonclinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies in the laboratory, which support subsequent clinical testing. These nonclinical tests include laboratory evaluation of product chemistry, formulation, stability and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the nonclinical tests must comply with federal regulations, including GLPs. The sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. Some nonclinical testing may continue even after the IND is submitted, but an IND must become effective before human clinical trials may begin. The central focus of

an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials, including concerns that human research subjects will be exposed to unreasonable health risks, and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

The clinical stage of development involves the administration of the drug candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completion. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

As part of the 21st Century Cures Act, or the Cures Act, which was signed into law on December 13, 2016, upon request, the FDA is to establish a process for the qualification of drug development tools. A drug development tool includes a biomarker including a surrogate endpoint, a clinical outcome assessment including a patient-reported outcome, and any other method, material or measure that the FDA determines aids drug development and regulatory review. A drug development tool is qualified if the FDA has determined that the tool and its proposed context of use can be relied upon to have a specific interpretation and application in drug development and regulatory review. A qualified drug development tool may be used to support the investigational use of a drug or support or obtain NDA approval.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA so long as the clinical trial is conducted in compliance with GCP and FDA is able to validate the data through an onsite inspection if the agency deems it necessary.

Clinical trials

Clinical trials are generally conducted in three sequential phases that may overlap, known as Phase 1, Phase 2 and Phase 3 clinical trials.

- Phase 1 clinical trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug.

- Phase 2 clinical trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits and provide a preliminary evaluation of efficacy. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks.
- Phase 3 clinical trials generally involve large numbers of patients at multiple sites (from several hundred to several thousand subjects) and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for physician labeling. Phase 3 clinical trials may include comparisons with placebo and/or comparator treatments.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators within 15 calendar days for serious and unexpected suspected adverse events, finding from other studies or animal or *in vitro* testing that suggests a significant risk for human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Additionally, a sponsor must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within 7 calendar days. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. 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 or patients 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. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial.

Pursuant to the Cures Act, the manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the later of 60 calendar days after the date of enactment of the Cures Act or the first initiation of a Phase 2 or Phase 3 trial of the investigational drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

NDA and FDA review process

The results of the nonclinical studies and clinical trials, together with other detailed information, including extensive manufacturing information and information on the composition of the drug and proposed labeling, are submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more specified indications. The FDA reviews an NDA to determine, among other things, whether a drug 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. FDA approval of an NDA must be obtained before a drug may be offered for sale in the United States.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and efficacy 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 grant deferrals for submission of pediatric data or full or partial waivers.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective from October 1, 2016 through September 30, 2017, the user fee for an application requiring clinical data, such as an NDA, is $2,038,100. PDUFA also imposes an annual product fee for human drugs ($97,750) and an annual establishment fee ($512,200) on facilities used to manufacture prescription drugs. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, for drugs that do not contain a new chemical entity the FDA has 10 months from the receipt date in which to complete its initial review of a standard NDA and respond to the applicant, and six months from the receipt date for a priority NDA. For drugs containing a new chemical entity, these 10 and six month review timeframes are from the filing date of an NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA 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 will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. The review and

evaluation of an NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

After the FDA evaluates an NDA, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may resubmit the NDA addressing all of the deficiencies identified in the letter, withdraw the application, or request an opportunity for a hearing. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a drug product for marketing in the United States and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug's safety and efficacy and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA also may place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing. As a condition to the FDA's approval of Probuphine, we were required to put the Probuphine REMS in place.

505(b)(2) Approval process

Section 505(b)(2) of the FDCA provides an alternate regulatory pathway to FDA approval for new or improved formulations or new uses of previously approved drug products. Specifically, Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments, and permits the filing of an NDA where at least one or more of the investigations relied upon by the applicant for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The applicant may rely upon the FDA's prior findings of safety and effectiveness for a previously approved product or on published scientific literature, in support of its application. The FDA may also require 505(b)(2) applicants to perform additional trials to support the changes from the previously approved drug and to further demonstrate the new drug's safety and

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

Expedited development and review programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug may request the FDA to designate the drug as a Fast Track product at any time during the clinical development of the product. Unique to a Fast Track product, the FDA may review sections of the marketing application on a rolling basis before the complete NDA is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under the Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or offers a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review.

Additionally, a drug may be eligible for designation as a breakthrough therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinical development. The benefits of breakthrough therapy designation includes the same benefits as fast track designation, plus intensive guidance from FDA to ensure an efficient drug development program. Fast Track designation, priority review, and breakthrough designation do not change the standards for approval but may expedite the development or approval process.

We initially applied for fast track designation for CAM2038 for the treatment of chronic pain and for BBO817 for the treatment of schizophrenia, but the FDA denied our requests. Since then, we believe that we have developed, and continue to develop, clinical data that will allow us to resubmit our requests. Even if a drug candidate qualifies for one or more of these programs, the FDA may later decide that the drug candidate no longer meets the conditions for qualification. Moreover, the time period for FDA review may not actually be shortened even if a drug candidate has qualified for an expedited development program.

Pediatric trials

The Food and Drug Administration Safety and Innovation Act, or FDASIA, which was signed into law on July 9, 2012, amended the FDCA to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial PSP must

include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials and/or other clinical development programs.

Post-marketing requirements

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the FDA of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as ''off-label use''), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the applicant to develop additional data or conduct additional nonclinical studies and clinical trials. As with new NDAs, the review process is often significantly extended by FDA's requests for additional information or clarification. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or the PDMA, a part of the FDCA.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These manufacturers must comply with cGMP regulations that require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market.

Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development. Changes in statutes, regulations, or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. For example, pursuant to the recently signed Cures Act, the FDA is to establish a program to evaluate the potential use of real world evidence to help support approval of a new indication for a previously approved drug and to help support or satisfy postapproval study requirements. Real world evidence is defined as data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials. Within two years of the date of enactment of the Cures Act, the FDA is to establish a draft framework for the implementation of this program and implement the program to evaluate the potential use of real world evidence.

Orange book listing

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A Section 505(b)(2) NDA is an application in which the applicant, in part, relies on investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. Limited changes must be preapproved by the FDA via a suitability petition. ANDAs are termed ''abbreviated'' because they are generally not required to include nonclinical and clinical data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents having claims that cover the applicant's product and method of use. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book. These products may be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must make patent certifications to the FDA that (1) no patent information on the drug or method of use that is the subject of the application has been submitted to the FDA; (2) the patent has expired; (3) the date on which the

patent has expired and approval will not be sought until after the patent expiration; or (4) the 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. The last certification is known as a paragraph IV certification. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through a paragraph IV certification or if the applicant is not seeking approval of a patented method of use. If the applicant does not challenge the listed patents or does not indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

If the competitor has provided a paragraph IV certification to the FDA, the competitor must also send notice of the paragraph IV certification to the holder of the NDA for the reference listed drug and the patent owner within 20 days after the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a paragraph IV certification notice prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of 30 months from the date of the lawsuit, expiration of the patent, settlement of the lawsuit, a decision in the infringement case that is favorable to the applicant or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay.

In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owners regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

U.S. marketing exclusivity

Marketing exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving abbreviated new drug applications, or ANDAs, for drugs containing the active agent for the original indication or condition of use. The FDCA also provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. Three-year and five-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well-controlled clinical trials necessary to

demonstrate safety and efficacy. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued ''Written Request'' for such a trial.

Drug enforcement administration regulation

Because our product and product candidates are subject to the Controlled Substances Act, or CSA, we must comply with various requirements set forth by that legislation, as amended, its implementing regulations and as enforced by the DEA. The CSA imposes various registration, record-keeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls, prescription and order form requirements and restrictions on prescription refills for certain kinds of pharmaceutical products. A principal factor for determining the particular requirements of the CSA applicable to a product, if any, is its actual or potential abuse profile. A product may be listed as a Schedule I, II, III, IV or V controlled substance, with Schedule I presenting the highest perceived risk of abuse and Schedule V presenting the least. For example, Schedule I controlled substances have no currently accepted medical use in treatment in the United States and a lack of accepted safety for use under medical supervision. The active ingredient in our product, buprenorphine, is a Schedule III controlled substance and under various restrictions, including, but not limited to, mandatory written prescriptions and a labeling statement informing patients that selling or giving away Probuphine is against the law. In addition, under the Drug Addiction Treatment Act, which amended the Controlled Substances Act, use of Probuphine in the treatment of opioid addiction is limited to physicians who meet certain qualifying requirements, and who have notified the Secretary of Health and Human Services of their intent to prescribe or dispense the product for the treatment of opioid addiction and have been assigned a unique identification number that must be included on every prescription. The HHS regulates the number of patients that physicians can treat with buprenorphine for opioid addiction and recently increased this number from a maximum of 100 patients to 275 patients for qualified physicians.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized. Separate registrations also are required for separate facilities.

The DEA typically inspects a facility to review its security measures prior to issuing a registration and on a periodic basis. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II controlled substances. Required security measures include background checks on employees and physical control of inventory through measures such as vaults and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA, for example distribution reports for Schedule I and II controlled substances. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must be accompanied by special order forms, with copies provided to the DEA. The DEA establishes annually an aggregate quota for how much of a controlled substance may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. The limited aggregate

amount that the DEA allows to be produced in the United States each year is allocated among individual companies, which must submit applications annually to the DEA for individual production and procurement quotas. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments.

To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in administrative, civil or criminal enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate administrative proceedings to revoke those registrations. In some circumstances, violations could result in criminal proceedings.

In addition to federal scheduling, some drugs may be subject to state-controlled substance regulation and thus more extensive requirements than those determined by the DEA and FDA.

Other regulatory matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services including the Office of the Inspector General, the United States Department of Justice, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local regulatory authorities. In the United States, sales, marketing and scientific/educational programs must also comply with state and federal fraud and abuse laws. These laws include the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Although we would not submit claims directly to payors, drug manufacturers can be held liable under the federal civil False Claims Act, which prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. The government may deem manufacturers to have ‘‘caused’’ the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. Penalties for a False Claims Act violation include three times the actual damages sustained by the

government, plus mandatory civil penalties of between $10,781 and $21,563 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in our stock price. In addition, private individuals have the ability to bring actions under the federal False Claims Act and certain states have enacted laws modeled after the federal False Claims Act.

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 federal 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 statute imposes penalties 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. Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that any of our product candidates, if approved, are sold in a foreign country, we may be subject to similar foreign laws.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, including the final omnibus rule published on January 25, 2013, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and criminal penalties. Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws. There has also been a recent trend of increased federal

and state regulation of payments made to physicians. Certain states mandate implementation of compliance programs, impose restrictions on drug manufacturers' marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

European Union drug development

In the European Union, our future products may also be subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of nonclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation is currently undergoing a revision process mainly aimed at harmonizing and streamlining the clinical trials authorization process, simplifying adverse event reporting procedures, improving the supervision of clinical trials and increasing their transparency.

European Union drug review and approval

In the European Economic Area, or EEA, which is comprised of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations:

The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Rest of the world regulation

For other countries outside of the European Union and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor by payor basis. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Third-party payors are increasingly reducing reimbursements for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our products or a decision by a third-party payor to not cover our

products could reduce physician usage of the products and have a material adverse effect on our sales, results of operations and financial condition.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

Reimbursement for injectable and implantable medications that are administered by a healthcare provider generally require a J-Code for the drug itself. We submitted our application for a permanent J-Code for Probuphine in June 2016. On November 1, 2016, the U.S. Centers for Medicare & Medicaid Services, or CMS, released a final rule that assigned a specific J-Code for Probuphine beginning January 1, 2017. Separate reimbursement codes are required for the Probuphine insertion and removal procedures. Our initial request for interim ‘‘G’’ fee codes to cover reimbursement for the insertion and removal procedures was declined. In order to address the reimbursement for the multiple implant insertion and removal pertaining to Probuphine, several strategies are currently being pursued. In the interim, the code 17999 or codes 11981-11983 along with a modifier can be utilized to bill for reasonable and customary charges related to the implantation and removal of Probuphine.

The primary strategies to address the procedural reimbursement are to petition CMS for the establishment a set of G fee codes with a specified reimbursement amount that can be utilized or referenced by both commercial and government payors. In addition to G fee codes, we are developing a letter of intent to establish an Alternative Payment Methodology that would address both the procedural insertion and removal, along with the monthly global patient management through the recently released Medicare Access and CHIP Reauthorization Act of 2015 Final Rule. Several commercial payers have now published medical coverage policies that describe the use of specific drug and procedure codes addressing the coding and billing options for the physicians, clinics and institutions delivering care.

Additional opportunity exists to work with commercial payors by establishing codes specific to Probuphine to more appropriately recognize the Probuphine procedures which would enable physicians to both obtain prior authorization or medical pre-certification approval as well as code and bill for services which will reduce the time to reimbursement. We will continue to pursue the establishment of specific CPT codes that address the insertion and removal of multiple non-biodegradable implants via a Coding Change Proposal application through the American Medical Association, or AMA, to be submitted mid-2017. The timeline for the creation of the various procedural reimbursement pathways will vary based on the required governmental process or market needs for accurately tracking and reimbursing for the delivery of Probuphine and related procedural services.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our products, if any such product or the condition that it is intended to treat is the subject of a trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our products. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Affordable Care Act and other reform initiatives

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare.

For example, in March 2010, the ACA, was enacted in the United States. The ACA includes measures that have significantly changed, and are expected to continue to significantly change, the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA of greatest importance to the pharmaceutical industry are the following:

- The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the U.S. Department of Health and Human Services in exchange for state Medicaid coverage of most of the manufacturer's drugs. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs to 23.1% of average manufacturer price, or AMP, and adding a new rebate calculation for ''line extensions'' (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP.
- The ACA imposed a requirement on manufacturers of branded drugs to provide a 50% point-of-sale discount off the negotiated price of branded drugs dispensed to Medicare Part D beneficiaries in the

coverage gap (i.e., ''donut hole'') as a condition for a manufacturer's outpatient drugs being covered under Medicare Part D.

- The ACA imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs.
- The ACA imposed new reporting requirements on drug manufacturers for payments made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for ''knowing failures''), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers are required to submit reports to CMS by the 90th day of each calendar year.
- The ACA established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products. The ACA established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation through 2019.

Many of the details regarding the implementation of the ACA are yet to be determined, and at this time, it remains unclear the full effect that the ACA would have on our business. There have been judicial and Congressional challenges to the ACA, and we expect such challenges and amendments to continue in the future.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013, following passage of the Bipartisan Budget Act of 2013, and will remain in effect through 2025 unless additional congressional action is taken. Further, in January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices.

Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to

increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates and may affect our overall financial condition and ability to develop product candidates.

Employees

As of January 1, 2017, we have 97 employees in the United States; 61 are field-based employees engaged in sales, physician training and other marketing support functions, nine are engaged in positions directly related to sales and marketing, 13 are engaged in positions related to clinical development, product development, regulatory and operations and 14 are engaged in positions related to general and administrative. None of our employees are represented by unions or work councils and we consider our relationship with our employees to be good.

Property

Our headquarters are located in Princeton, New Jersey, where we lease a total of 4,636 square feet of commercial office space, with a current lease term that expires in October 2018. In December 2015, we executed a 10-year lease for approximately 33,940 square feet of space in Morrisville, North Carolina for the location of our manufacturing facility. We believe current office space and manufacturing space is sufficient to meet our near-term plans and requirements.

Legal proceedings

As of the date of this prospectus, we were not party to any legal matters or claims.

Management

Executive officers and directors

The following table provides information regarding our executive officers, key employees and directors as of December 31, 2016:

Name	Age	Position(s)
Behshad Sheldon	53	President and Chief Executive Officer, Director
David J. McIntyre	46	Executive Vice President, Chief Financial Officer and Treasurer, Director
Frank E. Young, M.D., Ph.D.	85	Executive Vice President, Regulatory and Medical
Sonnie Kim	44	Senior Vice President, Clinical Development & Medical Affairs
Craig C. Brown	52	Senior Vice President, Commercialization and Program Management
Seth Harrison, M.D.	56	Executive Chairman
Jerry Karabelas, Ph.D.(1)	64	Director
Dennis H. Langer, M.D., J.D.(1)	65	Director

(1) Member of the audit committee.

Each executive officer serves at the discretion of our board of directors and holds office until his or her successor is duly elected and qualified or until his or her earlier resignation or removal. There are no family relationships among any of our directors or executive officers.

Behshad Sheldon has served as our President and Chief Executive Officer since January 2014 and as a member of our board of directors since September 2015. She previously served as our President and Chief Operating Officer from August 2013 to December 2013 and Executive Vice President, Chief Commercial Officer from September 2012 to August 2013. Ms. Sheldon has served as a partner at Apple Tree Partners, of which we are a wholly-owned portfolio company, since September 2012. Prior to joining us, Ms. Sheldon spent 10 years at Otsuka Pharmaceuticals, Co., Ltd., or Otsuka, from 2002 to 2012 having co-founded its Princeton, New Jersey office in 2002. Ms. Sheldon last served as a member of the board of directors of the Otsuka R&D organization, contributing to the oversight of 18 pre-approval programs for 13 products in CNS, cardio-renal, pain, dermatology and oncology. Simultaneously, she served as senior vice president, patient & branding strategy in the commercial organization, where she was responsible for global and United States marketing, alliance management and early development strategy. Prior to Otsuka, Ms. Sheldon held positions with increasing responsibility at GlaxoSmithKline plc and Bristol-Myers Squibb Co. She also served on the board of directors of Cerecor Inc. from July 2014 to September 2016. Throughout her 27-year career, Ms. Sheldon has driven the success of blockbuster products such as Glucophage, Plavix, and Abilify, and has contributed to several strategic alliances and acquisitions, including the landmark 2011 agreement between Otsuka and H. Lundbeck A/S involving five CNS products. Ms. Sheldon holds a B.S. degree in Neuroscience from the University of Rochester. We believe that the numerous years that Ms. Sheldon has served as an executive officer in pharmaceutical companies qualifies her to serve as a member of our board of directors.

David J. McIntyre has served as our Executive Vice President, Chief Financial Officer and Treasurer since October 2016 and as a member of our board of directors since January 2016. He has served as a Partner at Apple Tree Partners, of which we are a wholly-owned portfolio company, since 2012 and he serves on the board of directors of Gala Therapeutics, Inc. and Vytronus, Inc. Prior to Apple Tree Partners, Mr. McIntyre was Executive Vice President, Chief Financial Officer of HeartWare International, Inc., or Heartware, from 2005 through 2011, and assumed the additional responsibilities of Chief Operating Officer

during HeartWare's global commercialization phase for the period from 2008 through 2011. Prior to HeartWare, he practiced as a senior attorney in private practice specializing in corporate, mergers and acquisitions and equity capital markets with Baker & McKenzie and KPMG LLP as well as holding various senior financial roles in multi-national companies including Coal & Allied Limited, a publicly traded subsidiary of the Rio Tinto Group of companies. Mr. McIntyre currently serves as a Director of Vytron US, Inc, Gala Therapeutics, Inc., Rox Medical, Inc., Tusker Medical, Inc. and Redflex Holdings Limited. From 2013 to 2015, Mr. McIntyre also served as a Director of Tendyne Holdings Inc. Mr. McIntyre holds a Bachelor of Economics (Accounting) from the University of Sydney (Australia), a Bachelor of Law from the University of Technology, Sydney (Australia) and a Masters of Business Administration (Fuqua Scholar) from Duke University. He is also a Certified Practicing Accountant (CPA) and is admitted as a Legal Practitioner of the Supreme Court of New South Wales (in Australia). We believe that Mr. McIntyre's professional qualifications in finance and law, combined with his extensive financial and operational experience qualifies him to serve as a member of our board of directors.

Frank E. Young, M.D., Ph.D., has served as our Executive Vice President, Regulatory and Medical since September 2013. Prior to joining us, Dr. Young served as Venture Partner at Apple Tree Life Sciences Inc. from October 2013 to December 2015. Dr. Young served as Commissioner of the U.S. Food and Drug Administration from 1984-1989 during the Reagan and Bush administrations. Subsequently he served as Deputy Assistant Secretary in the H.W. Bush administration, and Director of both the Office of Emergency Preparedness and the National Disaster Medical System during the Clinton Administration. Prior to entering government, Dr. Young served as Chairman of the Department of Microbiology and Professor of Microbiology, Pathology, Radiation Biology and Biophysics at the University of Rochester, New York, as well as Dean of the School of Medicine and Dentistry, Director of the Medical Center and Vice President for Health Affairs at the University of Rochester. Dr. Young has contributed to more than 200 scientific articles in the fields of biotechnology and microbiology, including development of some of the earliest cloning enzymes, vectors and vehicles. Dr. Young has extensive corporate experience through membership on over seven board of directors, consultant positions with over 21 companies and most recently Interim Vice President for Clinical and Regulatory Affairs at Bioventus LLC. He was co-founder and CEO of the Cosmos Alliance. Dr. Young also served as a partner of Essex Woodlands from 2006-2013 and continues as Adjunct Partner. Dr. Young received a M.D. from SUNY Upstate Medical University and a Ph.D. in Microbiology from Case Western Reserve University.

Sonnie Kim, Pharm.D. has served as our Senior Vice President, Clinical Development & Medical Affairs since June 2016 and previously served as our Vice President, Medical & Scientific Affairs from March 2014 to June 2016. Prior to joining us, Dr. Kim was the Director of Clinical Strategy of Medscape, LLC from June to November 2012. From December 2007 to June 2011 Dr. Kim served as the Director, Medical Affairs/ Hospital Medicine with Otsuka America Pharmaceutical, Inc. Dr. Kim's previous experience also includes roles as Vice President and member of the board of directors of Columbia Medcom Group, Inc., and its subsidiary, Medicallaince, Inc., and a teaching and clinical role at the University of Maryland School of Pharmacy. Dr. Kim received a B.S. degree from University of Maryland Baltimore and a Doctorate of Pharmacy from the University of Maryland School of Pharmacy.

Craig C. Brown has served as our Senior Vice President, Commercialization and Manufacturing since June 2016 and was previously our Senior Director, Commercialization and Manufacturing from June 2013 to June 2016. Prior to joining us, Mr. Brown served as Senior Director, Global Commercialization at Otsuka. from 2003 to 2012 where he oversaw the early development of the Global CNS pipeline and the global management of the CNS franchise. Prior to joining Otuska, Mr. Brown held various roles with increasing

responsibility at Bristol Myers Squibb Co. Mr. Brown holds a BBA in Management from Georgia State University.

Seth Harrison, M.D., has served as a member of our board of directors since September 2012 and as Executive Chairman since May 2014. Dr. Harrison has served as the managing partner of Apple Tree Partners since 1999. He has invested in life sciences since 1991. Dr. Harrison has served as founding investor, acting CEO or chairman of numerous portfolio companies. Currently, Dr. Harrison serves as a member of the board directors of Cure Forward, Corp., Elstar Therapeutics, Inc., Limelight Bio, Inc., Stoke Therapeutics, Inc., Syntimmune, Inc., CleanSlate Addiction Treatment Centers, Inc., Apple Tree Life Sciences, Inc. and Corvidia Therapeutics, Inc. He previously served as Chairman of Tokai Pharmaceuticals, Inc., Deputy Chairman of Heartware International Inc. and is a member of the board of directors of Cerecor Inc. Dr. Harrison also serves on the board of directors of the Harrison Atelier Foundation and Tortoise Foundation. From 2002 to 2010 he served on the board of the International Partnership for Microbicides, a Rockefeller Foundation/Gates Foundation sponsored public-private partnership engaged in the development of anti-HIV microbicides. Prior to founding Apple Tree Partners, Dr. Harrison was a general partner at Oak Investment Partners and earlier was a venture partner at Sevin Rosen Funds. His prior investments include: ArQule Inc., Coelacanth Corp., Cyrano Sciences, Inc., Gloucester Pharmaceuticals, Inc., Informed Access Systems Inc., SGX Pharmaceuticals, Inc., UltraCision, Inc. and ViroPharma Inc. Dr. Harrison received an A.B. from Princeton University, an M.D. and M.B.A. both from Columbia University and completed a surgery internship at the Presbyterian Hospital in the City of New York. We believe that Dr. Harrison's extensive experience as a senior executive and service on the board of directors of other life science companies qualifies him to serve as a member of our board of directors.

Jerry Karabelas, Ph.D., has served as a member of our board of directors since January 2016. He is currently a partner at Care Capital LLC, a position he has held since 2001. He has held a number of senior executive positions in major pharmaceutical companies, including Head of Healthcare and CEO of Worldwide Pharmaceuticals for Novartis from 1998 to 2000, where he had full responsibility for Novartis Pharma and Ciba Vision, as well as strategic and operational leadership of research and development. Dr. Karabelas was also Executive Vice President of GlaxoSmithKline plc from 1992 to 1998 with responsibility for U.S. and European operations, regulatory and strategic marketing. Currently, Dr. Karabelas serves as a member of the board of directors of biopharmaceutical companies RegenXbio Inc., Valeant Pharmaceuticals International Inc. and currently chairs the board of Polyphor Ltd. Previously, he served as a member of the boards of Human Genome Sciences, Inc., Vanda Pharmaceuticals, Inc., SkyePharma PLC and chaired the board of Inotek Pharmaceuticals, Inc. Dr. Karabelas received a B.A. in Biochemistry from the University of New Hampshire, a Ph.D. in Pharmacokinetics from the Massachusetts College of Pharmacy. We believe that Dr. Karabelas' extensive experience as an executive and a board member qualifies him to serve as a member of our board of directors.

Dennis H. Langer, M.D., J.D., has served as a member of our board of directors since January 2016. He has served as director of several biotechnology, specialty pharmaceutical, and diagnostic companies, and has been CEO and/or co-founder of several health care companies. From January 2013 to July 2014 he served as Chairman and Chief Executive Officer of AdvanDx, Inc., a healthcare solutions company. From 2005 to 2010, Dr. Langer served as a Managing Partner of Phoenix IP Ventures, a private equity/venture capital firm specializing in life sciences. Previously, he was President, North America, of Dr. Reddy's Laboratories, Limited, a multinational pharmaceutical company. From September 1994 until January 2004, Dr. Langer held several high-level positions at GlaxoSmithKline plc, and its predecessor, SmithKline Beecham, including most recently as a Senior Vice President of Research and Development. Prior to SmithKline Beecham, Dr. Langer was President and CEO of Neose Technologies, Inc. and before that held R&D and marketing

positions at pharmaceutical companies Eli Lilly and Company, Abbott Laboratories and G. D. Searle & Company. Dr. Langer currently serves as a Director of Myriad Genetics, Inc., Dicerna Pharmaceuticals, Inc., Pernix Therapeutics Holdings, Inc., and several private companies. Previously, Dr. Langer served as a Director of several pharmaceutical and biotechnology companies, including Ception Therapeutics, Inc., Cytogen Corporation, Pharmacopeia, Inc., Sirna Therapeutics, Inc., Transkaryotic Therapies, Inc., Delcath Systems, Inc., Auxilium Pharmaceuticals, Inc. and Myrexis, Inc. Dr. Langer received a J.D. from Harvard Law School, a M.D. from Georgetown University School of Medicine, and a B.A. in Biology from Columbia University. We believe that Dr. Langer's extensive experience as an executive and a board member qualifies him to serve as a member of our board of directors.

Board composition

Our board of directors currently consists of five members. Our board of directors may consider a broad range of factors relating to the qualifications and background of nominees, which may include diversity, which is not only limited to race, gender or national origin. We have no formal policy regarding board diversity. Our board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape and professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the completion of this offering also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Director independence

Upon the completion of this offering, Apple Tree and its affiliated entities will continue to control a majority of our common stock. As a result, we are a ''controlled company'' within the meaning of the NASDAQ listing standards. Under these rules, a company of which more than 50% of the voting power is held by an individual, a group or another company is a ''controlled company'' and may elect not to comply with certain NASDAQ corporate governance requirements, including (1) the requirement that a majority of the board of directors consist of independent directors (2) the requirement that we have a compensation committee and nominating and corporate governance committee that are composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities. Following this offering, we intend to rely on certain of these exemptions.

Our board of directors has determined that a majority of the members of the board of directors, including Ms. Sheldon, Dr. Harrison and Mr. McIntyre, are not independent directors, for purposes of the rules of The NASDAQ Global Market and the SEC. As a controlled company, we are exempt from complying with the requirement that a majority of our board of directors consist of independent directors and we intend to rely on that exemption. In making such independence determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5%

of our common stock. Ms. Sheldon is not an independent director under these rules because she is an executive officer of Braeburn, Mr. McIntyre is not an independent director under these rules because he is an executive officer of Braeburn and he and Dr. Harrison are not independent directors under these rules because they are affiliated with our principal stockholder Apple Tree. There are no family relationships among any of our directors or executive officers.

Staggered board

In accordance with the terms of our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the completion of this offering, our board of directors will be divided into three staggered classes of directors of the same or nearly the same number and each will be assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2018 for Class I directors, 2019 for Class II directors and 2020 for Class III directors.

- Our Class I director will be Mr. McIntyre;
- Our Class II directors will be Ms. Sheldon and Dr. Karabelas; and
- Our Class III directors will be Drs. Langer and Harrison.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the number of our directors shall be fixed from time to time by a resolution of the majority of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class shall consist of one third of the board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

Board leadership structure and board's role in risk oversight

The positions of our executive chairman of the board and chief executive officer are separated. Separating these positions allows our chief executive officer to focus on our day-to-day business, while allowing the executive chairman of the board to lead the board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors recognizes the time, effort and energy that the chief executive officer must devote to her position in the current business environment, as well as the commitment required to serve as our executive chairman, particularly as the board of directors' oversight responsibilities continue to grow. Our board of directors also believes that this structure ensures a greater role for the independent directors in the oversight of our company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our board of directors. Our board of directors believes its administration of its risk oversight function has not affected its leadership structure.

Although our bylaws that will be in effect upon the completion of this offering will not require our executive chairman and chief executive officer positions to be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including those described under the section entitled "Risk Factors." Our board of directors is actively involved in oversight of risks that could affect us. This oversight is conducted primarily by our full board of directors, which has responsibility for general oversight of risks.

Following the completion of this offering, our board of directors will satisfy this responsibility through full reports by each committee chair regarding the committee's considerations and actions, as well as through regular reports directly from officers responsible for oversight of particular risks within our company. Our board of directors believes that full and open communication between management and the board of directors is essential for effective risk management and oversight.

Board committees

Our board of directors has established an audit committee, which will operate pursuant to a charter adopted by our board of directors that will be effective upon completion of the offering. Upon the completion of this offering, the composition and functioning of our audit committee will comply with all applicable requirements of the Sarbanes-Oxley Act of 2002, NASDAQ and the SEC rules and regulations.

Audit committee

Effective upon completion of this offering, our audit committee will be composed of Dr. Karabelas and Dr. Langer, with Dr. Langer serving as chairman of the committee. The transition rules of the SEC provide that two members of the audit committee may be exempt from independence requirements for 90 days after the effectiveness of this registration statement, and one member may be exempt for one year after the effectiveness of this registration statement. Our board of directors intends to cause our audit committee to comply with the transition rules within the applicable time periods. Our board of directors has determined that each member of the audit committee meets the independence requirements of Rule 10A-3 under the Exchange Act and the applicable NASDAQ rules. Our board of directors has determined that Dr. Langer is an "audit committee financial expert" within the meaning of the SEC regulations and applicable NASDAQ rules. The audit committee's responsibilities upon completion of this offering will include:

- appointing, approving the compensation of, reviewing the performance of, and assessing the independence of our independent registered public accounting firm;
- pre-approving audit and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the internal audit plan with the independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;

- recommending, based upon its review and discussions with management and the independent registered public accounting firm, whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- preparing the audit committee report required by the rules of the SEC to be included in our annual proxy statement;
- reviewing all related party transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing policies related to risk assessment and risk management; and establishing, maintaining and overseeing our Code of Business Conduct and Ethics.

All audit services to be provided to us and all non-audit services, other than de minimis non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

Compensation committee interlocks and insider participation

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or compensation committee. None of the members of our compensation committee has ever been employed by us.

Code of business conduct and ethics

Our board of directors has adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Upon the completion of this offering, our code of business conduct and ethics will be available on our website, which is located at www.braeburnpharmaceuticals.com. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website, or in a current report on Form 8-K.

Executive compensation

Summary compensation table

The following table sets forth information regarding compensation awarded to, earned by or paid to each of our named executive officers during the fiscal year ending December 31, 2016.

Name and principal position	Year	Salary ($)	Bonus ($)(1)(2)	Stock awards ($)(3)	Total ($)
Behshad Sheldon *Chief Executive Officer and President*	2016	$464,844	$387,500	$5,587,927	$6,440,271
Frank E. Young *Executive Vice President, Regulatory and Medical*	2016	$ 478,333	$ 29,083	$ 557,844	$1,065,260
David J. McIntyre *Executive Vice President, Chief Financial Officer*	2016	$ 95,000(4)	$ 38,000	$ 3,111,892	$3,244,892

(1) A one-time bonus equal to $150,000 and $7,500 was paid to Ms. Sheldon and Mr. Young in connection with FDA approval of Probuphine, respectively.

(2) Represents discretionary annual bonuses payable to our executive officers for 2016.

(3) Amount shown reflects the grant date fair value of restricted stock units granted to our named executive officers in 2016, as determined in accordance with FASB ASC Topic 718. Assumptions used to calculate this amount are included in our financial statements included elsewhere in this prospectus.

(4) Mr. McIntyre became our Executive Vice President, Chief Financial Officer in October 2016.

Narrative to summary compensation table

Employment arrangements with our named executive officers

We have entered into an employment agreement or letter agreement with each of our named executive officers in connection with their employment with us. These employment agreements and offer letters provide for "at will" employment.

Behshad Sheldon. On April 17, 2014, we entered into an employment agreement, or the Prior Sheldon Agreement, with Ms. Sheldon for the position of President and Chief Executive Officer and on September 1, 2016 we entered into a second employment agreement with Ms. Sheldon, which superseded, amended and restated the Prior Sheldon Agreement. Ms. Sheldon currently receives an annual base salary of $475,000, which shall be considered annually by our board of directors. Ms. Sheldon is also eligible for an annual discretionary bonus of up to 50% of her base salary. The amount of any such bonus is subject to the sole discretion of our board of directors or the compensation committee. Ms. Sheldon is eligible to participate in employee benefit plans generally available to our executive employees, subject to the terms of those plans.

In the event Ms. Sheldon's employment is terminated by us without cause or Ms. Sheldon terminates her employment for good reason, then, subject to execution of a general release of claims, she will be eligible to receive (i) 12 months of salary continuation at her then current base salary, (ii) subject to her election of COBRA health continuation coverage and copayment of premium amounts at the active employee rate, up to 12-months of the remainder of COBRA premium coverage and (iii) outplacement services. In the event Ms. Sheldon's employment is terminated by us without cause or Ms. Sheldon terminates her

employment for good reason, in either case, within six months prior to or 12 months following the date of a change in control, then in lieu of the foregoing severance benefits and subject to her execution of a general release of claims, Ms. Sheldon shall be entitled to receive (i) 18 months of salary continuation, (ii) subject to her election of COBRA health continuation coverage and copayment of premium amounts at the active employee rate, up to 12-months of the remainder of COBRA premium coverage, (iii) 100% acceleration of all time-based equity awards held as of the date of termination and (iv) outplacement services.

In addition, in the event of Ms. Sheldon's death or termination of her employment due to disability, Ms. Sheldon (or her estate, if applicable) shall receive a prorated bonus for the year in which the termination occurs.

For purposes of the employment agreements with Ms. Sheldon, "cause" means she has: (i) committed an act of fraud, embezzlement, misappropriation or breach of fiduciary duty, (ii) been convicted of, or plead guilty or nolo contendere to, any crime triable upon indictment or involving moral turpitude, (iii) been chronically absent from work, (iv) refused, after explicit written notice, to obey any lawful direction by the chairman which is consistent with her duties, and such refusal has continued for thirty days following written notice of the refusal, (v) engaged in the unlawful use or possession of illegal drugs on our premises, (vi) we reasonably determine that Ms. Sheldon has been guilty of misconduct or failed to perform the duties incident to her employment with us, and such misconduct or failure has continued within a period of three months after written notice specifying such failure in reasonable detail, (vii) violated laws, rules or regulations applicable to us, (viii) violated any Company policy or policies or confidentiality responsibilities applicable to her, or (ix) materially breached any of the provisions of her employment agreement, which breach has, in the good faith judgment of our chairman, resulted in a material detriment to us.

For purposes of the employment agreement with Ms. Sheldon, "good reason" means any of the following events or circumstances, without her consent: (i) a material diminution in base salary except for across-the-board salary reductions based on our financial performance similarly affecting all or substantially all senior management employees of the company, (ii) a material diminution in authority, duties or responsibilities, (iii) the relocation of her principal place of business more than fifty (50) miles, or (iv) a material breach by us of her employment agreement; provided however, that such a termination can only occur if (x) she has reasonably determined in good faith that a "good reason" condition has occurred, (y) she has provided us with written notice of such termination within sixty (60) days after the initial occurrence of the condition and we have not cured the condition within thirty (30) days after receipt of notice, and (y) she terminates her employment within sixty (60) days thereafter.

David J. McIntyre. On October 1, 2016, we entered into an employment agreement with Mr. McIntyre for the position of Executive Vice President, Chief Financial Officer and Treasurer. Mr. McIntyre currently receives an annual base salary of $380,000, which shall be considered annually by our board of directors. Mr. McIntyre is also eligible for an annual discretionary bonus of up to 40% of his base salary. The amount of any such bonus is subject to the sole discretion of our board of directors or the compensation committee. Mr. McIntyre is eligible to participate in employee benefit plans generally available to our executive employees, subject to the terms of those plans.

In the event Mr. McIntyre's employment is terminated by us without cause or Mr. McIntyre terminates his employment for good reason, then, subject to execution of a general release of claims, he will be eligible to receive (i) nine (9) months of salary continuation at his then current base salary, (ii) subject to his election of COBRA health continuation coverage and copayment of premium amounts at the active

employee rate, up to twelve (12) months of the remainder of COBRA premium coverage and (iii) outplacement services. In the event Mr. McIntyre's employment is terminated by us without cause or Mr. McIntyre terminates his employment for good reason, in either case, within six months prior to or twelve (12) months following the date of a change in control, then in lieu of the foregoing severance benefits and subject to his execution of a general release of claims, Mr. McIntyre shall be entitled to receive (i) twelve (12) months of salary continuation, (ii) subject to his election of COBRA health continuation coverage and copayment of premium amounts at the active employee rate, up to twelve (12) months of the remainder of COBRA premium coverage, (iii) 100% acceleration of all time-based equity awards held as of the date of termination and (iv) outplacement services.

In addition, in the event of Mr. McIntyre's death or termination of his employment due to disability, Mr. McIntyre (or his estate, if applicable) shall receive a prorated bonus for the year in which the termination occurs.

For purposes of the employment agreements with Mr. McIntyre, "cause" means he has: (i) committed an act of fraud, embezzlement, misappropriation or breach of fiduciary duty, (ii) been convicted of, or plead guilty or nolo contendere to, any crime triable upon indictment or involving moral turpitude, (iii) been chronically absent from work, (iv) refused, after explicit written notice, to obey any lawful direction by the person to whom Mr. McIntyre directly reports which is consistent with his duties, and such refusal has continued for thirty days following written notice of the refusal, (v) engaged in the unlawful use or possession of illegal drugs on our premises, (vi) we reasonably determine that Mr. McIntyre has been guilty of misconduct or failed to perform the duties incident to his employment with us, and such misconduct or failure has continued within a period of three months after written notice specifying such failure in reasonable detail, (vii) violated laws, rules or regulations applicable to us, (viii) violated any Company policy or policies or confidentiality responsibilities applicable to him, or (ix) materially breached any of the provisions of his employment agreement.

For purposes of the employment agreement with Mr. McIntyre, "good reason" means any of the following events or circumstances, without his consent: (i) a material diminution in his authority, duties or responsibilities, (ii) a material diminution in his base salary except for across-the-board salary reductions based on our financial performance similarly affecting all or substantially all senior management employees of the company, (iii) the relocation of his principal place of business more than fifty (50) miles, or (iv) a material breach by us of his employment agreement; provided however, that such a termination can only occur if (x) he has reasonably determined in good faith that a "good reason" condition has occurred, (y) he has provided us with written notice of such termination within sixty (60) days after the initial occurrence of the condition and we have not cured the condition within thirty (30) days after receipt of notice, and (z) he terminates his employment within sixty (60) days thereafter.

Frank E. Young. On January 1, 2016, we entered into an employment agreement, or the Prior Young Agreement, with Dr. Young for the position of Executive Vice President, Clinical and Regulatory Affairs. During a review of Dr. Young's employment arrangements, we decided to better align his compensation to that of his peers and on November 1, 2016, we entered into a second employment agreement with Dr. Young, which superseded, amended and restated the Prior Young Agreement, which provided for a reduction in base salary from $500,000 to $370,000 and added an annual discretionary bonus opportunity. Dr. Young currently receives an annual base salary of $370,000, which shall be considered annually by our board of directors. Dr. Young is also eligible for an annual discretionary bonus of up to 35% of his base salary. The amount of any such bonus is subject to the sole discretion of our board of directors or the compensation committee. Dr. Young is eligible to participate in employee benefit plans generally available to our executive employees, subject to the terms of those plans.

In the event Dr. Young's employment is terminated by us without cause or Dr. Young terminates his employment for good reason, then, subject to execution of a general release of claims, he will be eligible to receive (i) twelve (12) months of salary continuation at his then current base salary, (ii) subject to his election of COBRA health continuation coverage and copayment of premium amounts at the active employee rate, up to twelve (12) months of the remainder of COBRA premium coverage and (iii) outplacement services. In the event Dr. Young's employment is terminated by us without cause or Dr. Young terminates his employment for good reason, in either case, within six months prior to or twelve (12) months following the date of a change in control, then in lieu of the foregoing severance benefits and subject to his execution of a general release of claims, Dr. Young shall be entitled to receive (i) twelve (12) months of salary continuation, (ii) subject to his election of COBRA health continuation coverage and copayment of premium amounts at the active employee rate, up to twelve (12) months of the remainder of COBRA premium coverage, (iii) 100% acceleration of all time-based equity awards held as of the date of termination and (iv) outplacement services.

In addition, in the event of Dr. Young's death or termination of his employment due to disability, Dr. Young (or his estate, if applicable) shall receive a prorated bonus for the year in which the termination occurs.

For purposes of the employment agreement with Dr. Young, "cause" means he has: (i) committed an act of fraud, embezzlement, misappropriation or breach of fiduciary duty, (ii) been convicted of, or plead guilty or nolo contendere to, any crime triable upon indictment or involving moral turpitude, (iii) been chronically absent from work, (iv) refused, after explicit written notice, to obey any lawful direction by the CEO which is consistent with his duties, and such refusal has continued for thirty days following written notice of the refusal, (v) engaged in the unlawful use or possession of illegal drugs on our premises, (vi) we reasonably determine that Dr. Young has been guilty of misconduct or failed to perform the duties incident to his employment with us, and such misconduct or failure has continued within a period of three months after written notice specifying such failure in reasonable detail, (vii) violated laws, rules or regulations applicable to us, (viii) violated any Company policy or policies or confidentiality responsibilities applicable to him, or (ix) materially breached any of the provisions of his employment agreement.

For purposes of the employment agreement with Dr. Young, "good reason" means any of the following events or circumstances, without his consent: (i) a material diminution in base salary, (ii) a material diminution in authority, duties or responsibilities; (iii) the relocation of his principal place of business more than fifty (50) miles; or (iv) a material breach by us of his employment agreement; provided however, that such a termination can only occur if (x) he has reasonably determined in good faith that a "good reason" condition has occurred, (y) he has provided us with written notice of such termination within sixty (60) days after the initial occurrence of the condition and we have not cured the condition within thirty (30) days after receipt of notice, and (z) he terminates his employment within sixty (60) days thereafter.

Employee confidentiality, non-competition, non-solicitation and assignment agreements

Each of our named executive officers has entered into a standard form agreement, or an employment agreement, with respect to confidential information and assignment of inventions. Among other things, this agreement obligates each named executive officer to refrain from disclosing any of our proprietary information received during the course of employment and to assign to us any inventions conceived or developed during the course of employment. Such agreement also provides that during the period of the named executive officer's employment and for the period ending on the first anniversary of such executive officer's termination of employment, the named executive officer will not compete with us and will not solicit our employees, consultants, customers or suppliers; provided that the noncompetition restriction is only applicable if we continue to pay the named executive officer's base salary through the restrictive

period (including for this purpose, any salary confirmation payable upon a termination of employment as described above).

Outstanding equity awards at fiscal year-end—2016

The following table sets forth information concerning outstanding equity awards for each of our named executive officers at December 31, 2016 taking into account the reverse stock split effective as of January , 2017:

		Stock awards(1)	
Name	Grant date	Equity incentive plan awards: number of unearned shares, units or other rights that have not vested (#)	Equity incentive plan awards: market or payout value of unearned shares, units or other rights that have not vested ($)(2)
Behshad Sheldon	September 1, 2015	380,490	7,419,555
	October 24, 2016	522,789(3)	10,779,386
	December 28, 2016	7,475(4)	145,763
Frank E. Young	September 1, 2015	47,561	927,440
	October 24, 2016	35,993(5)	701,864
	October 31, 2016	8,504(6)	165,828
	December 28, 2016	8,102(4)	157,989
David J. McIntyre	September 1, 2015	47,561	927,440
	October 1, 2016	207,728(7)	4,050,696
	October 24, 2016	45,491(8)	887,075
	October 31, 2016	10,630(9)	207,285
	December 28, 2016	30,484(4)	594,438

(1) All awards in this column are restricted stock units (or RSUs). RSUs issued to our executive officers only vest upon the satisfaction of both (i) a service-based vesting condition and (ii) a liquidity-based vesting condition. Except as set forth below, the service-based vesting condition is satisfied over four years, with 25% of the RSUs satisfying the time-based vesting on the first anniversary of the Vesting Start Date, and the remaining 75% of the RSUs satisfying the time-based vesting in thirty-six (36) equal monthly installments thereafter. The liquidity-based vesting condition is (a) 180 days following the effective date of our initial public offering or (b) a change in control, in either case, occurring prior to the expiration date of the RSU award. Each award expires upon the tenth anniversary of the grant date. If the named executive officer remains in service through the date of a change in control, than 100% of the RSUs shall automatically vest in full.

(2) The market price for our common stock is based on the assumed initial public offering price of the common stock of $19.50 per share, the midpoint of the price range on the cover page of this prospectus.

(3) The service-based vesting condition shall be satisfied in forty-eight (48) equal monthly installments on the first day of each calendar month following the applicable Vesting Start Date. The applicable Vesting Start Date with respect to 12,363 RSUs is January 1, 2016; 357,991 RSUs is February 1, 2016; 99,222 RSUs is June 1, 2016; and 53,212 RSUs is July 1, 2016.

(4) The service-based vesting condition shall be satisfied in forty-eight (48) equal monthly installments on the first day of each calendar month following the Vesting Start Date of January 1, 2017.

(5) The service-based vesting condition shall be satisfied in forty-eight (48) equal monthly installments on the first day of each calendar month following the applicable Vesting Start Date. The applicable Vesting Start Date with respect to 776 RSUs is January 1, 2016; 7,783 RSUs is February 1, 2016; 9,922 RSUs is June 1, 2016; 5,321 RSUs is July 1, 2016; and 12,129 RSUs is September 1, 2016.

(6) The service-based vesting condition shall be satisfied in forty-eight (48) equal monthly installments on the first day of each calendar month following the Vesting Start Date. The Vesting Start Date is November 1, 2016.

(7) The service-based vesting condition shall be satisfied in forty-eight (48) equal monthly installments on the first day of each calendar month following the Vesting Start Date of October 1, 2016.

(8) The service-based vesting condition shall be satisfied in forty-eight (48) equal monthly installments on the first day of each calendar month following the applicable Vesting Start Date. The applicable Vesting Start Date with respect to 1,545 RSUs is January 1, 2016; 9,729 RSUs is February 1, 2016; 12,402 RSUs is June 1, 2016; 6,651 RSUs is July 1, 2016; and 15,162 RSUs is September 1, 2016.

(9) The service-based vesting condition shall be satisfied in forty-eight (48) equal monthly installments on the first day of each calendar month following the Vesting Start Date. The Vesting Start Date is November 1, 2016.

Director compensation

The following table sets forth a summary of the compensation we paid to our non-employee directors during the year ended December 31, 2016. Other than as set forth in the table and described more fully below, we did not pay any compensation, reimburse any expense of, make any equity awards or non-equity awards to, or pay any other compensation to any of the other nonemployee members of our board of directors in 2016. We reimburse nonemployee directors for reasonable travel expenses.

Name	Fees earned or paid in cash ($)	Stock awards ($)(1)	Total ($)
Seth Harrison, M.D.	—	—	—
Jerry Karabelas, Ph.D.(2)	$80,000	$416,664	$496,664
Dennis H. Langer, M.D., J.D.(3)	$80,000	$416,664	$496,664

(1) Amount shown reflects the grant date fair value of restricted stock units granted to our non-employee directors, as determined in accordance with FASB ASC Topic 718. Assumptions used to calculate this amount are included in our financial statements included elsewhere in this prospectus.

(2) As of December 31, 2016, Dr. Karabelas held unvested RSUs with respect to 56,904 shares of our common stock.

(3) As of December 31, 2016, Dr. Langer held unvested RSUs with respect to 56,904 shares of our common stock.

We have not adopted a formal compensation policy for our non-employee directors.

Compensation risk assessment

We believe that although a portion of the compensation provided to our executive officers and other employees is performance-based, our executive compensation program does not encourage excessive or unnecessary risk-taking. This is primarily due to the fact that our compensation programs are designed to encourage our executive officers and other employees to remain focused on both short-term and long-term strategic goals, in particular in connection with our pay-for-performance compensation philosophy. As a result, we do not believe that our compensation programs are reasonably likely to have a material adverse effect on the company.

Stock option plans

2015 Equity incentive plan

The 2015 Equity Incentive Plan was approved by our board of directors and our stockholders on June 2, 2015. Under the 2015 Equity Incentive Plan, 1,426,840 shares of common stock were initially reserved for issuance in the form of options, stock appreciation rights, restricted stock units or any combination of the foregoing after giving effect to the stock split. In December 2016, our board of directors approved an amendment to the 2015 Equity Incentive Plan to increase the number of shares of common stock reserved for issuance from 1,426,840 to 4,444,444 after giving effect to the stock split. The shares issuable pursuant to awards granted under the 2015 Equity Incentive Plan are authorized but unissued shares. If any shares covered by an award are not purchased or are forfeited or expire or if an award otherwise terminates without delivery of any shares subject thereto or is settled in cash, then the shares will be added back to the shares available for issuance.

The 2015 Equity Incentive Plan is administered by our board of directors or at the discretion of the board of directors, a committee of the board comprised of one or more directors, which has full power to select

the employees, directors and service providers to whom awards will be granted and to determine the specific terms and conditions of each award, subject to the provisions of the 2015 Equity Incentive Plan.

The option exercise price of each option granted under the 2015 Equity Incentive Plan is determined by our board of directors and may not be less than the fair market value of a share of common stock on the date of grant. The term of each option may not exceed ten years from the date of grant or such prior date as fixed by the board of directors. The board of directors determines at what time or times each option may be exercised when granting the option.

The 2015 Equity Incentive Plan provides that, upon a change in control of Braeburn, unless provision is made in connection with the change in control in the sole discretion of the parties thereto for the assumption or continuation of the awards by the successor entity or substitution of the awards with new awards of the successor entity, with appropriate adjustment, all restricted stock units shall be deemed to have vested and all options and stock appreciation rights outstanding shall become exercisable for a period of 15 days prior to the scheduled consummation of the change in control, unless the board elects to cancel such options, stock appreciation rights and/or restricted stock units and pay to the holder an amount in cash or capital stock having a value as determined by the board of directors, in the case of restricted stock units, equal to the per share cash consideration payable to stockholders in the change in control for our common stock, and in the case of options or stock appreciation rights, equal to the difference between the per share cash consideration payable to stockholders in the change in control for our common stock and the exercise price of the options or stock appreciation rights.

Our board of directors may amend the 2015 Equity Incentive Plan but no such action may adversely affect the rights of an award holder without such holder's consent. Approval by our stockholders of amendments to the 2015 Equity Incentive Plan must be obtained if required by law.

As of January 1, 2017, 2,692,474 restricted stock units and 738,553 stock options were outstanding under the 2015 Equity Incentive Plan. Our board of directors has determined that, following completion of this offering, no additional awards shall be granted under the 2015 Equity Incentive Plan.

2017 Stock option and incentive plan, or 2017 Stock option plan

On January 17, 2017, our board of directors adopted and our stockholders approved our 2017 Stock Option Plan, which will replace the 2015 Equity Incentive Plan. Our 2017 Stock Option Plan provides us flexibility to use various equity-based incentive and other awards as compensation tools to motivate our workforce. These tools include stock options, stock appreciation rights, restricted stock, restricted stock units, unrestricted stock, performance share awards, dividend equivalent rights and cash-based awards. The 2017 Stock Option Plan will become effective on the date immediately prior to the date on which the registration statement of which this prospectus is part is declared effective.

We have initially reserved 1,100,000 shares of common stock for the issuance of awards under the 2017 Stock Option Plan, or Initial Limit, which may be increased on the first day of each fiscal year by up to 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or Annual Increase. This number is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

The shares issuable pursuant to awards granted under the 2017 Stock Option Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards from the 2017 Stock Option Plan and the 2015 Equity Incentive Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior

to vesting, satisfied without any issuance of common stock, expire or are otherwise terminated (other than by exercise) under the 2017 Stock Option Plan will be added back to the shares available for issuance under the 2017 Stock Option Plan.

Under the 2017 Stock Option Plan, stock options or stock appreciation rights with respect to no more than 1,000,000 shares may be granted to any one individual in any one calendar year and the maximum aggregate number of shares that may be issued in the form of incentive stock options shall not exceed the the Initial Limit, cumulatively increased on January 1, 2018 and on each January 1 thereafter by the lesser of the Annual Increase, or 1,000,000 shares. The grant date fair value of all awards made under the 2017 Stock Option Plan and all other cash compensation paid by us to any nonemployee director in any calendar year shall not exceed $500,000.

The 2017 Stock Option Plan will be administered by the board of directors or the compensation committee of the board of directors or a similar committee performing the functions of the compensation committee and which is comprised of not less than two independent non-employee directors. The administrator has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2017 Stock Option Plan. Employees, nonemployee directors and other key persons (including consultants) are eligible to receive awards under the 2017 Stock Option Plan.

The 2017 Stock Option Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The exercise price of each stock option will be determined by our board of directors but may not be less than 100% of the fair market value of our common stock on the date of grant or, in the case of an incentive stock option granted to a 10% owner, less than 110% of the fair market value of our common stock on the date of grant. The term of each stock option will be fixed by the board of directors and may not exceed ten years from the date of grant (or five years in the case of an incentive stock option granted to a 10% owner). The board of directors will also determine vesting schedule for granted stock options.

The board of directors may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price of each stock appreciation right may not be less than 100% of the fair market value of the common stock on the date of grant.

The board of directors may award restricted stock or restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment or service with us through a specified vesting period. The board of directors may also grant cash-based awards to participants subject to such conditions and restrictions as it may determine. Our board of directors may also grant shares of common stock that are free from any restrictions under the 2017 Stock Option Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

The board of directors may grant performance share awards to participants that entitle the recipient to receive share awards of common stock upon the achievement of certain performance goals and such other conditions as our board of directors shall determine. Our board of directors may grant dividend equivalent

rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of common stock.

The board of directors may grant cash bonuses under the 2017 Stock Option Plan to participants, subject to the achievement of certain performance goals.

The board of directors may grant performance-based awards to participants in the form of restricted stock, restricted stock units, performance shares or cash-based awards upon the achievement of certain performance goals and such other conditions as the board of directors shall determine. To the extent we are subject to Section 162(m) of the Code, the board of directors may grant such performance-based awards under the 2017 Stock Option Plan that are intended to qualify as ''performance-based compensation'' under Section 162(m), but we expect to be exempt from Section 162(m) compliance until the annual stockholder meeting in 2021. Those awards would only vest or become payable upon the attainment of performance goals that are established by our board of directors and related to one or more performance criteria. The performance criteria that could be used with respect to any such awards include: total shareholder return, earnings before interest, taxes, depreciation and amortization, net income (loss) (either before or after interest, taxes, depreciation and/or amortization), changes in the market price of our common stock, economic value-added, funds from operations or similar measure, sales or revenue, development, clinical or regulatory milestones, acquisitions or strategic transactions, operating income (loss), cash flow (including, but not limited to, operating cash flow and free cash flow), return on capital, assets, equity, or investment, return on sales, gross or net profit levels, productivity, expense, margins, operating efficiency, customer satisfaction, working capital, earnings (loss) per share of stock, sales or market shares and number of customers, any of which may be measured either in absolute terms or as compared to any incremental increase or as compared to results of a peer group. From and after the time that we become subject to Section 162(m) of the Code, the maximum award that is intended to qualify as ''performance-based compensation'' under Section 162(m) of the Code that may be made to any one covered employee as defined by Section 162(m) during any one calendar year period is 500,000 shares with respect to a stock-based award and $2,000,000 with respect to a cash-based award.

The 2017 Stock Option Plan provides that upon the effectiveness of a ''sale event,'' as defined in the 2017 Stock Option Plan, an acquirer or successor entity may assume, continue or substitute for the outstanding awards under the 2017 Stock Option Plan. To the extent that awards granted under the 2017 Stock Option Plan are not assumed or continued or substituted by the successor entity, all unvested awards granted under the 2017 Stock Option Plan shall terminate. In such case, except as may be otherwise provided in the relevant award agreement, all options and stock appreciation rights that are not exercisable immediately prior to the effective time of the sale event shall become fully exercisable as of the effective time of the sale event, all other awards with time-based vesting, conditions or restrictions, shall become fully vested and nonforfeitable as of the effective time of the sale event and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and nonforfeitable in the discretion of the board of directors. In addition, in connection with the termination of the 2017 Stock Option Plan upon a sale event, we may make or provide for a cash payment to participants holding options and stock appreciation rights equal to the difference between the per share cash consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights.

Our board of directors may amend or discontinue the 2017 Stock Option Plan and our board of directors may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, including option repricing, but no such action may adversely affect rights under an award without the holder's consent. Certain amendments to the 2017 Stock Option Plan may require the approval of our stockholders.

No awards may be granted under the 2017 Stock Option Plan after the date that is ten years from the date of stockholder approval of the 2017 Stock Option Plan.

Senior executive cash incentive bonus plan

In January 2017, our board of directors adopted the Senior Executive Cash Incentive Bonus Plan, or the Bonus Plan. The Bonus Plan provides for cash bonus payments based upon the attainment of performance targets established by our board of directors. The payment targets will be related to financial and operational measures or objectives with respect to our company, or corporate performance goals, as well as individual performance objectives.

Our board of directors may select corporate performance goals from among the following: achievement of specified research and development, publication, clinical and/or regulatory milestones, adjusted billings, earnings before interest, taxes, depreciation and amortization, net income (loss) (either before or after interest, taxes, depreciation and/or amortization), changes in the market price of our common stock, economic value-added, funds from operations or similar measure, sales or revenue, acquisitions or strategic transactions, operating income (loss), cash flow (including, but not limited to, operating cash flow and free cash flow), return on capital, assets, equity, or investment, stockholder returns, return on sales, gross or net profit levels, productivity, efficiency, margins, operating efficiency, customer satisfaction, working capital, earnings (loss) per share of stock, bookings, new bookings or renewals, sales or market shares; number of customers number of new customers or customer references; operating income and/or net annual recurring revenue, any of which may be measured in absolute terms, as compared to any incremental increase, in terms of growth, or as compared to results of a peer group, against the market as a whole, compared to applicable market indices and/or measured on a pre-tax or post-tax basis.

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the board of directors and communicated to each executive. The corporate performance goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as the board of directors determines. If the corporate performance goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period. Subject to the rights contained in any agreement between the executive officer and us, an executive officer must be employed by us on the bonus payment date to be eligible to receive a bonus payment. The Bonus Plan also permits the board of directors to adjust or approve additional bonuses to executive officers in its sole discretion.

Other compensation

We currently maintain broad-based benefits that are provided to all employees, including health insurance, life and disability insurance and dental insurance. We maintain a 401(k) plan for employees. The 401(k) plan is intended to qualify under Section 401(k) of the Internal Revenue Service Code of 1986, as amended, so that contributions to the 401(k) plan by employees or by us, and the investment earnings thereon, are not taxable to the employees until withdrawn from the 401(k) plan, and so that contributions by us, if any, will be deductible by us when made. Under the 401(k) plan, employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit and to have the amount of such reduction contributed to the 401(k) plan. The 401(k) plan permits us to make contributions up to the limits allowed by law on behalf of all eligible employees. Historically, we have not made any matching contributions to the 401(k) plan.

Certain relationships and related party transactions

In addition to the compensation arrangements, including employment arrangements and indemnification arrangements, discussed, when required, in the sections titled ‘‘Management’’ and ‘‘Executive Compensation’’ and the registration rights described in the section titled ‘‘Description of Capital Stock—Registration Rights,’’ the following is a description of each transaction since our inception on September 21, 2012 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amount involved exceeded or exceeds $120,000; and
- any of our directors, executive officers, or holders of more than 5% of our capital stock, or any immediate family member of, or person sharing the household with, any of these individuals, had or will have a direct or indirect material interest.

We adopted a written policy, effective upon completion of this offering, that requires all future transactions between us and any director, executive officer, holder of 5% or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of them, or any other related persons (as defined in Item 404 of Regulation S-K) or their affiliates, in which the amount involved is equal to or greater than $120,000, be approved in advance by our audit committee. Any request for such a transaction must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee is to consider the relevant facts and circumstances available and deemed relevant to the audit committee, including, but not limited to, the extent of the related party’s interest in the transaction, and whether the transaction is on terms no less favorable to us than terms we could have generally obtained from an unaffiliated third party under the same or similar circumstances.

All of the transactions described below were entered into prior to the adoption of this written policy but each was approved by our board of directors. Prior to our board of directors’ consideration of a transaction with a related person, the material facts as to the related person’s relationship or interest in the transaction were disclosed to our board of directors, and the transaction was not approved by our board of directors unless a majority of the directors approved the transaction. Our current policy with respect to approval of related person transactions is not set forth in writing.

Private placement of securities

Braeburn BVBA

On January 14, 2013, we issued Braeburn BVBA, 100 shares of our common stock at a price of $100.00 per share and on November 27, 2014, we issued Braeburn BVBA 2,063,262 shares of our common stock at a price of $1.00 per share.

On June 4, 2015, we exchanged 2,063,262 shares of our common stock held by Braeburn BVBA for 2,073,262 shares of our series A preferred stock, having an agreed fair market value of $2,073,262, or $1.00 per share. On May 22, 2015, we entered into three separate agreements with Braeburn BVBA relating to the contribution of its License Agreement with Titan Pharmaceuticals, Inc., License Agreement with Camurus AB and Asset and Purchase and Sale Agreement with Endo Pharmaceuticals Solutions Inc. to the capital of Braeburn in exchange for 57,370,000, 21,910,000 and 9,200,000 shares of our series A preferred stock, respectively, which agreed upon fair market value equated to $1.00 per share for such

capital contributions. Dr. Harrison, the executive chairman of our board of directors, was a member of the board of managers of Braeburn BVBA. In November 2015, Braeburn BVBA was voluntarily dissolved.

Apple Tree Partners

On July 6, 2015, we issued 10,000,000 shares of our series A preferred stock as consideration for a $10,000,000 capital contribution from Apple Tree Partners IV, L.P., or ATP. On October 7, 2015, we issued 8,500,000 shares of series A preferred stock as consideration for a $8,500,000 capital contribution from ATP. In November 2015, upon the dissolution of Braeburn BVBA, we exchanged 90,553,262 shares of our series A preferred stock held by Braeburn BVBA and issued such shares to Apple Tree Investments SARL, or ATI, for no consideration. On December 7, 2015, we issued and sold 10,000,000 shares of our series A preferred stock to ATP for aggregate consideration of $10,000,000. On January 8, 2016, we issued and sold 23,750,000 shares of our series A preferred stock to ATP for aggregate consideration of $23,750,000. On May 12, 2016, we issued and sold 30,000,000 shares of our series A preferred stock to ATP for aggregate consideration of $30,000,000. On June 13, 2016, we issued and sold 15,000,000 shares of our series A preferred stock to ATP for aggregate consideration of $15,000,000. On August 3, 2016, we issued and sold 35,000,000 shares of series A preferred stock to ATP for aggregate consideration of $35,000,000. On October 31, 2016, we issued and sold 22,000,000 shares of our series A preferred stock to ATP for aggregate consideration of $22,000,000. On December 28, 2016, we issued and sold 22,000,000 shares of our series A preferred stock to ATP for aggregate consideration of $22,000,000. ATP has agreed to purchase $40 million of our common stock in a separate private placement concurrent with the completion of this offering at a price per share equal to the initial public offering price. The sale of such shares will not be registered under the Securities Act. The closing of this offering is not conditioned upon the closing of such concurrent private placement. Dr. Harrison, the executive chairman of our board of directors, is the managing partner ATP, Mr. McIntyre, who is also a member of our board of directors and our Chief Financial Officer, is a general partner of ATP, and Ms. Sheldon is a partner at ATP.

Agreements with stockholders

On December 15, 2015, we entered into an Investor Rights Agreement with ATP. This agreement provides ATP with certain rights relating to the registration of its shares under the Securities Act. For a more detailed description of these registration rights, see the section titled "Description of Capital Stock—Registration Rights." This agreement also establishes certain "information and observer" rights and rights of first offer. On the closing of this offering, all provisions relating to these rights, other than registration rights, will terminate.

During the fiscal years ended December 31, 2014 and 2015, we incurred consulting fees to ATP and its subsidiaries in the amount of $1.1 million and $0.9 million, respectively. During the nine months ended September 30, 2015 and 2016, we incurred consulting fees to ATP and its subsidiaries in the amount of $0.7 million and $0, respectively. ATP is the beneficial owner of all of our voting securities. Dr. Harrison and Mr. McIntyre are members of our board of directors and Dr. Harrison is a managing partner of ATP, and Mr. McIntyre is a partner of ATP and our Chief Financial Officer, Executive Vice President and Treasurer. These fees were paid to ATP in consideration of certain strategic and ordinary course business operations consulting services provided to us on an as-needed basis, from time to time, by individuals related to ATP, including Mr. Young. Such fees were payable pursuant to invoices submitted to us by ATP from time to time. None of these fees were paid directly or indirectly to Dr. Harrison or Mr. McIntyre and none of these fees paid to ATP exceeded 5% of the consolidated gross revenue of ATP during any of these fiscal years.

Executive officer and director compensation

See ‘‘Executive Compensation’’ for information regarding compensation of our executive officers and directors.

Employment agreements

We have entered into offer letters or employment agreements with our executive officers. For more information regarding our agreements with our named executive officers for the fiscal year ended December 31, 2016, see ‘‘Executive Compensation—Narrative to Summary Compensation Table—Employment Arrangements with our Named Executive Officers.’’

Indemnification agreements

We have entered into or plan to enter into indemnification agreements with each of our directors and officers, the form of which is attached as an exhibit to the registration statement of which this prospectus is a part. The indemnification agreements and our amended and restated certificate of incorporation and amended and restated by-laws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law.

Reserved share program

At our request, the underwriters have reserved for sale, at the initial public offering price, up to 5% of the shares offered by this prospectus for sale to some of our directors, officers, employees, business associates and related persons. If these persons purchase reserved shares it will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus.

Participation in offering

Apple Tree has indicated an interest in purchasing an aggregate of approximately $50 million of shares of our common stock in this offering at the initial public offering price. Indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to Apple Tree, or Apple Tree may determine to purchase more, less or no shares in this offering.

Concurrent private placement

Apple Tree has agreed to purchase $40 million of our common stock in a concurrent private placement with the completion of this offering at a price per share equal to the initial public offering price. The sale of such shares will not be registered under the Securities Act. The closing of this offering is not conditioned upon the closing of such concurrent private placement.

Principal stockholders

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of December 31, 2016, and as adjusted to reflect the sale of common stock offered by us in this offering assuming no exercise of the underwriters' option to purchase additional shares, for:

- each of our named executive officers;
- each of our directors;
- all of our directors and executive officers as a group; and
- each person known by us to be the beneficial owner of more than five percent of any class of our voting securities.

We have determined beneficial ownership in accordance with the rules of the SEC, and thus it represents sole or shared voting or investment power with respect to our securities. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable. We have deemed shares of our common stock subject to restricted stock units or stock options that will vest within 60 days of December 31, 2016 to be outstanding and to be beneficially owned by the person holding restricted stock units or stock options for the purpose of computing the percentage ownership of that person but have not treated them as outstanding for the purpose of computing the percentage ownership of any other person. The table does not give effect to any shares that may be acquired by our shareholders, directors or executive officers pursuant to the reserved share program.

We have based percentage ownership of our common stock before this offering on shares of our common stock outstanding as of December 31, 2016, assuming conversion of all outstanding shares of preferred stock upon the closing of the offering and the concurrent private placement of $40 million of our common stock to Apple Tree (or 2,051,282 shares assuming such shares are sold to Apple Tree at the assumed initial public offering price of $19.50 per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus).

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Braeburn Pharmaceuticals, Inc., 47 Hulfish Street, Suite 441, Princeton, New Jersey 08542.

	Shares beneficially owned prior to offering		Shares beneficially owned after the offering	
Name and address of beneficial owner	**Shares(1)**	**Percentage**	**Shares**	**Percentage**
5% of greater stockholders:				
Entities affiliates with Apple Tree(2)	19,763,204	100%	21,814,486	73.9%
230 Park Avenue, Suite 2800 New York, NY 10169				
Directors and named executive officers:				
Seth Harrison, MD	—	*	—	*
Jerry Karabelas, Ph.D.	—	*	—	*
Dennis H. Langer, M.D., J.D.	—	*	—	*
Behshad Sheldon	—	*	—	*
Frank E. Young, M.D., Ph.D.	—	*	—	*
David J. McIntyre	—	*	—	*
All executive officers and directors as a group (8 persons)	—	*	—	*

* Represents beneficial ownership of less than 1% of our outstanding common stock.

(1) There are currently no RSUs or options which will become releasable or exercisable within 60 days of December 31, 2016 to the benefit of the individuals listed in the table above.

(2) Consists of (i) 13,055,556 shares of common stock underlying convertible preferred stock held by Apple Tree Partners IV, L.P., (ii) 6,707,648 shares of common stock underlying convertible preferred stock held by Apple Tree Investments SARL and (iii) 2,051,282 shares of common stock from the concurrent private placement, based on the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range on the cover of this prospectus. Dr. Seth Harrison, a member of our board of directors, and David J. McIntyre, a member of our board of directors and our Chief Financial Officer, Executive Vice President and Treasurer, are each principals of the general partner of each of Apple Tree Partners IV, L.P. and Apple Tree Investments SARL, and disclaim beneficial ownership of the shares held by each of Apple Tree Partners IV, L.P. and Apple Tree Investments SARL, except to the extent of their respective pecuniary interest therein.

Description of capital stock

General

The following description summarizes the most important terms of our capital stock, as they are expected to be in effect upon the completion of this offering. We expect to adopt an amended and restated certificate of incorporation and amended and restated bylaws in connection with this offering, and this description summarizes the provisions that are expected to be included in such documents. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description of the matters set forth in ''Description of Capital Stock,'' you should refer to our amended and restated certificate of incorporation and amended and restated bylaws, which are or will be included as exhibits to the registration statement of which this prospectus forms a part, and to the applicable provisions of Delaware law. Immediately following the completion of this offering, our authorized capital stock will consist of 90,000,000 shares of common stock, $0.0001 par value per share, and 1,000,000 shares of undesignated preferred stock, $0.0001 par value per share.

Assuming the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock, which will occur upon the completion of this offering, as of December 31, 2016, there were 19,763,204 shares of our common stock outstanding, held by Apple Tree, and no shares of our convertible preferred stock outstanding. Our board of directors is authorized, without stockholder approval except as required by the listing standards of The NASDAQ Global Market to issue additional shares of our capital stock.

Common stock

Upon the completion of this offering, we will be authorized to issue one class of common stock. Holders of our common stock are entitled to one vote for each share of common stock held of record for the election of directors and on all matters submitted to a vote of stockholders. Holders of our common stock are entitled to receive dividends ratably, if any, as may be declared by our board of directors out of legally available funds, subject to any preferential dividend rights of any preferred stock then outstanding. Upon our dissolution, liquidation or winding up, holders of our common stock are entitled to share ratably in our net assets legally available after the payment of all our debts and other liabilities, subject to the preferential rights of any preferred stock then outstanding. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future. Except as described under ''Anti-Takeover Provisions'' below, a majority vote of the holders of common stock is generally required to take action under our amended and restated certificate of incorporation and amended and restated by-laws.

Preferred stock

Upon the completion of this offering, our board of directors will be authorized, without action by the stockholders, to designate and issue up to an aggregate of 1,000,000 shares of preferred stock in one or more series. Our board of directors can designate the rights, preferences and privileges of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of common stock. The issuance of preferred stock, while providing

flexibility in connection with possible future financings and acquisitions and other corporate purposes could, under certain circumstances, have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying, deferring or preventing a change in control of our company, which might harm the market price of our common stock.

Our board of directors will make any determination to issue such shares based on its judgment as to our company's best interests and the best interests of our stockholders. Upon the completion of this offering, we will have no shares of preferred stock outstanding and we have no current plans to issue any shares of preferred stock following completion of this offering.

Registration rights

Upon the completion of this offering, the holders of our common stock, including shares issuable upon the conversion of our convertible preferred stock or their permitted transferees, are entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of the investor rights agreement. The investor rights agreement includes demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations under the investor rights agreement will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Demand registration rights

Upon the completion of this offering, the holders of 13,055,555 shares of our common stock, including shares issuable upon the conversion of our convertible preferred stock or their permitted transferees, are entitled to demand registration rights. Under the terms of the investor rights agreement, we will be required, upon the written request of holders of 25% of these securities (or a lesser percent if the anticipated aggregate offering price would exceed $10 million), to file a registration statement and use commercially reasonable efforts to effect the registration of all or a portion of these shares for public resale. We are required to effect only two registrations pursuant to this provision of the investor rights agreement. A demand for registration may not be made until 180 days after the completion of this offering.

Short form registration rights

Upon the completion of this offering, the holders of 13,055,555 shares of our common stock, including shares issuable upon the conversion of our convertible preferred stock or their permitted transferees, are also entitled to short form registration rights. Pursuant to the investor rights agreement, if we are eligible to file a registration statement on Form S-3, upon the request of 25% of these holders to sell registrable securities for an aggregate price of at least $5 million, we will be required to use our commercially reasonable efforts to effect a registration of such shares. We are required to effect only two registrations in any twelve month period pursuant to this provision of the investor rights agreement.

Piggyback registration rights

The holders of shares of our common stock, including shares issuable upon the conversion of our convertible preferred stock or their permitted transferees, are entitled to piggyback registration rights. If we register any of our securities either for our own account or for the account of other security holders, the holders of these shares are entitled to include their shares in the registration. Subject to certain exceptions contained in the investor rights agreement, we and the underwriters may limit the number of

shares included in the underwritten offering if the underwriters determine in good faith that marketing factors require a limitation of the number of shares to be underwritten.

Expiration of registration rights

The registration rights granted under the investor rights agreement will terminate upon the earlier of (i) a deemed liquidation event, as defined in our amended and restated certificate of incorporation, (ii) at such time when all registrable securities could be sold without restriction under Rule 144 of the Securities Act or (iii) the fifth anniversary of our initial public offering.

Anti-takeover provisions

Our certificate of incorporation and bylaws will contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of the board of directors and which may have the effect of delaying, deferring or preventing a future takeover or change in control of the company unless such takeover or change in control is approved by the board of directors.

These provisions include:

Classified board

Our certificate of incorporation will provide that our board of directors will be divided into three classes of directors, with the classes as nearly equal in number as possible. As a result, approximately one-third of our board of directors will be elected each year. The classification of directors will have the effect of making it more difficult for stockholders to change the composition of our board. Our certificate of incorporation will also provide that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors will be fixed exclusively pursuant to a resolution adopted by our board of directors. Upon completion of this offering, we expect that our board of directors will have seven members.

Action by written consent; special meetings of stockholders

Our certificate of incorporation will provide that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our certificate of incorporation and the bylaws will also provide that, except as otherwise required by law, special meetings of the stockholders can be called only by or at the direction of the board of directors pursuant to a resolution adopted by a majority of the total number of directors. Stockholders will not be permitted to call a special meeting or to require the board of directors to call a special meeting.

Removal of directors

Our certificate of incorporation will provide that our directors may be removed only for cause by the affirmative vote of at least 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors, voting together as a single class, at a meeting of the stockholders called for that purpose. This requirement of a supermajority vote to remove directors could enable a minority of our stockholders to prevent a change in the composition of our board.

Any vacancies resulting from an increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class may be filled by the stockholders, the affirmative vote of a majority of the directors then in office, although fewer than a quorum, or by a sole remaining director. Vacancies resulting from director resignations may be filled by a majority of the directors then in

office or, in the case of a director elected by holders of a class of stock, a majority of the directors then in office elected by such class.

Advance notice procedures

Our bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the bylaws will not give the board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the company.

Super majority approval requirements

The Delaware General Corporation Law generally provides that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless either a corporation's certificate of incorporation or bylaws requires a greater percentage. A majority vote of our board of directors or the affirmative vote of holders of at least 75% of the total votes of the outstanding shares of capital stock of the Company entitled to vote with respect thereto, voting together as a single class, will be required to amend, alter, change or repeal the bylaws. In addition, the affirmative vote of the holders of at least 75% of the total votes of the outstanding shares of capital stock of the Company entitled to vote with respect thereto, voting together as a single class, will be required to amend, alter, change or repeal, or to adopt any provisions inconsistent with, any of the provisions in our certificate of incorporation relating to amendments to our certificate of incorporation and bylaws and as described under "Action by Written Consent; Special Meetings of Stockholders", "Classified Board" and "Removal of Directors" above. This requirement of a supermajority vote to approve amendments to our bylaws and certificate of incorporation could enable a minority of our stockholders to exercise veto power over any such amendments.

Authorized but unissued shares

Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital and corporate acquisitions. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

Exclusive forum

Our certificate of incorporation will provide that, subject to limited exceptions, the state or federal courts located in the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our certificate

of incorporation or our bylaws, or (iv) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our certificate of incorporation described above. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with one or more actions or proceedings described above, a court could find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable.

Section 203 of the Delaware general corporation law

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a ''business combination'' with an ''interested stockholder'' for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A ''business combination'' includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An ''interested stockholder'' is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 75% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may ''opt out'' of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Transfer agent and registrar

Upon the completion of this offering, the transfer agent and registrar for our common stock will be Computer Share Trust Company, N.A.

Listing

We have applied for the listing of our common stock on the NASDAQ Global Market under the symbol ''BBRX.''

Shares eligible for future sale

Prior to this offering, there has been no public market for our common stock, and we cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Although we expect our common stock will be approved for listing on The NASDAQ Global Market, we cannot assure investors there will be an active public market for common stock following this offering. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Following the completion of this offering and the concurrent private placement, based on the number of shares of our capital stock outstanding as of December 31, 2016, we will have a total of 29,506,794 shares of our common stock outstanding or 30,660,640 shares of common stock if the underwriters exercise their option to purchase additional shares in full assuming the issuance of 2,051,282 shares of common stock offered by us in the concurrent private placement, based on the assumed initial public offering price of $19.50 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus. Of these outstanding shares, all of the shares of common stock sold in this offering will be freely tradable, except that any shares purchased in this offering by our affiliates, as that term is defined in Rule 144 under the Securities Act, would only be able to be sold in compliance with the Rule 144 limitations described below.

The remaining outstanding shares of our common stock will be deemed ‘‘restricted securities’’ as defined in Rule 144. Restricted securities may be sold in the public market only if they are registered or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, which rules are summarized below. In addition, all of our executive officers, directors and holders of substantially all of our common stock and securities convertible into or exchangeable for our common stock have entered into market standoff agreements with us or lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of our stock for at least 180 days following the date of this prospectus. As a result of these agreements and the provisions of our Investors Rights Agreement described above under ‘‘Description of Capital Stock—Registration Rights,’’ subject to the provisions of Rule 144 or Rule 701, based on an assumed offering date of February 1, 2017, shares will be available for sale in the public market as follows:

- beginning on the date of this prospectus, the shares of common stock sold in this offering will be immediately available for sale in the public market;
- beginning 90 days after the date of this prospectus, approximately 424,000 additional shares of common stock may become eligible for sale in the public market upon the satisfaction of certain conditions as set forth in ‘‘Lock-Up Agreements’’;
- beginning 120 days after the date of this prospectus, approximately 38,000 additional shares of common stock may become eligible for sale in the public market upon the satisfaction of certain conditions as set forth in ‘‘Lock-Up Agreements’’;

- beginning 150 days after the date of this prospectus, approximately 396,000 additional shares of common stock may become eligible for sale in the public market upon the satisfaction of certain conditions as set forth in "Lock-Up Agreements";
- beginning 181 days after the date of this prospectus, approximately 396,000 additional shares of common stock may become eligible for sale in the public market upon the satisfaction of certain conditions as set forth in "Lock-Up Agreements"; and
- the remainder of the shares of common stock will be eligible for sale in the public market from time to time thereafter subject in some cases to the volume and other restrictions of Rule 144, as described below.

Lock-up agreements

In connection with this offering, we, and all of our directors and officers, and the holders of substantially all of our outstanding stock and restricted stock units, have agreed that, without the prior written consent of J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated on behalf of the underwriters, we and they will not, during the period ending 180 days after the date of this prospectus, or the restricted period:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock,

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise subject to certain exceptions. In addition, we and all of our directors and officers, and the holders of substantially all of our capital stock and restricted stock units have agreed that, without the prior written consent of J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated on behalf of the underwriters, during the restricted period, no registration statement with the SEC relating to the offering of any shares of common stock or any security convertible into or exercisable or exchangeable for our common stock will be filed.

Following the lock-up periods set forth in the agreements described above, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

Under the terms of the lock-up agreements, beginning 90 days from the date of this prospectus through the end of the lock-up period, the holders of restricted stock units will be eligible to sell up to an aggregate of approximately 424,000 shares, 38,000 shares, 396,000 shares and 396,000 shares into the public market on the 90th day, the 120th day, the 150th day and the 180th day, respectively, after the date of this prospectus, which may be subject to increase as agreed in writing with the underwriters.

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain of our security holders, including our investor rights agreement and the standard forms of our option agreements and restricted stock unit agreements under our equity incentive plans, that contain market stand-off provisions imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus.

Rule 144

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 295,000 shares immediately after this offering; or
- the average weekly trading volume in our common stock on The NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the Securities and Exchange Commission and concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

In general, under Rule 144 as currently in effect, once we have been subject to the public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person would be entitled to sell those shares without complying with any of the requirements of Rule 144.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares pursuant to Rule 701.

Registration rights

Upon the completion of this offering, the holders of 13,055,555 shares of our common stock issued or issuable will be entitled to specified rights with respect to the registration of the offer and sale of their shares under 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 immediately upon the effectiveness of the registration statement. See the section of this prospectus titled "Description of Capital Stock—Registration Rights" for additional information.

Equity incentive plans

As soon as practicable after the completion of this offering, we intend to file a Form S-8 registration statement under the Securities Act to register shares of our common stock subject to options or restricted stock units outstanding or reserved for issuance under our stock plans. This registration statement will become effective immediately upon filing, and shares covered by this registration statement will thereupon be eligible for sale in the public markets, subject to Rule 144 limitations applicable to affiliates and any lock-up agreements. For a more complete discussion of our stock plans, see ''Executive Compensation—Stock Option Plans.''

Certain material U.S. federal income tax consequences

The following discussion is a summary of the material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a foreign corporation or any other foreign organization taxable as a corporation for U.S. federal income tax purposes or;
- a foreign estate or trust, the income of which is not subject to U.S. federal income tax on a net income basis.
- This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons that hold their common stock through partnerships or other pass-through entities. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any such change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset, generally property held for investment.

This discussion does not address all aspects of U.S. federal income that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any aspects of any U.S. federal tax other than the income tax, U.S. state, local or non-U.S. taxes, the alternative minimum tax, or the Medicare tax on net investment income. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt or governmental organizations;
- financial institutions;
- brokers or dealers in securities;
- pension plans;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;

- "qualified foreign pension funds," or entities wholly owned by a "qualified foreign pension fund";
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation; and
- certain U.S. expatriates.

All prospective non-U.S. holders of our common stock should consult their own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

Distributions on our common stock

Distributions, if any, on our common stock generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "Gain on sale, exchange or other disposition of our common stock." Any distributions will also be subject to the discussion below under the section titled "Withholding and Information Reporting Requirements—FATCA."

Subject to the discussion in the following two paragraphs in this section, dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing a U.S. tax return with the IRS.

Gain on sale or other taxable disposition of our common stock

Subject to the discussion below under "Backup Withholding and Information Reporting" and "Withholding and Information Reporting Requirements—FATCA," a non-U.S. holder generally will not be subject to any U.S. federal income or withholding tax on any gain realized upon such holder's sale or other taxable disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "Distributions on Our Common Stock" also may apply;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- we are, or have been, at any time during the five-year period preceding such sale of other taxable disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. If we are determined to be a U.S. real property holding corporation and the foregoing exception does not apply, then a purchaser may generally withhold 15% of the proceeds payable to a non-U.S. holder from a sale of our common stock and the non-U.S. holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. Although we expect our common stock to be regularly traded on an established securities market for purposes of the rules described above, no assurance can be provided that our common stock will be regularly traded on an established securities market.

Backup withholding and information reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate, currently 28%, with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in "Distributions on Our Common Stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them. Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS in a timely manner.

Withholding and information reporting requirements—FATCA

The Foreign Account Tax Compliance Act, or FATCA, generally imposes a U.S. federal withholding tax at a rate of 30% on payments of dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise exempt under FATCA. Under applicable U.S. Treasury regulations, withholding under FATCA currently applies to payments of dividends on our common stock, but will only apply to payments of gross proceeds from a sale or other disposition of our common stock made after December 31, 2018. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of this withholding tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

Underwriting

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated are acting as lead book-running managers of the offering and as representatives of the underwriters. Deutsche Bank Securities Inc. is acting as a book-running manager for this offering. Canaccord Genuity Inc. is acting as a co-manager for the offering. We have entered into an underwriting agreement with the representatives. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the initial public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name	Number of shares
J.P. Morgan Securities LLC	
Merrill Lynch, Pierce, Fenner & Smith Incorporated	
Deutsche Bank Securities Inc.	
Canaccord Genuity Inc.	
Total	7,692,308

The underwriters are committed to purchase all the common shares offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the common shares directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $ per share. Any such dealers may resell shares to certain other brokers or dealers at a discount of up to $ per share from the initial public offering price. After the initial offering of the shares to the public, the offering price and other selling terms may be changed by the underwriters. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to 1,153,846 additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the initial public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is $ per share. The following table shows the per share and total underwriting discounts and commissions to be

paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Without option to purchase additional shares exercise	With full option to purchase additional shares exercise
Per Share	$	$
Total	$	$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately $2,262,406. We have agreed to reimburse the underwriters for expenses of up to $35,000 related to clearance of this offering with the Financial Industry Regulatory Authority, Inc., or FINRA.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not (i) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or file with the Securities and Exchange Commission a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of common stock or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated for a period of 180 days after the date of this prospectus, other than (A) the shares of our common stock to be sold hereunder, (B) any shares of our common stock issued upon the exercise of options granted under our existing management incentive plans (C) upon the conversion of our preferred stock provided that the recipient execute a lock-up agreement for the remainder of the lock-up period, (D) up to 5% of our outstanding shares issued by us in connection with mergers, acquisitions or commercial or strategic transactions provided that the recipient execute a lock-up agreement, and (E) the filing by us of any registration statement on Form S-8 or a successor form thereto relating to a management incentive plan.

Our directors and executive officers and our shareholders have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, with limited exceptions, for a period of 180 days after the date of this prospectus, may not, without the prior written consent of J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated, (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including, without limitation, common stock or such other

securities which may be deemed to be beneficially owned by such directors, executive officers, managers and members in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant), (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common stock or such other securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common stock or such other securities, in cash or otherwise, or (3) make any demand for or exercise any right with respect to the registration of any shares of our common stock or any security convertible into or exercisable or exchangeable for our common stock, in each case subject to certain exceptions, including (A) the securities to be sold by the underwriters pursuant to the underwriting agreement, (B) transactions relating to shares of our common stock or other securities purchased in this offering (provided that the entity or person is not an officer or director of Braeburn) or in open market transactions, (C) the exercise, including by ''net'' exercise, of any options to acquire shares of our common stock or the conversion of any convertible security into common stock described in this prospectus, or issued pursuant to an equity plan described in the prospectus, except shares of our common stock received by the person or entity signing the lock-up upon such exercise, (D) the sale or transfer to us of such number of shares of our common stock acquired by the person or entity signing the lock-up acquired in connection with the exercise of such options on a ''net'' exercise basis described in (C), provided that any filing required under the Exchange Act shall clearly indicate in the footnotes thereto that such sale or transfer, as applicable, is for the purpose of satisfying tax obligations in connection with the 'net' exercise of options, (E) the sale or transfer to us of such number of shares of common stock necessary to generate only such amount of cash needed for the payment of taxes (including estimated taxes) due as a result of the exercise of such options or warrant described in clause (C), provided that any filing required under the Exchange Act shall clearly indicate in the footnotes thereto that such sale or transfer, as applicable, is for the purpose of satisfying tax obligations in connection with the 'net' exercise of options, (F) if (i) the person signing the lock-up is an employee of Braeburn as of the date of transfer who holds RSUs with respect to our common stock which become vested and settled during the lock-up period due to the acceleration as provided in the underwriting agreement, or otherwise by their terms, and (ii) we do not elect to settle payroll and income tax withholding and remittance obligations of the person signing the lock-up (or the employer of such person) in connection with the vesting of restricted stock units held by such person by withholding shares of our common stock pursuant to subclause (E) above, then from and after the 90th day after the date of this prospectus, such person may transfer up to that number of shares of our common stock delivered in connection with the vesting of such restricted stock units held by such person, to satisfy payroll and income tax withholding and remittance obligations in connection with the vesting of restricted stock units outstanding as of the date of this prospectus and described herein (for avoidance of doubt, this right to transfer shares of common stock will apply on a particular date only with respect to common stock underlying restricted stock units held by the person signing the lock-up that are vested and settled on or before such date), provided that any filing required under the Exchange Act shall clearly indicate in the footnotes that such sale or transfer, as applicable, is for purposes of satisfying tax obligations in connection with the settlement of the RSUs, (G) transfers of shares of common stock as a bona fide gift or gifts, or pursuant to a negotiated divorce settlement, or pursuant to a qualified domestic relations order, (H) distributions or transfers of shares of common stock or other securities to subsidiaries, limited or general partners, members, stockholders or affiliates of, or any investment fund or other entity that controls or manages, the entity or person signing the lock-up, or to any investment fund or other entity controlled or managed by the undersigned or under common control of the entity or person signing the lock-up, or if the entity or person signing the lock-up is an investment company registered under the Investment Company Act of 1940, as amended, or a Mutual Fund, pursuant to a merger or reorganization with or into another Mutual Fund that shares the same investment adviser registered pursuant to the

requirements of the Investment Advisers Act of 1940, as amended, (I) transfers of shares of common stock or other securities to any immediate family member, trusts for the direct or indirect benefit of a person signing the lock-up or the immediate family members of such person or any of their successors upon death, or any partnerships or limited liability company, the partners or members of which consist of or are for the direct or indirect benefit of such person and/or immediate family members or other dependent of such person, (J) transfers of shares of our common stock or other securities by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of the person signing the lock-up in a transaction not involving a disposition for value, and (K) conversion of preferred stock into shares of common stock in connection with the consummation of this offering, except that any such shares of common stock received by the such person or entity upon such conversion shall be subject to the restrictions on transfer set forth in the lock-up, provided that in the case of any transfer or distribution pursuant to clauses (F) through (J), each donee, distributee or transferee shall execute and deliver to the representatives of the underwriters a lock-up in the form of lock-up, and provided, further, that in the case of any transfer or distribution pursuant to clauses (B) through (J), no filing by any party (donor, donee, transferor or transferee) under the Exchange Act, or other public announcement reporting a reduction in the beneficial ownership shall be required or shall be made voluntarily in connection with such transfer or distribution (other than a filing on a Form 5 or 13F filing made after the expiration of 180-day period and any required Schedule 13G or 13G/A.

At our request, the underwriters have reserved for sale, at the initial public offering price, up to 5% of the shares offered by this prospectus for sale to some of our directors, officers, employees, business associates and related persons. If these persons purchase reserved shares it will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

We applied to have our common stock approved for listing/quotation on the NASDAQ Global Market under the symbol ‘‘BBRX’’.

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of the common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be ‘‘covered’’ shorts, which are short positions in an amount not greater than the underwriters’ option to purchase additional shares referred to above, or may be ‘‘naked’’ shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act of 1933, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the NASDAQ Global Market, in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our common shares, or that the shares will trade in the public market at or above the initial public offering price.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time,

certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Selling restrictions

Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the representatives are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

European Economic Area

In relation to each Member State of the European Economic Area (each, a ''Relevant Member State''), no offer of shares may be made to the public in that Relevant Member State other than:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,
- provided that no such offer of shares shall require the Company or the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed that it is a ''qualified investor'' within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive. In the case of any shares being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer

or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

The Company, the representatives and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

This prospectus has been prepared on the basis that any offer of shares in any Relevant Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly any person making or intending to make an offer in that Relevant Member State of shares which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the Company nor the underwriters have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for the Company or the underwriters to publish a prospectus for such offer.

For the purpose of the above provisions, the expression ''an offer to the public'' in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in the Relevant Member State by any measure implementing the Prospectus Directive in the Relevant Member State and the expression ''Prospectus Directive'' means Directive 2003/71/EC (including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member States) and includes any relevant implementing measure in the Relevant Member State and the expression ''2010 PD Amending Directive'' means Directive 2010/73/EU.

United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are ''qualified investors'' (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the ''Order'' and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as ''relevant persons'').

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other

offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority, or FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Dubai International Financial Centre, or DIFC

This prospectus relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority, or DFSA. This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for this document. The shares to which this document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this document you should consult an authorized financial advisor.

In relation to its use in the DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the shares may not be offered or sold directly or indirectly to the public in the DIFC.

United Arab Emirates

The shares have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of shares. Further, this prospectus does not constitute a public offer of shares in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

Australia

This prospectus:

- does not constitute a disclosure document under Chapter 6D.2 of the Corporations Act 2001 (Cth), or the Corporations Act;
- has not been, and will not be, lodged with the Australian Securities and Investments Commission, or ASIC, as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document under Chapter 6D.2 of the Corporations Act; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, or Exempt Investors, available under section 708 of the Corporations Act.

The shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those shares for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares you undertake to us that you will not, for a period of 12 months from the date of issue of the shares, offer, transfer, assign or otherwise alienate those shares to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Act. Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan.

Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to ''professional investors'' as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a ''prospectus'' as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the shares laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to ''professional investors'' as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the ''SFA'', (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified

in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,
- shares (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:
- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore

Bermuda

Securities may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of shares in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

Saudi Arabia

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority, or CMA, pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution number 1-28-2008, as amended, or the CMA Regulations. The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the shares offered hereby should conduct their own due diligence on the accuracy of the information relating to the shares. If you do not understand the contents of this document, you should consult an authorized financial adviser.

British Virgin Islands

The shares are not being, and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on behalf of us. The shares may be offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands), or BVI Companies, but

only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands.

This prospectus has not been, and will not be, registered with the Financial Services Commission of the British Virgin Islands. No registered prospectus has been or will be prepared in respect of the shares for the purposes of the Securities and Investment Business Act, 2010, or SIBA, or the Public Issuers Code of the British Virgin Islands.

China

This prospectus does not constitute a public offer of the shares, whether by sale or subscription, in the People's Republic of China, or the PRC. The shares are not being offered or sold directly or indirectly in the PRC to or for the benefit of, legal or natural persons of the PRC.

Further, no legal or natural persons of the PRC may directly or indirectly purchase any of the shares without obtaining all prior PRC's governmental approvals that are required, whether statutorily or otherwise. Persons who come into possession of this document are required by the issuer and its representatives to observe these restrictions.

Korea

The shares have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder, or the FSCMA, and the shares have been and will be offered in Korea as a private placement under the FSCMA. None of the shares may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder, or the FETL. The shares have not been listed on any of shares exchanges in the world including, without limitation, the Korea Exchange in Korea. Furthermore, the purchaser of the shares shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the shares. By the purchase of the shares, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the shares pursuant to the applicable laws and regulations of Korea.

Malaysia

No prospectus or other offering material or document in connection with the offer and sale of the shares has been or will be registered with the Securities Commission of Malaysia, or Commission, for the Commission's approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services Licence; (iii) a person who acquires the shares, as principal, if the offer is on terms that the shares may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months; (vii) a corporation with total net assets

exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the shares is made by a holder of a Capital Markets Services License who carries on the business of dealing in shares. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any shares requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

Taiwan

The shares have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant shares laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the shares in Taiwan.

South Africa

Due to restrictions under the shares laws of South Africa, the shares are not offered, and the Offer shall not be transferred, sold, renounced or delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions applies:

- the offer, transfer, sale, renunciation or delivery is to duly registered banks, mutual banks, financial services provider, financial institution, the Public Investment Corporation (in each case registered as such in South Africa), a person who deals with shares in their ordinary course of business, or a wholly owned subsidiary of a bank, mutual bank, authorized services provider or financial institution, acting as agent in the capacity of an authorized portfolio manager for a pension fund (duly registered in South Africa), or as manager for a collective investment scheme(registered in South Africa); or
- the contemplated acquisition cost of the shares, for any single addressee acting as principal is equal to or greater than R1,000,000.

This prospectus does not, nor is it intended to, constitute an "*offer to the public*" (as that term is defined in the South African Companies Act, 2008, or the SA Companies Act, and does not, nor is it intended to, constitute a prospectus prepared and registered under the SA Companies Act. This prospectus is not an "*offer to the public*" and must not be acted on or relied on by persons who do not fall within Section 96(1)(a) of the SA Companies Act (such persons being referred to as "relevant persons"). Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons.

Legal matters

Goodwin Procter LLP, Boston, Massachusetts, which has acted as our counsel in connection with this offering, will pass upon the validity of the shares of common stock being offered by this prospectus. The underwriters have been represented by Davis Polk & Wardwell LLP, New York, New York.

Experts

The consolidated financial statements as of December 31, 2015 and 2014, and for each of the two years in the period ended December 31, 2015, included in this Prospectus and elsewhere in the Registration Statement, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein and elsewhere in the Registration Statement. Such consolidated financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

Additional information

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified by the filed exhibit. You may obtain copies of this information by mail from the Public Reference Section of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov. As a result of this offering, we will become subject to the information and reporting requirements of the Securities Exchange Act of 1934 and, in accordance with this law, will file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at www.braeburnpharmaceuticals.com. Upon completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

Index to financial statements

Index to consolidated financial statements

Index to unaudited interim condensed consolidated financial statements

The accompanying consolidated financial statements give effect to a 1 for 2.7 reverse split for the common stock of Braeburn Pharmaceuticals, Inc. and subsidiaries, which will take place prior to the effective date of the registration statement. The following report is in the form which will be furnished by Deloitte & Touche LLP, an independent registered public accounting firm, upon completion of the 1 for 2.7 reverse split of the common stock of Braeburn Pharmaceuticals, Inc. and subsidiaries described in the second paragraph of the basis of presentation section in Note 1 to the consolidated financial statements and assuming that from November 2, 2016 to the date of such completion no other material events have occurred that would affect the accompanying consolidated financial statements or disclosures therein.

/s/ Deloitte & Touche LLP
Parsippany, New Jersey
January 18, 2017

Report of independent registered public accounting firm

To the Board of Directors and Shareholders of
Braeburn Pharmaceuticals, Inc.
Princeton, New Jersey

We have audited the accompanying consolidated balance sheets of Braeburn Pharmaceuticals, Inc. and subsidiaries (the ''Company'') as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, shareholders' equity (deficit), and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its 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 consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Braeburn Pharmaceuticals, Inc. and its subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred losses and negative cash flows from operations, and expects to continue to incur losses. Accordingly, there is substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also discussed in Note 1 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Parsippany, New Jersey
November 2, 2016
(except for the second paragraph of the basis of presentation section in Note 1 to the consolidated financial statements, as to which the date is January , 2017)

Braeburn Pharmaceuticals, Inc. and subsidiaries
Consolidated balance sheets
As of December 31, 2015 and 2014

	December 31, 2015	December 31, 2014
Current assets:		
Cash and cash equivalents	$ 5,507,371	$ 8,755,204
Restricted cash	225,000	–
Accounts receivable	30,248	–
Prepaid expenses	2,707,531	127,393
Other current assets	53,734	–
Due from Apple Tree Consolidated SPRL	–	198,184
Investment in Titan Pharmaceuticals	5,045,455	2,887,500
Total current assets:	13,569,339	11,968,281
Property and equipment, net	423,234	175,944
Deposits and other assets	97,813	49,813
Total assets:	$ 14,090,386	$ 12,194,038
Current liabilities:		
Accounts payable	$ 1,319,296	$ 948,718
Accrued expenses	5,925,116	2,720,368
Other current liabilities	5,082	–
Due to Apple Tree Life Sciences	64,582	7,120,436
Due to Apple Tree Partners IV	–	3,645,436
Total current liabilities:	7,314,076	14,434,957
Note payable to Apple Tree Consolidated SPRL	–	364,650
Other liabilities	9,214	–
Total liabilities:	7,323,290	14,799,607
Commitments and contingencies (notes 1, 3, 5, 6, and 11)		
Shareholders' Equity / (Deficit):		
Braeburn Pharmaceuticals BVBA SPRL common shares: €1.00 par value; 0 and 64,544,778 shares authorized, issued and outstanding as of December 31, 2015 and 2014, respectively	–	81,294,595
Braeburn Pharmaceuticals, Inc. common shares: $0.0001 par value; 60,000,000 shares authorized; 0 shares issued and outstanding as of December 31, 2015 and 2014, respectively	–	–
Braeburn Pharmaceuticals, Inc. preferred shares: $0.0001 par value; 201,000,000 shares authorized; 119,053,262 and 0 shares issued and outstanding as of December 31, 2015 and 2014, respectively	11,905	–
Additional paid-in-capital	129,831,950	–
Accumulated deficit	(123,104,414)	(81,787,664)
Accumulated other comprehensive income / (loss)	27,655	(2,112,500)
Total shareholders' equity / (deficit):	6,767,096	(2,605,569)
Total liabilities and shareholders' equity / (deficit):	$ 14,090,386	$ 12,194,038

See accompanying notes to consolidated financial statements

Braeburn Pharmaceuticals, Inc. and subsidiaries
Consolidated statements of operations and comprehensive loss
For the years ended December 31, 2015 and 2014

	December 31, 2015	December 31, 2014
Revenues		
Service	$ 25,000	$ –
Total revenues	25,000	–
Expenses		
Research and development	31,373,604	37,194,578
General and administrative	6,964,152	3,076,397
Total expenses	38,337,755	40,270,975
Loss from operations	(38,312,755)	(40,270,975)
Other income (expense)		
Interest income	–	365
Interest expense	(19,550)	–
Foreign currency transaction loss	(630,571)	(185,086)
Total other income / (expense), net	(650,121)	(184,721)
Loss before income tax expense	(38,962,876)	(40,455,696)
Income tax expense	1,599,986	–
Net loss	$(40,562,862)	$(40,455,696)
Other comprehensive loss		
Unrealized gain / (loss) during period, net of tax of $18,000 and $0, respectively	2,140,155	(925,000)
Comprehensive loss	$(38,422,707)	$(41,380,696)
Net loss per common share, basic and diluted	$ (0.36)	$ (1.85)
Net loss per preferred share, basic and diluted	$ (0.33)	
Weighted average basic and diluted common shares outstanding	76,932,160	21,867,489
Weighted average basic and diluted preferred shares outstanding	39,826,161	
Pro forma net loss per Braeburn BVBA common share, basic and diluted	$ (0.59)	
Pro forma net loss per Braeburn Pharmaceuticals, Inc. common share, basic and diluted	$ (0.30)	
Weighted-average Braeburn BVBA common shares, basic and diluted	76,932,160	
Weighted-average Braeburn Pharmaceuticals, Inc. common shares, basic and diluted	2,663,120	

See accompanying notes to consolidated financial statements

Braeburn Pharmaceuticals, Inc. and subsidiaries
Consolidated statements of shareholders' equity / (deficit)
For the years ended December 31, 2015 and 2014

	Preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total shareholders' equity (deficit)
	Shares	Amount	Shares	Amount				
Balance, December 31, 2013	–	$ –	17,391,779	$ 22,773,966	$ –	$ (1,187,500)	$ (41,331,968)	$ (19,745,502)
Net proceeds from sale of common stock of Braeburn Pharmaceuticals BVBA SPRL	–	–	47,152,999	58,520,629	–	–	–	58,520,629
Other comprehensive loss	–	–	–	–	–	(925,000)	–	(925,000)
Net loss	–	–	–	–	–	–	(40,455,696)	(40,455,696)
Balance, December 31, 2014	–	–	64,544,778	81,294,595	–	(2,112,500)	(81,787,664)	(2,605,569)
Net proceeds from sale of common stock of Braeburn Pharmaceuticals BVBA SPRL	–	–	18,050,000	20,049,260	–	–	–	20,049,260
Dissolution of Braeburn Pharmaceuticals BVBA SPRL and issuance of Braeburn Pharmaceuticals, Inc. preferred stock	90,553,262	9,055	(82,594,778)	(101,343,855)	101,334,800	–	–	–
Dividend upon dissolution of Braeburn Pharmaceuticals BVBA SPRL	–	–	–	–	–	–	(753,888)	(753,888)
Net proceeds from sale of preferred stock of Braeburn Pharmaceuticals, Inc.	28,500,000	2,850	–	–	28,497,150	–	–	28,500,000
Other comprehensive income	–	–	–	–	–	2,140,155	–	2,140,155
Net loss	–	–	–	–	–	–	(40,562,862)	(40,562,862)
Balance, December 31, 2015	119,053,262	$ 11,905	–	$ –	$ 129,831,950	$ 27,655	$ (123,104,414)	$ 6,767,096

See accompanying notes to consolidated financial statements

Braeburn Pharmaceuticals, Inc. and subsidiaries
Consolidated statements of cash flows
For the years ended December 31, 2015 and 2014

	2015	2014
Cash flows from operating activities:		
Net loss	$(40,562,862)	$(40,455,696)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	67,553	64,626
Foreign currency remeasurement	835,030	169,784
(Increase) decrease in operating assets:		
Accounts receivable	(30,248)	55,000
Prepaid expenses and other current assets	(2,580,137)	(113,861)
Other assets	(100,936)	–
Due from Apple Tree Consolidated SPRL	178,493	18,400
Increase (decrease) in operating liabilities		
Accounts payable and accrued expenses	3,511,870	2,527,560
Other liabilities	14,296	–
Due to Apple Tree Life Sciences	(7,034,979)	202,214
Due to Apple Tree Partners IV	(3,645,436)	(12,876,143)
Net cash used in operating activities	(49,347,356)	(50,408,116)
Cash flows from investing activities:		
Capital expenditures	(286,499)	(11,944)
Increase in restricted cash	(225,000)	–
Net cash used in investing activities	(511,499)	(11,944)
Cash flows from financing activities:		
Proceeds from note payable from Apple Tree Consolidated SPRL	–	364,650
Principal payments on note payable from Apple Tree Consolidated SPRL	(350,047)	–
Proceeds from sale of common shares	20,049,260	58,520,629
Proceeds from sale of preferred shares	28,500,000	–
Dividends paid	(753,888)	–
Net cash provided by financing activities	47,445,325	58,885,279
Net (decrease) increase in cash and cash equivalents	(2,413,530)	8,465,218
Effect of exchange rates on cash and cash equivalents	(834,304)	(134,234)
Cash and cash equivalents, beginning of year	8,755,204	424,219
Cash and cash equivalents, end of year	$ 5,507,371	$ 8,755,204
Supplemental cash flow disclosure		
Cash paid for income taxes	$ 1,558,029	$ –
Cash paid for interest	$ 19,781	$ –

See accompanying notes to consolidated financial statements

Braeburn Pharmaceuticals Inc.
Notes to consolidated financial statements
December 31, 2015 and 2014
(Amounts in $USD unless otherwise indicated)

1. Nature of business, basis of presentation and summary of significant accounting policies

Braeburn Pharmaceuticals, Inc., its, our, us, or the Company, is a specialty pharmaceutical company focusing on novel, long-acting implantable and injectable therapies for serious neurological and psychiatric disorders, including addiction, pain, and schizophrenia. The Company is part of the Apple Tree Partners family of companies.

The Company, a Delaware incorporated entity, was founded in 2012 as a wholly-owned subsidiary of Braeburn Pharmaceuticals BVBA SPRL, or Braeburn BVBA, a Belgium domiciled entity also founded in 2012. Together, the Companies were a wholly owned portfolio company of Apple Tree Partners IV, L.P., or ATP IV, and its subsidiaries.

In November 2015, Braeburn BVBA was voluntarily dissolved, and as a result, Braeburn Pharmaceuticals Inc. became a wholly owned portfolio company of ATP IV. See Note 13. The financial statements and accompanying notes thereto refer to the consolidated operations of Braeburn Pharmaceuticals, Inc. and Braeburn BVBA.

The Company has its principal executive offices in Princeton, New Jersey.

Since inception, the Company has incurred losses and negative cash flows from operations, and expects to continue to incur losses. As of December 31, 2015 and 2014, the Company has sustained cumulative losses of approximately $123.1 million and $81.8 million, respectively. The Company expects to incur substantial expenditures in the foreseeable future for the development of its product candidates. The Company has historically funded its operations to date through issuance of common and preferred equity securities to its parent company, ATP IV, and its subsidiaries. The Company will require additional financing to develop its product candidates, prepare regulatory filings and obtain regulatory approvals, establish its manufacturing operations, sales, and marketing capabilities. The Company will seek funds through additional equity financings from ATP IV or through other sources of financing. Accordingly, there is substantial doubt regarding the Company's ability to continue as a going concern. The Company's failure to raise capital as and when needed would have a material adverse impact on its financial condition, solvency, and ability to pursue its business strategies. The Company's liquidity over the next 12 months could be materially affected by, among other things: the successful launch and commercialization of its product, Probuphine; costs related to its development of the CAM2038, BBO817, BBO417, and BB1216 clinical programs; the continued financing through equity offerings of its parent company, ATP IV; and other factors.

The accompanying financial statements have been prepared as though the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Basis of presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) and include all adjustments necessary for the fair presentation of the Company's financial statements for the periods presented.

All Braeburn Pharmaceuticals share and per share amounts give retroactive effect to a 1 for 2.7 reverse split of our common stock effected on January , 2017.

In November 2015, Braeburn BVBA was dissolved into the Company (See Note 13). Due to the dissolution of Braeburn BVBA, the Company has presented the consolidated financial statements, reflecting a downstream merger with Braeburn BVBA, which was a transaction between entities under common control. This transaction has been accounted for in a manner similar to a pooling of interests of companies under common control which requires that the merged entities be combined at their historical cost. Accordingly, the accompanying consolidated financial statements are presented as if the Transaction occurred on January 1, 2014.

Significant accounting policies

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant estimates in these consolidated financial statements have been made in connection with certain accruals related to the Company's research and development expenses, the provision for or benefit from income taxes, and valuation allowances against net deferred tax assets. Actual results could differ from those estimates. Changes in estimates are reflected in reported results in the period in which they become known.

Consolidation

The consolidated financial statements include the accounts of Braeburn Pharmaceuticals, Inc. and Braeburn BVBA, which was voluntarily dissolved in November 2015. All inter-company accounts, transactions, and profits have been eliminated in consolidation.

Cash and cash equivalents

The Company considers all highly liquid investments with original maturities of 90 days or less to be cash equivalents. Cash equivalents are carried at cost which approximates fair value due to their short-term nature.

Restricted cash

Restricted cash as of December 31, 2015 represents amounts held as collateral with a bank in relation to the Company's employee credit card program.

Fixed assets

Fixed assets are stated at cost, less accumulated depreciation. Depreciation is computed starting the first full month after an asset is available for its intended use on a straight-line basis over the estimated useful life of the related asset, which range from three to seven years. Leasehold improvements are amortized over the shorter of the non-cancelable term of the operating lease or their economic useful lives. Additions and improvements that extend the economic useful life of the asset are capitalized. The cost and accumulated depreciation of assets sold or retired are removed from the respective accounts with any resulting gain or loss reflected in current earnings.

The Company reviews long-lived assets, such as property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Fair value is determined through various valuation techniques, including discounted cash flow models, quoted market values and third-party independent appraisals, as considered necessary. If any long-lived assets are considered to be impaired, the impairment to be recognized equals the amount by which the carrying value of the asset exceeds its fair value. There were no impairments of fixed assets during 2015 and 2014.

Deferred rent

Rent expense is recorded on a straight-line basis over the initial lease term. The difference between the actual cash paid and the straight-line rent expense is recorded as deferred rent.

Leases

The Company has non-cancelable leases for its manufacturing and office spaces. The leases are reviewed for classification as operating or capital leases. For operating leases, rent is recognized on a straight-line basis over the lease period. For capital leases, the Company records the leased asset with a corresponding liability. Payments are recorded as reductions to the liability with an appropriate interest charge recorded based on the then-outstanding remaining liability.

The Company considers the nature of the renovations and the Company's involvement during the construction period of newly leased office space to determine if it is considered to be the owner of the construction project during the construction period. If the Company determines that it is the owner of the construction project, it is required to capitalize the fair value of the asset, including potentially the building, construction costs incurred, and capitalized interest, on its consolidated balance sheet along with a corresponding financing liability (''build-to-suit accounting''). Upon occupancy for build-to-suit leases, the Company assesses whether the circumstances qualify for sales recognition under the sale-leaseback accounting guidance. If the lease meets the sale-leaseback criteria, the Company will remove the asset and related financial obligation from the balance sheet and evaluate the lease for treatment as a capital or operating lease. If upon completion of construction, the project does not meet the sale-leaseback criteria, the leased property will be treated as a capital lease for financial reporting purposes.

Investments

The Company's investments are comprised of securities classified as available-for-sale. Available-for-sale securities are carried at fair value, with changes in fair value reported in *Other comprehensive income/ (loss)* until realized.

The Company regularly evaluates its investments for impairment. When a decline in fair value, if any, is determined to be other-than-temporary, an impairment charge is recorded and a new cost basis in the investment is established.

Fair value of financial instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, based on the Company's principal or, in absence of a principal, most advantageous market for the specific asset or liability.

The Company uses a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent to their initial measurement. The hierarchy requires the

Company to use observable inputs when available, and to minimize the use of unobservable inputs when determining fair value. The three tiers are defined as follows:

- Level 1—Unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
- Level 2—Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (i.e., interest rates, yield curves, etc.), and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).
- Level 3—Inputs are unobservable and reflect the Company's assumptions as to what market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available.

Cash and cash equivalents, as well as restricted cash, are reflected in the accompanying financial statements at fair value. The carrying amount of receivables and accounts payable, accrued expenses, note payable and other liabilities approximates fair value due to the short-term nature of those instruments.

Foreign currency transactions

The Company's functional currency is the US dollar. The Company pays certain vendor invoices in their respective foreign currency. The Company records an expense in US dollars at the time the liability is incurred. Changes in the applicable foreign currency rate between the date an expense is recorded and the payment date is recorded as a foreign currency gain or loss.

Prior to the dissolution of Braeburn BVBA, the Company held foreign-currency denominated cash accounts, which were remeasured to US dollars at each reporting period and recorded as foreign currency gain or loss. As of December 31, 2015, the Company no longer has any foreign-currency denominated cash accounts.

Revenues

The Company may perform certain research and development services using its proprietary technologies. The Company recognizes revenues as these services are performed. As of December 31, 2015 and 2014, the Company recognized $25,000 and $0 from services, respectively.

Income taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and net operating loss and credit carryforwards. Deferred tax assets and liabilities are measured at rates expected to apply to taxable income in the years in which those temporary differences and carryforwards are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the statement of operations in the period that includes the enactment date. A valuation allowance is recorded when it is not more likely than not that all or a portion of the net deferred tax assets will be realized.

The Company uses a two-step approach to recognizing and measuring uncertain tax positions accounted for in accordance with the guidance on judgments regarding the realizability of deferred taxes. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates it

is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount which is more than 50% likely of being realized upon ultimate settlement. The Company considers many factors when evaluating and estimating its tax positions and tax benefits, which may require periodic adjustments and which may not accurately anticipate actual outcomes.

Income tax returns subject to review by taxing authorities include 2012 through 2015.

Segment information

Operating segments are defined as components of an enterprise (business activity from which it earns revenue and incurs expenses) about which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company's chief decision maker, who is the Chief Executive Officer, reviews operating results on a consolidated basis to make decisions about allocating resources and assessing performance for the entire Company. The Company views its operations and manages its business as one operating segment.

Net income / (loss) per common share

In accordance with *ASC-260, Earnings Per Share*, the Company used the two-class method for calculating basic earnings per share and applied the if-converted method in calculating diluted earnings per share for the year ended December 31, 2015 and 2014. Basic net income / (loss) per common share is the amount of allocated income / (loss) for the period divided by the sum of the weighted average shares of common stock outstanding during the reporting period. Diluted income / (loss) per common share is the allocated amount of income / (loss) for the period divided by the sum of the weighted average shares of common stock outstanding during the reporting period and weighted averages shares that would have been outstanding assuming the issuance of common shares for all dilutive potential common shares.

Share-based compensation

The Company recognizes all share-based payments to employees, including grants of employee stock options and restricted share units, or RSUs, at estimated fair value. If and when a liquidation event occurs, the Company will amortize the fair value of RSU grants, as measured on the grant date of the award, on a straight-line basis over the remaining service period of the RSU grant, which generally equals the remaining vesting period. The vesting period has a time-based vesting provision consisting of a 4-year period, with 25% vesting on the first anniversary of the vesting start date, and 2.08% vesting every month thereafter. The vesting period of all equity shares are also subject to the occurrence of certain performance conditions. Equity shares will not become exercisable until the occurrence of a liquidation event, defined as 180 days after an initial public offering or certain change of control transactions, which is considered a performance condition.

As of December 31, 2015 and 2014, the Company has not granted any employee stock options.

Research and development expense

Research and development expense consists of costs incurred in connection with the development of our product candidates, including:

- fees paid to consultants and clinical research organizations, or CROs, including in connection with our nonclinical and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis;
- licensing fees;

- costs related to acquiring clinical trial materials;
- costs related to compliance with regulatory requirements; and
- costs related to salaries, bonuses, and other compensation for employees in research and development functions.

All research and development costs are expensed as incurred. Costs incurred in obtaining technology licenses are charged immediately to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future uses.

Recent accounting pronouncements

In March 2016, the Financial Accounting Standards Board, or FASB, issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting. The ASU is intended to simplify accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and the classification of share-based awards on the statement of cash flows. The ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted. The Company is evaluating the timing of adopting ASU 2016-09, which contains both retrospective and prospective application of certain data. The Company is currently evaluating the impact of ASU 2016-09 on its financial position and results of operations.

In February 2016, the FASB issued ASU 2016-02, Leases. The ASU is intended to improve financial reporting about leasing transactions. The ASU will require organizations that lease assets referred to as ‘‘Lessees’’ to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. An organization is to provide disclosures designed to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from leases. These disclosures include qualitative and quantitative requirements concerning additional information about the amounts recorded in the financial statements. Under the new guidance, a lessee will be required to recognize assets and liabilities for leases with lease terms of more than 12 months. Consistent with current GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a finance or operating lease. However, unlike current GAAP which requires only capital leases to be recognized on the balance sheet, the new ASU will require both types of leases (operating and capital) to be recognized on the balance sheet. The FASB lessee accounting model will continue to account for both types of leases. The capital lease will be accounted for in substantially the same manner as capital leases are accounted for under existing GAAP. The operating lease will be accounted for in a manner similar to operating leases under existing GAAP, except that lessees will recognize a lease liability and a lease asset for all of those leases.

Public companies will be required to adopt the new leasing standard for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. Transition will require application of the new guidance at the beginning of the earliest comparative period presented. The Company is currently in the process of evaluating the impact that this new leasing ASU will have on its financial statements.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities. The ASU affects the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, it includes a clarification related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. For public business entities, the amendments in the ASU are effective for

fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. All entities can early adopt the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in other comprehensive income. Early adoption of these provisions can be elected for all financial statements of fiscal years and interim periods that have not yet been issued (for public business entities) or that have not yet been made available for issuance. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

In November 2015, the FASB issued ASU 2015-17, Income Taxes Balance Sheet Classification of Deferred Taxes. This ASU requires entities to present deferred tax assets, or DTA's, and deferred tax liabilities, or DTL's, as noncurrent in a classified balance sheet. The ASU simplifies the current guidance, which requires entities to separately present DTA's and DTL's as current and noncurrent in a classified balance sheet. Netting of DTA's and DTL's by tax jurisdiction is still required under the new guidance. The amendments apply to all organizations that present a classified balance sheet. For public companies, the amendments are effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted and the Company adopted this ASU retrospectively in its fiscal year ended December 31, 2015.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements—Going Concern. This ASU provides guidance on management's responsibility to evaluate whether there is substantial doubt about a company's ability to continue as a going concern and requires related footnote disclosures. The update is effective for annual periods ending after December 15, 2016, and interim periods thereafter. Early adoption is permitted. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

In June 2014, the FASB issued ASU 2014-12, Accounting for Share-Based Payments When the Terms of an Award Provide a Performance Target Could Be Achieved after the Requisite Service Period. The ASU is intended to resolve the diverse accounting treatment of these types of awards in practice. The amendments require that a performance target that affects vesting and that could be achieved after the requisite service period is treated as a performance condition. A reporting entity should apply existing guidance in "Compensation-Stock Compensation (Topic 718)" as it relates to awards with performance conditions that affect vesting to account for such awards. As such, the performance target should not be reflected in estimating the grant-date fair value of the award. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved, and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. If the performance target becomes probable of being achieved before the end of the requisite service period, the remaining unrecognized compensation cost should be recognized prospectively over the remaining requisite service period. The ASU is effective for interim and annual reporting periods that begin after December 15, 2015. The Company early adopted this ASU in its fiscal year ended December 31, 2015.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"). ASU 2014-09 supersedes the revenue recognition requirements of ASC-605, Revenue Recognition, and most industry-specific guidance throughout the ASC, resulting in the creation of ASC-606, Revenue from Contracts with Customers. ASU 2014-09 requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. This ASU provides alternative methods of adoption. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers, Deferral of the Effective Date ("ASU 2015-14"). ASU 2015-14 defers the effective date of ASU

2014-09 by one year to December 15, 2017 for fiscal years, and interim periods within those years, beginning after that date and permits early adoption of the standard, but not before the original effective date for fiscal years beginning after December 15, 2016. In March 2016, the FASB issued ASU 2016-08, Revenue from Contracts with Customers, Principal versus Agent Considerations (Reporting Revenue Gross versus Net) (“ASU 2016-08”) clarifying the implementation guidance on principal versus agent considerations. Specifically, an entity is required to determine whether the nature of a promise is to provide the specified good or service itself (that is, the entity is a principal) or to arrange for the good or service to be provided to the customer by the other party (that is, the entity is an agent). The determination influences the timing and amount of revenue recognition. In April 2016, the FASB issued ASU 2016-10, Revenue from Contracts with Customers, Identifying Performance Obligations and Licensing, clarifying the implementation guidance on identifying performance obligations and licensing. Specifically, the amendments reduce the cost and complexity of identifying promised goods or services and improves the guidance for determining whether promises are separately identifiable. The amendments also provide implementation guidance on determining whether an entity’s promise to grant a license provides a customer with either a right to use the entity’s intellectual property (which is satisfied at a point in time) or a right to access the entity’s intellectual property (which is satisfied over time). The effective date and transition requirements for ASU 2016-08 and ASU 2016-10 are the same as the effective date and transition requirements for ASU 2014-09. The Company is currently assessing the potential impact of adopting ASU 2014-09, ASU 2016-08 and ASU 2016-10 on its financial statements and related disclosures.

2. License agreements

(a) Titan Pharmaceuticals

In December 2012, the Company entered into a license agreement, or the Titan Agreement, with Titan Pharmaceuticals Inc., or Titan, pursuant to which it received an exclusive right and license to commercialize Probuphine in the United States of America and its territories, including Puerto Rico, and Canada, or the Territory. Under the Titan Agreement, prior to the earlier of (i) Titan’s receipt of a complete response letter, or CRL, from the FDA, or (ii) the New Drug Application, or NDA, Transfer Date (as defined as ten business days from receipt by Titan of the milestone payment by the Company upon FDA approval of Probuphine), Titan was solely responsible for all development and regulatory costs associated with and required for the approval of Probuphine. During this period, Titan owned and controlled all regulatory documents related to Probuphine, and was solely responsible for those costs. Subsequent to the earlier of (i) Titan’s receipt of a CRL from the FDA or (ii) the NDA Transfer Date, the Company would be solely responsible for all costs associated or required for the approval of Probuphine in the Territory; own and control all regulatory documents, including costs for preparation, filing, prosecution, and maintenance of those documents; and use reasonable efforts to commercialize and promote Probuphine in the Territory. Under the Titan Agreement, the Company made a non-refundable up-front license fee payment of $15.75 million in December 2012, which was recorded in research and development expense in the same period.

In May 2013, the Company entered into an amendment with Titan to the Titan Agreement, or the Amendment. The Amendment provided the Company the right to terminate the Titan Agreement in the event that (i) after May 28, 2013, based on written or oral communications from or with the FDA, the Company reasonably determines either that the FDA will require significant development to be performed before approval of the Probuphine NDA can be given, such as, but not limited to, one or more additional controlled clinical studies with a clinical efficacy endpoint, or substantial post-approval commitments that may materially impact the products financial returns; or, that the FDA will require one or more changes in the proposed label, which change(s) the Company determines will materially reduce the authorized prescribed patient base, or (ii) the NDA has not been approved by the FDA on or before June 30, 2014. The Amendment also provided that, prior to the NDA transfer date, the Company shall become solely responsible for all costs associated with or required for approval of Probuphine by the FDA, with the exception of legal and consulting fees, to which the Company shall bear the first $1.5 million, with both the Company and Titan sharing equally any fees in excess of the $1.5 million.

In July 2013, upon notice of a CRL from the FDA, the Company entered into a second amendment to the Titan Agreement, or the Second Amendment, primarily to establish and provide the parameters for a committee comprised of representatives of Braeburn and Titan responsible for and with the authority to make all decisions regarding the development and implementation of a strategic plan to seek approval from the FDA of Probuphine for subdermal use in the maintenance treatment of adult patients with opioid addiction, including development of the strategy for all written and oral communications with the FDA.

In November 2013, the Company entered into a third amendment to the Titan Agreement, or the Third Amendment, which modified the amount and timing of the approval and sales milestone payments payable under the Titan Agreement. Under the Third Amendment, the Company will pay to Titan a $15 million payment upon FDA approval of the NDA and royalties on net sales of Probuphine ranging in percentage from the mid-teens to the low twenties. The Third Amendment also provided for up to $165 million in one-time sales milestones.

In addition, the Third Amendment provided for up to $35 million in regulatory milestones. In addition, the Company is required to pay royalties on a percentage of sales of any of other continuous delivery treatments for opioid dependence as defined in the Third Amendment; additionally, Titan can elect to receive royalties on sales, if any, of other products in the addiction market in exchange for a similar reduction in our royalties on Probuphine. As of December 31, 2015 and 2014, the Company has not triggered any royalty, sales, or regulatory milestones, and has not accrued any amounts as the events are not considered probable. Refer to Note 17 for a material subsequent event.

Under the Third Amendment, ending on the NDA Transfer Date as defined above, the Company is responsible for all costs associated with or required for approval of Probuphine, with the exception of legal and consulting fees incurred by Titan. After the NDA Transfer Date, the Company is solely responsible for all costs associated with or required for the approval of Probuphine.

In November 2013, the Company entered into a stock purchase agreement with Titan, to which it made a $5 million equity investment in Titan in exchange for 6,250,000 shares of common stock. The Company accounts for these shares using the fair value method of accounting. See Note 4.

Unless earlier terminated, the Titan Agreement will expire on the later of (i) the 15th anniversary of the date of product launch in the Territory or (ii) the expiration of the last to expire patent in the Territory covered by the Agreement, or the Term. Either party may terminate the Agreement prior to the expiration of the Term in the event of a material breach by the other party that remains uncured or in the event of the other party's bankruptcy. The Company may terminate the Titan Agreement in the event that it, notwithstanding good faith efforts to do so, is unable to enter into an agreement for the supply of ethylene-vinyl acetate, or EVA; or if such a supply agreement is terminated by material breach; or the supplier fails to provide EVA for a period of at least three months. The Company may also terminate the Titan Agreement (i) on a country by country basis upon six months' notice following the occurrence of any "significant competition" in such country, as such term is defined in the Titan Agreement; or, (ii) immediately upon notice if the Company determines, in good faith, that it is inadvisable to continue commercialization as a result of any actual or perceived safety issues. Titan may terminate the Titan Agreement if, for reasons other than force majeure, regulatory, safety, manufacturing or product quality issues, the Company discontinues commercial sale of the product and fails to resume sales within 30 days following notice or in the event the Company or any of its affiliates or sub-licensees commences any legal proceeding seeking to challenge or dispute the validity or ownership of the licensed patents.

(b) Camurus AB

In November 2014, the Company entered into a license agreement, or the Camurus Agreement, with Camurus AB, or Camurus, pursuant to which it received the exclusive right and license to develop and commercialize CAM2038, subcutaneous weekly or monthly depot injections of buprenorphine for the treatment of opioid dependence and pain in North America, or the Camurus Territory. Camurus also granted the Company an exclusive option, on a country-by-country and product-by-product basis, to include Japan, Taiwan, South Korea, and China in the Camurus Territory and a right of first negotiation to include other countries outside the European Union in the Camurus Territory, subject to certain conditions. Under the Camurus Agreement, the Company and Camurus developed a plan, or the Development Plan, in which both parties shall be responsible for certain clinical, regulatory, and manufacturing efforts.

Under the Development Plan, the Company is responsible for all costs of future clinical programs, including one Phase 2 study (HS-13-478) and two Phase 3 studies (HS-11-421 and HS-14-499). Camurus is responsible for completing two ongoing Phase 1 studies, of which the Company will reimburse Camurus for all costs and expenses, including Camurus' personnel costs, provided that these costs do not exceed the Development Plan budgeted costs by more than 20%, unless approved by the Company. The Company is responsible for obtaining, submitting, prosecuting, and maintaining all necessary regulatory approvals, of which Camurus may provide assistance in and receive reimbursement by the Company. The Company is responsible for all costs to commercialize the product, as well as any post registration studies. The Company is also solely responsible for all costs of patent prosecution of product intellectual property, or IP, in the Territory.

Under the Camurus agreement, the Company may purchase non-commercial supply of CAM2038 from Camurus at Camurus' manufacturing cost. The Company has the right to request Camurus to provide, to the Company or its designated contract manufacturing organization, or CMO, a technology transfer as necessary to enable the Company or its CMO to manufacture the products for nonclinical, clinical and commercial use. The Company will fully reimburse Camurus for out-of-pocket expenses and Camurus' personnel costs related to the technology transfer.

Under the Camurus Agreement, the Company paid to Camurus a non-refundable and non-creditable signing fee of $20 million in the fourth quarter of 2014. The up-front license payment was recorded in research and development expense in the same period. The Company did not attribute value to the country-by-country option, as substantial costs outside of the agreement would be required by the Company to obtain regulatory approval in the option territories. In addition, the Company agreed to reimburse Camurus $1.25 million for certain preparation costs of a Phase 3 trial upon FDA authorization of the Investigational New Drug, or IND, application of the first product for the treatment of opioid addiction. The Camurus Agreement also includes up to $56 million in one-time, non-refundable development milestones achievable upon certain regulatory successes and on a product-by-product basis up to mid-teen $75 million in one-time, non-refundable sales milestones. The Company is also required to pay to Camurus royalties on a product-by-product and country-by-country basis of annual net sales, until the later of (i) 12 years after the date of first commercial sale of such product in such country; or (ii) the expiration of the last to expire valid claim of all licensed patent rights in such country covering such product.

(c) FX/Endo Pharmaceuticals

In October 2014, the Company entered into an agreement with FX Therapeutics, Inc., or FX, to purchase an option agreement for $8 million for the right to purchase assets from Endo Pharmaceuticals, Inc., or Endo, relating to the MedLaunch Implant Program, or MedLaunch. The MedLaunch Implant is a novel excipient that releases certain molecularly similar compounds at certain time intervals at a near zero release profile.

The Company intends to use the MedLaunch technology in its product candidate, BBO817. In November 2014, the Company purchased the MedLaunch assets from Endo for $1.2 million. The assets purchased included intellectual property and a small quantity of research and development materials. In addition to the payment, the Company also agreed to pay Endo $2 million in milestone payments upon the first commercial sale of any FDA approved MedLaunch product in the United States. The Company is required to pay Endo low single-digit royalties of worldwide net sales of any MedLaunch product until the later of (i) the tenth anniversary of the closing of the Company's acquisition of Medlaunch or (ii) until such product is no longer covered by a valid claim in the patents the Company has acquired from Endo.

The Company considered guidance in *ASC-805, Business Combinations*, and determined that the acquired MedLaunch assets do not constitute a business as defined under *ASC-805*. Under *ASC-805*, a business consists of inputs and processes applied to those inputs that have the ability to create outputs. An input is defined as any economic resource that creates, or has the ability to create, outputs when one or more processes are applied to it. A process is defined as any system, standard, protocol, convention, or rule that when applied to an input or inputs, creates or has the ability to create outputs. An output is defined as the result of inputs and processes applied to those inputs that provide or have the ability to provide a return in the form of dividends, lower costs, or other economic benefits directly to investors or other owners, members, or participants.

While the Company acquired certain historical research and development records from Endo, the Company has independently developed or will develop all necessary future clinical and regulatory processes and procedures. Additionally, the Company did not receive any employees working on the development of the MedLaunch program. As the intellectual property and materials acquired had no alternative future use on the date of acquisition, the option and subsequent transaction payments of $8 million and $1.2 million, respectively, were charged in research and development expense in the period incurred.

(d) Lubrizol Advanced Materials, Inc.

In September 2015, the Company entered into an exclusive supply agreement with Lubrizol Advanced Materials, Inc., or Lubrizol, in which the Company has the exclusive right to purchase Lubrizol's implantable thermoplastic polyurethane resin and tubing product, or the Product, as an excipient in its MedLaunch implant. The Company paid to Lubrizol a non-refundable, non-creditable upfront fee of $108,000 upon signing. The Company capitalized the payment and is amortizing over the service period of the agreement. The supply agreement has a termination effective 20 years after commencement, with the Company having the option to extend the term for additional 5-year terms, provided the Company notify Lubrizol with advanced written notice of at least six months. Under the supply agreement, the Company has the right to purchase the product, in both quality grades of GMP and non-GMP, at a pre-determined, fixed price for the first eight years of the term. In addition to the upfront payment, the Company also agreed to pay to Lubrizol up to $217,000 in milestone payments related to certain regulatory successes. The Company will pay to Lubrizol a royalty of 0.5% of net sales of any commercial product utilizing the Lubrizol materials, beginning on first commercial sale of the product and ending on the earlier of: (a) the later of: (i) the expiration of the last valid claim in an issued patent owned or controlled by the Company, and (ii) the expiration of the last marketing exclusivity covering the product granted a regulatory authority; or (b) the approval by a regulatory authority of an abbreviated new drug application for any product using the Company's product as reference.

(e) Oncothyreon Inc.

In January 2015, the Company entered into an agreement, or the Oncothyreon Agreement, with Oncothyreon Inc. for the exclusive license worldwide to research, develop, and commercialize ATI-9242, a

novel antipsychotic for the treatment of schizophrenia and other psychiatric disorders. The Company has the right to sublicense under the Oncothyreon Agreement, at which time it would pay to Oncothyreon a percentage, ranging from 2.5% to 12.5%, of any license fees, license maintenance fees, milestone payments and any other cash or non-cash considerations. This does not include royalties paid to the Company by the sublicensee. Under the Oncothyreon Agreement, the Company paid to Oncothyreon an initial license fee of $25,000 in April 2015. This upfront fee was expensed in research and development expense in January 2015. The Company is required to pay to Oncothyreon $250,000 as reimbursements for patent costs incurred by Oncothyreon prior to the execution of the Oncothyreon Agreement, payable on the first anniversary of the Oncothyreon Agreement. The Company is also required to make certain milestone payments to Oncothyreon, totaling $6.3 million, achievable by certain regulatory and commercial successes. As of December 31, 2015, the Company accrued $250,000 to research and development expense for the full reimbursement for patent costs. The Company paid the reimbursement costs of $250,000 in January 2016.

Under the Oncothyreon Agreement, the Company will pay to Oncothyreon tiered royalties based on annual net sales on a product-by-product and country-by-country basis ranging from 3% to 5%. The Company is required to pay a minimum royalty on the aggregate of the annual product sales of $200,000. The royalty term country-by-country expires the earlier of (a) the later of the (i) expiration of the last valid claim of an Oncothyreon patent, (ii) the expiration of any exclusive marketing period, or (iii) ten years after first commercial; or (b) the first commercial sale of a generic competitor of such licensed product.

3. Earnings per share

The computation of basic and diluted net loss per share for the year ended December 31, 2015 and 2014 is as follows:

	December 31, 2015	December 31, 2014
Numerator:		
Net loss	$ (40,562,862)	$ (40,455,696)
Net loss available to all shareholders	$ (40,562,863)	$ (40,455,697)
Net loss attributable to common shareholders	$ (27,480,794)	$ (40,455,697)
Net loss attributable to preferred shareholders	$ (13,082,069)	
Denominator:		
Weighted-average common shares, basic and diluted	76,932,160	21,867,489
Weighted-average preferred shares, basic and diluted	39,826,161	
Net loss per common share, basic and diluted	$ (0.36)	$ (1.85)
Net loss per preferred share, basic and diluted	$ (0.33)	

For the year ended December 31, 2015, the $754,000 dividend paid by Braeburn BVBA is calculated in the allocation of net loss available to common and preferred shareholders under the two-class method. As the dividend occurred on the date of dissolution, when the outstanding common stock ceased to exist, the divided is treated as earnings on the preferred shareholders and additive to the losses of the common shareholders.

The Company's preferred stock is participating and accumulates an 8% dividend that is not included in the earnings per share calculation above. Prior to and subsequent of the Company's dissolution of Braeburn BVBA, the Company's equity is owned solely by ATP IV. As of December 31, 2015 and 2014, the cumulative

preferred dividend was $4.7 million and $0, respectively, as the Company's preferred shares were issued by Braeburn Inc. to Braeburn BVBA and eliminated upon consolidation.

The following table sets forth the potential common shares that could potentially dilute basic income per share in the future that were not included in the computation of diluted income / (loss) per share because to do so would have been anti-dilutive:

	December 31, 2015	December 31, 2014
Conversion of restricted stock units	989,465	–
Total potential dilutive effect	989,465	–

The following table illustrates the unaudited pro forma net loss and basic and diluted net loss per common share calculated under the two-class method for each attributable shareholder of their respective class of shares, as consistent with the US GAAP calculation in the above table. The net loss attributable to each class of common shareholders was allocated relative to their shares outstanding during the year. The pro forma adjustments reflected in the table below are as follows: (i) the effects of time-based vesting for the share-based compensation for restricted stock units and non-qualified stock options granted under the 2015 Equity Incentive Plan that were now only subject to time-based vesting criteria at completion of the Company's initial public offering (as discussed further in Note 10) assuming the initial public offering occurred on January 1, 2015. Due to the current performance criteria of a liquidity event, no share-based compensation expense has been recognized in the historical financial statements for the year ended December 31, 2015; (ii) the conversion of all outstanding Braeburn Pharmaceuticals issued convertible preferred stock as it became outstanding throughout the year into shares of Braeburn Pharmaceuticals common stock at the applicable conversion rate of 13.5 preferred shares for one common share, assuming the transaction occurred at the date of the first issuance; and (iii) the issuance of 991,110 shares of common stock related to restricted stock units that were both service-based vested and liquidity-based vested as of the completion of this offering. The pro forma net loss per share does not include the shares expected to be sold and related proceeds to be received from the Company's proposed initial public offering.

	December 31, 2015
	(Unaudited)
Numerator:	
Net loss—as reported	$ (40,562,862)
Share-based compensation	(5,877,544)
Pro forma net loss, including the effect of share-based compensation expense, available to all shareholders	$ (46,440,407)
Pro forma net loss attributable to Braeburn BVBA common shareholders	$ (45,640,479)
Pro forma net loss attributable to Braeburn Pharmaceuticals Inc. common shareholders	$ (799,928)
Denominator:	
Weighted-average Braeburn BVBA common shares, basic and diluted	76,932,160
Weighted-average Braeburn Pharmaceuticals, Inc. common shares, basic and diluted	2,663,120
Pro forma net loss per Braeburn BVBA common share, basic and diluted	$ (0.59)
Pro forma net loss per Braeburn Pharmaceuticals, Inc. common share, basic and diluted	$ (0.30)

4. Financial instruments

The following is a summary of the Company's available-for-sale securities:

	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Fair value
As of December 31, 2015:				
Equity securities:				
Investment in Titan Pharmaceuticals	$5,000,000	$45,455	$–	$5,045,455
Total investment securities	$5,000,000	$45,455	$–	$5,045,455

	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Fair value
As of December 31, 2014:				
Equity securities:				
Investment in Titan Pharmaceuticals	$5,000,000	$–	$2,112,500	$2,887,500
Total investment securities	$5,000,000	$–	$2,112,500	$2,887,500

During the years ended December 31, 2015 and 2014, the Company did not have any realized gains/losses from the sale of marketable securities.

5. Fair value measurement

Fair value of certain investments is based upon market prices using quoted prices in active markets for identical assets quoted on the measurement day. The Company reviews its investments on a periodic basis for other-than-temporary impairments. This review is subjective, as it requires management to evaluate whether an event or change in circumstances has occurred in that period that may have a significant adverse effect on the fair value of the investment. The Company did not recognize any other-than-temporary impairments as of December 31, 2015 and 2014.

The following represents the fair value using the hierarchy described in Note 1 for the Company's financial assets that are required to be measured at fair value on a recurring basis as of December 31, 2015 and 2014:

	As of December 31, 2015			
	Level 1	Level 2	Level 3	Total
Equity investments, classified as available-for-sale	$–	$5,045,455	$–	$5,045,455
Total assets	$–	$5,045,455	$–	$5,045,455

	As of December 31, 2014			
	Level 1	Level 2	Level 3	Total
Equity investments, classified as available-for-sale	$–	$2,887,500	$–	$2,887,500
Total assets	$–	$2,887,500	$–	$2,887,500

The Company classifies its available-for-sale securities as Level 2 in the fair value hierarchy, due to the relatively low trading volume and percentage of shares held by insiders.

Unrealized gains and losses are reported as a component of accumulated other comprehensive (loss) income in shareholders' equity.

6. Prepaid expenses and other current assets

Prepaid expenses and other current assets at December 31, 2015 and 2014 consists of the following:

	December 31,	
	2015	2014
Prepaid research and development	$2,455,721	$ 95,223
Prepaid general and administrative	125,807	–
Prepaid rent	81,618	12,453
Prepaid insurance	44,737	19,717
Other	53,383	–
Total prepaid expenses and other current assets	$2,761,265	$127,393

7. Plant, property, and equipment

Property and equipment is recorded at cost and consists of the following:

	December 31,	
	2015	2014
Leasehold Improvements	$ 185,018	$ 89,755
Computer Equipment	120,188	21,002
Furniture and Office Equipment	207,283	182,607
Construction in Process	95,718	–
Total Fixed Assets	608,207	293,364
Less: Accumulated Depreciation	(184,973)	(117,420)
Total Property and Equipment	$ 423,234	$175,944

The Company begins depreciation on property and equipment in the month following the asset being placed into service. Depreciation expense was approximately $68,000 and $65,000 for the years ended December 31, 2015 and 2014, respectively.

8. Leases

Princeton, NJ operating lease

The Company has a non-cancelable operating lease of approximately 4,600 square feet of office space for its corporate headquarters in Princeton, New Jersey that expires in 2018.

North Carolina build-to-suit lease

In December 2015, the Company entered into a lease agreement for approximately 33,900 square feet of manufacturing and office space in Durham, North Carolina, commencing in 2016. The lease agreement expires in 2026, with the Company's option to extend to 2031 or 2036. The Company intends to modify the space to meet its manufacturing and supply chain needs, and may be reimbursed for construction costs of up to $3.9 million from the landlord. As a result of the nature and involvement in the construction period of the leased space, the Company is determined to be the "deemed owner", for accounting purposes only, of the construction project, and is required to capitalize the fair value of the construction costs incurred by the Company, pursuant to *ASC-840, Leases*, and the accounting policy described in Note 1. As of

December 31, 2015, as commencement of the project had not yet begun, the Company did not record an asset nor a lease obligation in its consolidated balance sheet related to the North Carolina build-to-suit space.

Rent-free periods and other incentives granted under the leases and scheduled rent increases are charged to rent expense on a straight-line basis over the related terms of the lease. Rental expense for operating leases was approximately $164,953 and $149,440 for 2015 and 2014, respectively.

The future lease payments under non-cancelable operating leases as of December 31, 2015 are as follows:

	Princeton, NJ operating lease	North Carolina build-to-suit lease
2016	$188,296	$ 130,103
2017	188,296	784,523
2018	156,913	808,055
2019	–	832,265
2020	–	857,155
Thereafter	–	5,535,501
Total	$533,505	$8,947,602

9. Accounts payable and accrued expenses

Accounts payable and accrued expenses at December 31, 2015 and 2014 consist of the following:

	December 31,	
	2015	2014
Accounts Payable	$1,319,296	$ 948,718
Accrued Research and Development Expense	4,436,876	2,135,178
Accrued General and Administrative Expense	586,833	196,541
Accrued Bonuses	901,407	343,904
Accrued Vacation	–	44,746
	$7,244,412	$3,669,087

10. Stock plans

2015 Equity Incentive Plan

In June 2015, the Board of Directors approved the 2015 Equity Incentive Plan, or the 2015 Plan, pursuant to which 1,426,840 shares of common stock were authorized for issuance to employees, directors, officers, and other parties as determined by the Board of Directors. Shares may be issued as restricted stock units, stock appreciation rights, nonqualified stock options, and incentive stock options. Equity shares generally vest over a 4-year period, with 25% vesting on the first anniversary of the vesting start date, and 2.08% vesting every month thereafter. However, vesting of these equity shares are subject to the occurrence of certain performance conditions. Equity shares will not become exercisable until the occurrence of a liquidation event, defined as 180 days after an initial public offering or certain change of control transactions, which is considered a performance condition. Upon termination of service, the grantee will remain eligible to vest in the number of equity shares in which the grantee was otherwise eligible to vest in upon a liquidation event or certain change of control transactions at the date of termination. The 2015

Plan also provides that, in the event of certain change of control transactions prior to termination of service, all outstanding, unvested equity shares shall automatically vest. Equity shares granted under the 2015 Plan expire on the tenth anniversary of the date they were granted.

As of December 31, 2015, 989,465 restricted stock units to purchase 989,465 shares of common stock were outstanding under the 2015 Plan. As of December 31, 2015 and 2014, the Company recognized $0 and $0 of compensation expense, respectively, as none of the performance conditions have been satisfied, and such performance conditions are not deemed probable of occurring.

The Company uses a third-party valuation specialist to assist in the estimation of the fair value of its common stock. The Company utilizes significant estimates and assumptions in determining the fair value of its common stock. Management has determined the estimated fair value of the Company's common stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector, discounted cash flows and the likelihood of achieving a liquidity event, such as an IPO of common stock or a sale of the Company.

The Company utilized various valuation methodologies in accordance with the framework of the 2013 American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, to estimate the fair value of its common stock. The methodologies included a probability-weighted expected return methodology that determined an estimated value under an IPO scenario and a sale scenario based upon an assessment of the probability of occurrence of each scenario. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates include assumptions regarding future performance, including the successful completion of preclinical studies and clinical trials and the time to complete an IPO or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

The Company uses a third-party valuation specialist to assist in the estimation of the fair value of its common stock. The Company utilized an option pricing model to allocate the estimated enterprise fair value of the Company between its common and preferred stock.

The following table summarizes information on the Company's restricted stock:

	Restricted stock	
	Number of shares	Weighted average grant date fair value
January 1, 2015	—	—
Granted	989,465	$2.73
Vested	—	—
Forfeited	—	—
Unvested at December 31, 2015	989,465	$2.73

As of December 31, 2015, there was approximately $2.7 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the 2015 Plan. This cost is expected to be recognized as compensation expense over the weighted average remaining service period of approximately 1.7 years.

11. Common stock

Since founding, the Company has received funding directly or indirectly from ATP IV and its subsidiaries and they were the only holders of the outstanding equity. The consolidated statements of shareholders' equity / (deficit) for the years ended December 31, 2015 and 2014 reflect the class of stock held by ATP IV that were not eliminated in consolidation. Prior to 2015, the Company's capitalization structure included only one class of common shares for each Braeburn BVBA and Braeburn Pharmaceuticals, as follows:

- In 2012, ATP IV and its subsidiaries contributed $17.7 million in capital to Braeburn BVBA in exchange for 13,645,650 common shares. Proceeds from these shares were used by Braeburn BVBA for the Probuphine license agreement upfront payment of $15.75 million.
- In 2012, Braeburn Pharmaceuticals issued 100 common shares to Braeburn BVBA in exchange for $10,000, or $100 per share. This amount eliminates in consolidation of the two companies.
- In 2013, ATP IV and its subsidiaries contributed $5.0 million in capital to Braeburn BVBA in exchange for 3,746,129 common shares.
- In 2014, ATP IV and its subsidiaries contributed $58.5 million in capital to Braeburn BVBA in exchange for 47,152,999 common shares.
- In 2014, Braeburn Pharmaceuticals issued 2,063,262 common shares to Braeburn BVBA in exchange for $2,063,262, or $1 per share. This amount eliminates in consolidation of the two companies.

As of December 31, 2014, the Company was authorized to issue 64,544,778 common shares, all of which were issued and outstanding to ATP IV and its subsidiaries.

During 2015, the Company had the following capitalization events:

- In May 2015, Braeburn Pharmaceuticals entered into three separate agreements with Braeburn BVBA, in which Braeburn BVBA contributed the Probuphine license agreement, Camurus license agreement, and Endo license agreement to Braeburn Pharmaceuticals in exchange for 57,370,000, 21,910,000, and 9,200,000 series A preferred shares with a fair market value of $1 per share. See Note 2 for discussion of license agreements and Note 12 for preferred stock.
- In June 2015, Braeburn Pharmaceuticals exchanged all outstanding common shares for 2,073,262 series A preferred shares with Braeburn BVBA.
- In September 2015, the investment of shares in Titan was transferred from Braeburn BVBA to Braeburn Pharmaceuticals, Inc.
- In November 2015, Braeburn BVBA was voluntarily dissolved, with resulting investment in Braeburn Pharmaceuticals, Inc. transferring to ATP IV and its subsidiaries. All Braeburn BVBA common shares were retired by ATP IV and its subsidiaries upon dissolution. See Note 13.

As of December 31, 2015, the Company is authorized to issue 60,000,000 shares of common stock, $0.0001 par value per share, with 0 shares issued and outstanding, all of which is Braeburn Pharmaceuticals. The voting, dividend and liquidation rights of the holders of the common stock are subject to and qualified by the rights, power and preferences of the holder of the preferred stock. The holders of the common stock are entitled to one vote for each share of common stock.

12. Preferred stock

As of December 31, 2015, the Company is authorized to issue 201,000,000 shares of preferred stock, $0.0001 par value per share, of which 200,000,000 are designated as Convertible Series A preferred stock and the remaining 1,000,000 to be designated by the Board of Directors from time to time in one or more additional series. As of December 31, 2015, 119,053,262 shares of Series A preferred stock were outstanding, which can be converted at the holder's discretion into 8,818,760 shares of common stock.

Liquidation preferences

In the event of any voluntary or involuntary liquation, dissolution, or winding up of the Company, the holders of shares of Series A preferred stock then outstanding are entitled to be paid out of the assets of the Company available for distribution to its shareholders before any payment shall be made to the holders of the common stock, an amount per share equal to the greater of (i) the Series A original issue price plus any accruing dividends accrued but unpaid or (ii) the amount per share as would have been payable had all shares of Series A preferred stock been converted to common stock immediately prior to such liquidation.

Voting rights

Each holder of outstanding shares of Series A preferred stock is entitled to one-fifth of a vote for each outstanding share.

Dividends

The holders of the convertible preferred stock are entitled to receive, when, as, and if declared by the Board of Directors, cumulative dividends at a rate of 8% of the original base amount per annum from the date of issuance. The base amount for a share of Series A preferred stock is an amount equal to the Series A original issue price plus the amount of any previously accrued but unpaid dividends. Accruing dividends accrue from day to day, and are cumulative.

Conversion rights

Each share of Series A preferred stock is convertible, at the option of the holder, at any time, at a rate of 13.5 preferred shares for one fully paid and non-assessable share of common stock.

13. Dissolution of Braeburn BVBA

In November 2015, Braeburn BVBA was voluntarily legally dissolved. As discussed in Note 1, this transaction represents a transaction among entities under common control and has been accounted for in a manner similar to the pooling of interests' method, which requires that the merged entities be combined at their historical cost. The Company's consolidated financial statements and related footnotes are presented as if the transaction occurred at the beginning of the earliest date presented. All remaining net assets of Braeburn BVBA, which consisted solely of cash, transferred to ATP IV and its subsidiaries. The transfer was accounted for as a liquidating cash dividend of $754,000. At time of dissolution, Braeburn BVBA had no additional paid-in capital, as common shares of Braeburn BVBA were issued at par. Therefore, the Company accounted for the liquidating dividend as an increase in accumulated deficit. Upon dissolution, the remaining Braeburn BVBA common shares were cancelled. The preferred shares held by Braeburn BVBA of Braeburn Inc. were transferred to ATP IV and its subsidiaries. As of September 30, 2016, all equity of the Company was held by ATP IV and its subsidiaries.

14. Income taxes

The components for the income tax expense (benefit) are as follows for the years ended December 31, 2015 and 2014:

	December 31,	
	2015	2014
Current:		
Federal	$ –	$–
State	–	–
Foreign	1,617,786	–
Total current provision (benefit)	$ 1,617,786	$–
Deferred Provision:		
Federal	$ (15,900)	$–
State	(1,900)	–
Foreign	–	–
Total deferred provision (benefit)	$ (17,800)	$–
Total	$ 1,599,986	$–

The United States and foreign components of (loss)/ income from operations before taxes are as follows for the years ended December 31, 2015 and 2014:

	December 31,	
	2015	2014
United States	$ (28,454,754)	$ 78,253
Foreign	(10,508,122)	(40,533,949)
Total (loss) / income from operations before taxes	$ (38,962,876)	$ (40,455,696)

Significant components of the Company's deferred tax assets and liabilities consist of the following for the years ended December 31, 2015 and 2014:

	December 31,	
	2015	2014
Non-current deferred tax assets:		
Intangible assets	$ 17,586,855	$ 15,856,335
Net operating loss carryforwards	11,664,355	11,735,359
Tax credits	641,902	–
Investment in Titan shares	–	718,039
Accrued expenses	322,197	–
Total gross deferred tax assets	30,215,309	28,309,733
Valuation allowance	(29,836,647)	(28,279,145)
Total non-current deferred tax assets, net of valuation allowance	$ 378,662	$ 30,588
Non-current deferred tax liabilities:		
Fixed assets	$ (17,614)	$ (30,588)
Investment in Titan shares	(361,048)	–
Net non-current deferred tax liability	(378,662)	(30,588)
Net deferred tax asset (liability)	$ –	$ –

At December 31, 2015 and 2014, the Company has provided a full valuation allowance against its net deferred tax assets in both the US and Belgium tax jurisdictions, since realization of these benefits is not more likely than not. The valuation allowance increased approximately $1.6 million from 2014 to 2015. At December 31, 2015, the Company had federal and state net operating loss carryforwards of approximately $29.7 million and $29.7 million, respectively. These net operating loss carryforwards expire in various amounts starting in 2033. At December 31, 2015, the Company had federal research credit carryforwards in the amount of $0.6 million. These carryforwards begin to expire in 2035. The utilization of the federal net operating loss carryforwards and credit carryforwards will depend on the Company's ability to generate sufficient taxable income prior to the expiration of the carryforwards. In addition, the maximum annual use of net operating loss and research credit carryforwards is limited in certain situations where changes occur in stock ownership.

As of December 31, 2015 and 2014, the Company had no unrecognized tax benefits. The Company has analyzed its filing positions in all significant federal and state jurisdictions where it is required to file income tax returns, as well as open tax years in these jurisdictions. The Company has all tax years (2012 - 2015) open to examination by federal tax and state tax jurisdictions. No income tax returns are currently under examination by taxing authorities.

Taxes computed at the statutory federal income tax rate of 35% are reconciled to the provision for income taxes as follows for the years ended December 31, 2015 and 2014:

	2015		2014	
	Amount	% of pretax earnings	Amount	% of pretax earnings
United States federal tax at statutory rate	$(13,637,007)	35.0%	$(14,159,494)	35.0%
State taxes (net of deferred benefit)	(1,202,213)	3.1%	3,306	(0.0)%
Nondeductible expenses	2,951	0.0%	18,521	(0.1)%
Research and development credits	(641,902)	1.6%	–	0.0%
Foreign tax rate differential	106,132	(0.3)%	409,393	(1.0)%
Taxable gain on distrubution of IP	16,275,652	(41.6)%	–	0.0%
Nontaxable gain on Titan shares	(297,413)	0.8%	–	0.0%
Recapture of Titan shares loss in Belgium	(558,912)	1.4%	–	0.0%
Other, net	(4,804)	0.0%	–	0.0%
Change in valuation allowance	1,557,502	(4.1)%	13,728,274	(33.9)%
Provision for income taxes	$ 1,599,986	(4.1)%	$ –	0.0%

15. Commitments and contingencies

Legal proceedings

The Company may become involved in or subject to, routine litigation, claims, disputes, proceedings and investigations in the ordinary course of business, which in management's opinion will not have a material effect on its financial condition, cash flows or results of operations.

16. Related party transactions

Transactions with affiliates of common parent (ATP IV)

The Company transacts with certain affiliates of our parent, ATP IV. Transactions involving related parties cannot be presumed to be carried out on an arm's-length basis, as the requisite conditions of competitive, free-market dealings may not exist.

As of December 31, 2015, due to affiliates were comprised of the following:

	December 31,	
	2015	2014
Due to Apple Tree Life Sciences	$ 64,582	$ 7,120,436
Due to ATP IV	—	3,645,436
Total due to affiliates	$ 64,582	$ 10,765,872

As of December 31, 2015 and 2014, due from affiliates comprised of the following:

	December 31,	
	2015	2014
Due from Apple Tree Consolidated SARL	$—	$ 198,184
Total due from affiliates	$—	$ 198,184

Apple Tree Life Sciences

The Company receives certain services from Apple Tree Life Sciences, or ATLS, a subsidiary of ATP IV. These include administrative services relating to accounting, finance, legal, human resources, and other administrative services. As well, these services also include research and development services including regulatory and clinical support. ATLS may charge us a service fee consisting of allocated internal time incurred on our projects by their employees, plus a pre-determined mark-up. Further, the Company pays or reimburses ATLS at cost for any expenses incurred by third parties on our behalf. Expenses from services rendered by ATLS, inclusive of the mark-up, for 2015 and 2014 are as follows:

	December 31,	
	2015	2014
Expenses from services by ATLS, inclusive of markup	$ 876,011	$ 1,066,202

During the years ended December 31, 2015 and 2014, the Company provided certain accounting and finance services to ATLS, consisting of allocated internal time by its employees on ATLS projects, of which are reimbursed to the Company. As of December 31, 2015 and 2014, those amounts are as follows:

	December 31,	
	2015	2014
Reimbursement from services provided to ATLS	$ 48,581	$ 84,309

Apple Tree Investments SARL

In December 2014, Braeburn BVBA entered into a five-year loan agreement with Apple Tree Investments SARL, a subsidiary of ATP IV, for €300,000 (equivalent to $364,650 USD) with an annual interest rate of 7%, payable at maturity date. Accrued interest at the end of December 31, 2014 was $0. The loan was repaid (with accrued interest of $19,781) in November 2015, prior to Braeburn BVBA's dissolution.

Apple Tree Consolidated SPRL

Braeburn BVBA receives reimbursement for certain expenses paid on behalf of Apple Tree Consolidated SPRL, a subsidiary of ATP IV. As of December 31, 2014, Apple Tree Consolidated SPRL owed Braeburn BVBA $198,184. As of December 31, 2015, the amount was $0, as all amounts were settled prior to dissolution.

17. Subsequent events

The Company has evaluated events that have occurred subsequent to December 31, 2015 through the date that the financial statements were available to be issued.

In January 2016, the Company announced that the Psychopharmacologic Drugs Advisory Committee (PDAC) of the FDA voted 12 to 5 in favor of approving Probuphine for the maintenance treatment of opioid addiction in clinically stable patients receiving 8 mg or less per day of buprenorphine.

In January 2016, the Company received a $23.75 million capital contribution from ATP IV and its subsidiaries in exchange for 23,750,000 preferred shares with a par value of $0.0001.

In January 2016, the Company increased the size of its board of directors to five while appointing four new board members: Behshad Sheldon, Braeburn Pharmaceuticals; David McIntyre, Apple Tree Partners; Dennis Langer; and Argeris Karabelas. The Company granted both Langer and Karabelas 23,762 RSU's, respectively, under the 2015 Plan with a vesting start date of September 1, 2015.

In January 2016, the Company announced that Jonathan Young resigned as Secretary of the Corporation and was succeeded by appointee Asher Rubin.

In February 2016, the Company entered in a sublicense agreement with Knight Therapeutics, Inc., or Knight, a specialty pharmaceutical company, whereby it granted to Knight the rights to commercialize Probuphine in Canada. The Company is the sole distributor to Knight, for which it has agreed to supply the product at an agreed upon price. The Company is entitled to receive tiered royalties on annual net sales ranging from ten to thirty-five percent.

In February 2016, the Company entered into a supply agreement with Titan Pharmaceuticals to purchase Probuphine implants at a fixed cost per implant. The term of the agreement is for six months, with an automatic renewal of an additional six months, unless (i) the Company provides written notice to Titan wishing to terminate, or (ii) the Company enters into a separate supply agreement with another manufacturer.

In May 2016, the FDA approved Probuphine for the maintenance treatment of opioid addiction in patients who have sustained clinical stability on low-to-moderate doses of buprenorphine, specifically 8 mg or less per day.

In May 2016, the Company received a $30 million capital contribution from ATP IV and its subsidiaries in exchange for 30,000,000 preferred shares with a par value of $0.0001.

In June 2016, the Company received a $15 million capital contribution from ATP IV and its subsidiaries in exchange for 15,000,000 preferred shares with a par value of $0.0001.

In June 2016, the Company paid to Titan a $15 million milestone payment for FDA approval (see Note 2 for more information).

In July 2016, the Company amended its certificate of incorporation with the state of Delaware to increase the number of common shares authorized to issue to 90,000,000 with a $0.0001 par value and to increase the number of preferred shares authorized to issue to 351,000,000 with a $0.0001 par value.

In July 2016, the Company granted 62,962 non-qualified stock options to new employees under the 2015 Equity Incentive Plan with one quarter of these options vesting on the first anniversary of the grant date, and the remainder vesting in twelve equal quarterly installments.

In August 2016, the Company received a $35 million capital contribution from ATP IV and its subsidiaries in exchange for 35,000,000 preferred shares with a par value of $0.0001.

In September 2016, the Company entered into an agreement with Avella of Dear Valley Inc., or Avella, to serve as an exclusive specialty pharmacy distributor of Probuphine, consistent with all of the REMS obligations to restrict distribution only to REMS-certified healthcare providers with the necessary DEA registration.

In October 2016, the Company announced that Marshall Woodworth, Chief Financial Officer and Treasurer, is no longer with the Company, and appointed David McIntyre as Chief Financial Officer.

In October 2016, the Company entered into the first amendment to the Camurus license agreement. The aforementioned amendment granted the Company the exclusive rights to develop and commercialize BB0417, a combination product containing buprenorphine and granisetron for the treatment of pain. The amendment obligates the Company to reimburse Camurus for up to $1.5 million of a Camurus-led Phase I clinical trial for BB0417. As well, the amendment adds an additional $7 million in one-time, non-refundable regulatory milestones. Further, the amendment adds BB0417 towards the aggregate sales milestones, as well as the royalty in the licensed territory, included in the original Camurus agreement.

In October 2016, the Company granted 83,672 non-qualified stock options to new employees under the 2015 Equity Incentive Plan with one quarter of these options vesting on the first anniversary of the grant date, and the remainder vesting in twelve equal quarterly installments. At the same time, the Company also granted an additional 1,236,581 restricted stock units and 199,833 non-qualified stock options to various individuals, with these equity grants vesting in forty-eight monthly installments with effect from the relevant vesting commencement dates, ranging from January 2016 through September 2016.

In October 2016, the Company received a $22 million capital contribution from ATP IV and its subsidiaries in exchange for 22,000,000 preferred shares with a par value of $0.0001 per share.

Braeburn Pharmaceuticals, Inc. and subsidiaries
Condensed consolidated balance sheets (unaudited)
As of September 30, 2016 and December 31, 2015

	September 30, 2016	December 31, 2015	Pro forma September 30, 2016
Current assets:			
Cash and cash equivalents	$ 23,528,350	$ 5,507,371	$ 23,528,350
Restricted cash	1,210,564	225,000	1,210,564
Accounts receivable	330,853	30,248	330,853
Inventory	773,948	–	773,948
Prepaid expenses and other current assets	3,596,326	2,761,265	3,596,326
Investment in Titan Pharmaceuticals	–	5,045,455	–
Total current assets:	29,440,041	13,569,339	29,440,041
Intangible assets, net	14,342,196	–	14,342,196
Property and equipment, net	11,407,478	423,234	11,407,478
Deposits and other assets	1,612,709	97,813	1,612,709
Total assets:	$ 56,802,424	$ 14,090,386	$ 56,802,424
Current liabilities:			
Accounts payable	$ 8,757,475	$ 1,319,296	$ 8,757,475
Accrued expenses and other current liabilities	9,711,750	5,994,780	9,711,750
Total current liabilities:	18,469,225	7,314,076	18,469,225
Financing obligation and other long-term liabilities	4,659,853	9,214	4,659,853
Total liabilities:	23,129,078	7,323,290	23,129,078
Commitments and contingencies (notes 1, 9, 11, and 17)			
Shareholders' Equity:			
Common shares: $0.0001 par value; 90,000,000 shares authorized; 0 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively; 17,495,055 shares issued and outstanding pro forma as of September 30, 2016	–	–	1,750
Preferred shares: $0.0001 par value; 351,000,000 shares authorized; 222,803,262 and 119,053,262 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively; 0 shares issued and outstanding pro forma as of September 30, 2016	22,280	11,905	–
Additional paid-in-capital	233,571,575	129,831,950	238,133,617
Accumulated deficit	(199,920,509)	(123,104,414)	(204,462,021)
Accumulated other comprehensive income	–	27,655	–
Total shareholders' equity:	33,673,346	6,767,096	33,673,346
Total liabilities and shareholders' equity:	$ 56,802,424	$ 14,090,386	$ 56,802,424

See accompanying notes to condensed consolidated financial statements

Braeburn Pharmaceuticals, Inc. and subsidiaries
Consolidated statements of operations and comprehensive loss (unaudited)
For the nine months ended September 30, 2016 and 2015

	September 30, 2016	September 30, 2015
Revenues		
Product sales, net	$ 41,543	$ –
Cost of product sales	44,201	–
Gross profit	(2,658)	–
Expenses		
Research and development	50,932,838	16,345,096
Selling, general and administrative	27,094,903	4,030,599
Total expenses	78,027,740	20,375,694
Loss from operations	(78,030,399)	(20,375,694)
Other income / (expense)		
Interest income	402	–
Interest expense	–	(17,365)
Gain on sale of investments, net	1,216,716	–
Foreign currency transaction loss	(2,814)	(629,334)
Total other income / (expense), net	1,214,304	(646,698)
Loss before income tax expense	(76,816,095)	(21,022,393)
Income tax expense	–	1,601,896
Net loss	$(76,816,095)	$(22,624,289)
Other comprehensive loss		
Unrealized gain during period, net of tax benefit of $0 and $0, respectively	(27,655)	1,635,257
Comprehensive loss	$(76,843,750)	$(20,989,032)
Net loss per common share, basic and diluted		$ (0.26)
Net loss per preferred share, basic and diluted	$ (0.45)	$ (0.26)
Weighted average basic and diluted common shares outstanding		76,019,503
Weighted average basic and diluted preferred shares outstanding	170,923,700	10,000,000
Pro forma net loss per common share, basic and diluted	$ (5.66)	
Pro forma weighted average basic and diluted common shares outstanding	14,355,563	

See accompanying notes to condensed consolidated financial statements

Braeburn Pharmaceuticals, Inc. and subsidiaries
Consolidated statements of shareholders' equity (unaudited)
For the nine months ended September 30, 2016

	Preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total shareholders' equity (deficit)
	Shares	Amount	Shares	Amount				
Balance, December 31, 2015	119,053,262	$ 11,905	–	$–	$129,831,950	$ 27,655	$ (123,104,414)	$ 6,767,096
Net proceeds from sale of preferred stock of Braeburn Pharmaceuticals, Inc.	103,750,000	10,375	–	–	103,739,625	–	–	103,750,000
Other comprehensive income, net	–	–	–	–	–	(27,655)	–	(27,655)
Net loss	–	–	–	–	–	–	(76,816,095)	(76,816,095)
Balance, September 30, 2016	222,803,262	$22,280	–	$–	$ 233,571,575	$ –	$(199,920,509)	$ 33,673,346

See accompanying notes to condensed consolidated financial statements

Braeburn Pharmaceuticals, Inc. and subsidiaries
Consolidated statements of cash flows (unaudited)
For the nine months ended September 30, 2016 and 2015

	September 30, 2016	September 30, 2015
Cash flows from operating activities:		
Net loss	$ (76,816,095)	$(22,624,289)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation / Amortization	753,865	53,822
Foreign currency remeasurement	–	745,956
Realized gain on marketable investment securities	(1,216,716)	–
(Increase) decrease in operating assets:		
Inventory	(773,948)	–
Accounts recievable	(300,606)	–
Prepaid expenses and other assets	(2,349,957)	(369,626)
Increase (decrease) in operating liabilities		
Accounts payable	6,785,395	(249,019)
Accrued expenses and other current liabilities	3,781,553	2,174,509
Other liabilities	42,327	–
Due to Apple Tree Partners IV	–	(3,641,723)
Due to Apple Tree Life Sciences	(64,582)	(6,964,912)
Net cash used in operating activities	(70,158,764)	(30,875,282)
Cash flows from investing activities:		
Capital expenditures	(5,819,209)	(78,705)
Sale of marketable investment securities	6,234,516	–
Acquisition of intangible assets	(15,000,000)	–
Increase in restricted cash	(985,564)	(225,000)
Net cash used in investing activities	(15,570,257)	(303,705)
Cash flows from financing activities:		
Proceeds from sale of common shares	–	20,049,260
Proceeds from sale of preferred shares	103,750,000	10,000,000
Net cash provided by financing activities	103,750,000	30,049,260
Net increase (decrease) in cash and cash equivalents	18,020,979	(1,129,727)
Effect of exchange rates on cash and cash equivalents	–	(735,130)
Cash and cash equivalents, beginning of period	5,507,371	8,755,204
Cash and cash equivalents, end of period	$ 23,528,350	$ 6,890,347
Supplemental disclosure of cash flow information		
Cash paid for income taxes	$ 4,000	$ 42,436
Supplemental disclosures of non cash investing activities		
Capital expenditures incurred but not yet paid	$ 698,929	$ –
Recognition of asset and financing obligation related to facility build out	$ 4,608,313	$ –

See accompanying notes to condensed consolidated financial statements

Braeburn Pharmaceuticals Inc.
Notes to condensed consolidated financial statements
September 30, 2016
(Amounts in $USDs unless otherwise indicated)

1. Nature of business, basis of presentation and summary of significant accounting policies

Braeburn Pharmaceuticals, Inc. is a specialty pharmaceutical company focusing on novel, long-acting implantable and injectable therapies for serious neurological and psychiatric disorders, including addiction, pain, and schizophrenia. The Company's first product, Probuphine, was approved by the FDA on May 26, 2016 for the maintenance treatment of opioid addiction in patients who have achieved sustained clinical stability on a dose equivalent to 8 mg per day or less of oral buprenorphine. The Company is part of the Apple Tree Partners family of companies.

The Company, a Delaware incorporated entity, was founded in 2012 as a wholly-owned subsidiary of Braeburn BVBA, a Belgium domiciled entity also founded in 2012. Together, the Companies were a wholly owned portfolio company of ATP IV and its subsidiaries. In November 2015, Braeburn BVBA was voluntarily dissolved, and as a result, Braeburn Pharmaceuticals Inc. became a wholly owned portfolio company of ATP IV and its subsidiaries. See Note 15. The financial statements and accompanying notes thereto refer to the consolidated operations of Braeburn Pharmaceuticals, Inc. and Braeburn BVBA.

The Company has its principal executive offices in Princeton, New Jersey.

Since inception, the Company has incurred losses and negative cash flows from operations, and expects to continue to incur losses. As of September 30, 2016, the Company has sustained cumulative losses of approximately $199.9 million. The Company expects to incur substantial expenditures in the foreseeable future for the commercialization of Probuphine and development of its product candidates. The Company has historically funded its operations to date through issuance of common and preferred equity securities to its parent company, ATP IV. The Company will require additional financing to commercialize Probuphine, develop its product candidates, prepare regulatory filings and obtain regulatory approvals, and establish its manufacturing operations, sales, and marketing capabilities. The Company will seek funds through additional equity financings from ATP IV or through other sources of financing. Accordingly, there is substantial doubt regarding the Company's ability to continue as a going concern. The Company's failure to raise capital as and when needed would have a material adverse impact on its financial condition, solvency, and ability to pursue its business strategies. The Company's liquidity over the next 12 months could be materially affected by, among other things: the successful launch and commercialization of its lead product, Probuphine; costs related to its development of the CAM2038, BBO817, BBO417 and BB1216 clinical programs; the continued financing through equity offerings of its parent company, ATP IV; and other factors.

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with GAAP for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. These unaudited consolidated interim financial statements have been prepared on the same basis as the audited consolidated financial statements and in the opinion of management, reflect all

adjustments of a normal, recurring nature that are necessary for the fair statement of the Company's financial position as of September 30, 2016 and its results of operations and cash flows for the nine months ended September 30, 2016 and 2015. The results for the nine months ended September 30, 2016 are not necessarily indicative of the results expected for the full fiscal year or any future period. All references to September 30 in these footnotes are unaudited.

All Braeburn Pharmaceuticals share and per share amounts give retroactive effect to a 1 for 2.7 reverse split of our common stock effected on January , 2017.

The balance sheet as of December 31, 2015 was derived from the audited financial statements. The accompanying unaudited financial statements and notes thereto should be read in conjunction with the audited financial statements for the years ended December 31, 2015 and 2014.

In November 2015, Braeburn BVBA was dissolved into the Company (See Note 15). Due to the dissolution of Braeburn BVBA, the Company has presented the consolidated financial statements, reflecting a downstream merger with Braeburn BVBA, which was a transaction between entities of common control. This transaction has been accounted for in a manner similar to a pooling of interests of companies under common control which requires that merged entities be combined at their historical cost. Accordingly, the accompanying consolidated financial statements are presented as if the Transaction occurred on January 1, 2014.

The unaudited pro forma consolidated balance sheet has been prepared assuming (i) the conversion of all outstanding convertible preferred stock into shares of common stock at the applicable conversion rate of 13.5 preferred shares to 1 common share and (ii) the fulfilment of the service-based vesting and liquidity-based vesting criteria of the Company's restricted stock units granted under the 2015 Equity Incentive Plan (as discussed in Note 12), which are assumed to be issued upon the completion of the Company's proposed initial public offering. The pro forma shareholders' equity does not assume any proceeds from the Company's proposed initial public offering, and is based on the Company's outstanding convertible preferred stock on September 30, 2016.

Significant accounting policies

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant estimates in these consolidated financial statements have been made in connection with certain accruals related to the Company's research and development expenses, the provision for or benefit from income taxes, the fair value of common stock, and valuation allowances against net deferred tax assets. Actual results could differ from those estimates. Changes in estimates are reflected in reported results in the period in which they become known.

Consolidation

The consolidated unaudited condensed financial statements include the accounts of Braeburn Pharmaceuticals, Inc. and Braeburn BVBA, which was voluntarily dissolved in November 2015. Subsequent to the dissolution, the financial statements are that of Braeburn Pharmaceuticals, Inc. All inter-company accounts, transactions, and profits have been eliminated in consolidation.

Restricted cash

Restricted cash as of September 30, 2016 represents amounts held as collateral with a bank in relation to the Company's employee credit card programs, as well as the Company's lease of a manufacturing facility in North Carolina.

Inventories

The Company reviews all facts and circumstances surrounding pre-approved products for proper classification as inventory or expense. In the United States, the FDA must approve pharmaceutical products before they can be sold or prescribed by doctors. Unless specific facts and circumstances exist that demonstrate with reasonable certainty that the product will receive FDA approval, the Company expenses all inventory costs as research and development until FDA approval.

Prior to the receipt of FDA approval for the Company's lead product Probuphine on May 26, 2016, the Company determined to expense all previously incurred inventory costs associated with Probuphine as research and development costs. Foremost among the factors that the Company considered when determining inventory was not capable of being held for sale and should instead be expensed was the inherent uncertainty as to whether the FDA would grant approval for Probuphine. Specifically, the Company had previously expected to receive FDA approval for Probuphine in 2013 following a positive endorsement from a FDA Advisory Committee, but approval was denied pursuant to a Complete Response Letter that the Company received in April 2013. The Company expensed approximately $1.1 million in commercial lots of Probuphine prior to approval as research and development expense. Subsequent to FDA approval of Probuphine, the Company began capitalizing costs related to the purchase and manufacture of Probuphine.

Inventories are stated at the lower of cost or net realizable value. As of September 30, 2016, the Company's inventory consisted mostly of raw materials of Probuphine and costs to package and label finished kits of Probuphine.

The Company analyzes its inventory levels quarterly, and writes down inventory that has become obsolete, or has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. The Company did not have any write-downs of inventory for the nine months ended September 30, 2016 and 2015, respectively.

Concentrations of credit risk and economic dependency

The financial instruments that potentially subject the Company to concentrations of credit risk are cash, cash equivalents, and accounts receivable.

The Company invests excess cash in high quality, money market instruments with a major financial institution. Such amounts may at times exceed federally insured limits. The Company has not experienced any significant losses on its cash or cash equivalents.

The Company's accounts receivable represents amounts due from customers of Probuphine. The Company performs credit evaluations of customers and set credit limits to minimize exposure for potential credit losses. An allowance for doubtful accounts is maintained based upon the aging of accounts receivable.

Impairment of long-lived assets

The useful life of the Company's long-lived assets is determined using the period of expected future cash flows, adjusted for entity-specific factors. Current facts or circumstances are periodically evaluated to determine if the carrying value of depreciable assets to be held and used may not be recoverable. If such circumstances exist, an estimate of undiscounted future cash flows generated by the long-lived asset, or the appropriate grouping of assets, is compared to the carrying value to determine whether an impairment exists at its lowest level of identifiable cash flows. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. An estimate of the asset's fair value is based on quoted market prices in active markets, if available. If quoted market prices are not available, the estimate of fair value is based on various valuation techniques using Level 3 fair

value inputs, including a discounted value of estimated future cash flows. There were no impairments of long-lived assets as of September 30, 2016 and December 31, 2015, respectively.

Leases

The Company has non-cancelable leases for its manufacturing and office spaces. The leases are reviewed for classification as operating or capital leases. For operating leases, rent is recognized on a straight-line basis over the lease period. For capital leases, the Company records the leased asset with a corresponding liability. Payments are recorded as reductions to the liability with an appropriate interest charge recorded based on the then-outstanding remaining liability.

The Company considers the nature of the renovations and the Company's involvement during the construction period of newly leased office space to determine if it is considered to be the owner of the construction project during the construction period. If the Company determines that it is the owner of the construction project, it is required to capitalize the fair value the asset, including potentially the building, construction costs incurred, and capitalized interest, on its consolidated balance sheet along with a corresponding financing liability ("build-to-suit accounting"). Upon occupancy for build-to-suit leases, the Company assesses whether the circumstances qualify for sales recognition under the sale-leaseback accounting guidance. If the lease meets the sale-leaseback criteria, the Company will remove the asset and related financial obligation from the balance sheet and evaluate the lease for treatment as a capital or operating lease. If upon completion of construction, the project does not meet the sale-leaseback criteria, the leased property will be treated as a capital lease for financial reporting purposes.

Investments

The Company's investments are comprised of securities classified as available-for-sale. Available-for-sale securities are carried at fair value, with changes in fair value reported in *Other comprehensive income/ (loss)* until realized.

The Company regularly evaluates its investments for impairment. When a decline in fair value, if any, is determined to be other-than-temporary, an impairment charge is recorded and a new cost basis in the investment is established.

Fair value of financial instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, based on the Company's principal or, in absence of a principal, most advantageous market for the specific asset or liability.

The Company uses a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent to their initial measurement. The hierarchy requires the Company to use observable inputs when available, and to minimize the use of unobservable inputs when determining fair value. The three tiers are defined as follows:

- Level 1—Unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
- Level 2—Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (i.e., interest rates,

yield curves, etc.), and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

- Level 3—Inputs are unobservable and reflect the Company's assumptions as to what market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available.

Cash and cash equivalents, as well as restricted cash, are reflected in the accompanying unaudited condensed financial statements at fair value. The carrying amount of receivables, inventories, accounts payable, accrued expenses and other liabilities approximate fair value due to the short-term nature of those instruments.

Revenue recognition

Product sales

The Company recognizes revenue from product sales when: (i) the price is substantially fixed or determinable (ii) the buyer has paid, or is obligated to pay, and the obligation is not contingent on resale of the product (iii) the obligation would not be changed in the event of theft or physical damage to the product (iv) there is no significant obligation for future performance to directly bring about resale of the product by the buyer and (v) returns can be reasonably estimated. Currently, product sales represent sales of Probuphine, which was approved by the FDA in May 2016. The Company records as deferred revenue any amounts not satisfying all revenue recognition criteria.

The Company launched Probuphine under a "buy and bill" distribution model under which individual REMS certified healthcare providers placed orders to purchase Probuphine through RxCrossroads, the Company's third-party logistics provider. A reimbursement hub managed by RxCrossroads assists with benefits verification. The Company's agreements with RxCrossroads require that Probuphine kits cannot be shipped until the healthcare provider placing the order satisfies all requirements of its REMS program, including verification that the provider holds a DEA registration number for the address to which product is being shipped and that the provider placing the order has been certified under the Probuphine REMS training program.

In July 2016, the DEA favorably answered the Company's written request to supplement "buy and bill" distribution with use of a specialty pharmacy model, whereby healthcare providers could prescribe Probuphine and have product shipped directly to the healthcare provider's practice setting in the name of the patient. The Company has entered into an agreement with Avella to serve as an exclusive specialty pharmacy distributor of Probuphine consistent with all of the REMS obligations to restrict distribution only to REMS-certified healthcare providers with the necessary DEA registration. This agreement does not prevent institutional pharmacies from placing orders under the "buy-and-bill" model on behalf of healthcare providers practicing in an institutional setting.

Gross-to-net adjustments against receivable balances primarily relate to cash discounts and rebates for co-pay/co-insurance reimbursements, and are recorded in the same period the related revenue is recognized, resulting in a reduction to product sales revenue and the recording of accounts receivable net of allowance. Gross-to-net adjustment accruals related to estimated Medicaid rebates, other sales rebates, and returns are recognized in the same period the related revenue is recognized, resulting in a reduction to product sales revenue, and are included in accrued expenses in the accompanying unaudited condensed consolidated balance sheets.

As Probuphine is a new product, is not an extension of an existing line of product, and the Company has no historical experience with products in a similar therapeutic category, revenue is deferred until the right

of return no longer exists and pricing is fixed or determinable (e.g. sufficient historical experience to estimate gross-to-net adjustments are developed). Specific considerations for Probuphine are as follows:

- *Rebates:* Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or legal requirements with public sector (e.g. Medicaid) benefit providers. The allowance for rebates is based on statutory rebate rates and expected utilization. The Company's estimate for expected utilization for rebates is based in part on actual and pending prescriptions for which it has validated the insurance benefits.

  Allowances for rebates also include co-pay or co-insurance rebates to patients. The Company may assist patients covered under private insurance (non-federal health care programs) for out-of-pocket costs due to co-pays or co-insurance, up to a maximum benefit based upon patient financial need. The Company also may assist patients who self-pay for out-of-pocket costs up to a maximum benefit based upon patient financial need. The Company's estimate for allowance for rebates for co-pay or co-insurance is based in part on actual and pending claim data received for reimbursement.

- *Returns:* Under the "buy and bill" model, the Company will accept product returns within 30 days of receipt by physician. Under the Avella agreement, the Company will only accept returns on damaged in transit product if notified within 2 days of receipt. The Company defers revenue until the right of return lapses.

- *Cash Discounts:* The Company extends a cash discount on all sales to the Company's exclusive specialty pharmacy distributor, Avella.

Share-based compensation

The Company recognizes all share-based payments to employees, including grants of employee stock options and RSUs, at estimated fair value. The Company's share-based awards contain a performance condition under *ASC-718* and are not exercisable until the occurrence of a liquidation event, defined as 180 days after an initial public offering or certain change of control transactions. If and when a liquation event occurs, the Company will amortize the fair value of stock option or RSU grants, as measured on the grant date of the award, on a straight-line basis over the remaining service period of the individual stock option or RSU grant, which generally equals the remaining vesting period. The Company does not have sufficient history to estimate the volatility of its common stock price or the expected life of the options. The Company calculates expected volatility based on reported data for similar publicly traded companies for which historical information is available and will continue to do so until the historical volatility of its common stock is sufficient to measure expected volatility for future option grants.

Segment information

Operating segments are defined as a component of a public entity that (i) engages in business activities from which it may earn revenues and incur expenses and (ii) has discrete financial information that is readily available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company's chief decision maker, who is the Chief Executive Officer, reviews operating results on a consolidated basis to make decisions about allocating resources and assessing performance for the entire Company. The Company views its operations and manages its business as one operating segment.

Net income / (loss) per common share

In accordance with *ASC-260, Earnings Per Share*, the Company used the two-class method for calculating basic earnings per share and applied the if-converted method in calculating diluted earnings per share for the nine months ended September 30, 2016 and 2015. Basic net income / (loss) per common share is the amount of allocated income / (loss) for the period, divided by the sum of the weighted average shares of common stock outstanding during the reporting period. Diluted income / (loss) per common share is the allocated amount of income / (loss) for the period divided by the sum of the weighted average shares of common stock outstanding during the reporting period and weighted averages shares that would have been outstanding assuming the issuance of common shares for all dilutive potential common shares.

Deferred Initial Public Offering Costs

The Company defers specific incremental costs directly attributable to a proposed or actual offering of securities and charges these deferred costs against the gross proceeds of the offering. As of September 30, 2016, the Company has deferred $168,000 in initial public offering costs.

Recent accounting pronouncements

In November 2016, the Financial Accounting Standards Board, or FASB, issued ASU 2016-18, Restricted Cash. The ASU requires that the statement of cash flows include restricted cash in the beginning and end-of-period total amounts shown on the statement of cash flows, and that the statement of cash flows explain changes in restricted cash during the period. The guidance will be effective for the Company for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted; however, adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The Company does not expect the adoption of ASU 2016-18 to have an impact on its financial position or result of operations and expects the impact to be disclosure only.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows. The ASU provides updated guidance on eight classification issues related to the statement of cash flows: debt prepayments and extinguishment costs, settlement of zero-'coupon bonds, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies, distributions received from equity method investees, beneficial interests in securitization transactions and separately identifiable cash flows and application of the predominance principle. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The Company is currently assessing the potential impact of adopting ASU 2016-15 on its financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting. The ASU is intended to simplify accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and the classification of share-based awards on the statement of cash flows. The ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted. The Company is evaluating the timing of adopting ASU 2016-09, which contains both retrospective and prospective application of certain data. The Company is currently evaluating the impact of ASU 2016-09 on its financial position and results of operations.

In February 2016, the FASB issued ASU 2016-02, Leases. The ASU is intended to improve financial reporting about leasing transactions. The ASU will require organizations that lease assets referred to as ''Lessees'' to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. An organization is to provide disclosures designed to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from leases. These disclosures include qualitative and quantitative requirements concerning additional information about the amounts recorded in the financial statements. Under the new guidance, a lessee will be required to recognize assets and liabilities for leases with lease terms of more than 12 months. Consistent with current GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a finance or operating lease. However, unlike current GAAP which requires only capital leases to be recognized on the balance sheet, the new ASU will require both types of leases (operating and capital) to be recognized on the balance sheet. The FASB lessee accounting model will continue to account for both types of leases. The capital lease will be accounted for in substantially the same manner as capital leases are accounted for under existing GAAP. The operating lease will be accounted for in a manner similar to operating leases under existing GAAP, except that lessees will recognize a lease liability and a lease asset for all of those leases.

Public companies will be required to adopt the new leasing standard for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. Transition will require application of the new guidance at the beginning of the earliest comparative period presented. The Company is currently in the process of evaluating the impact that this new leasing ASU will have on its financial statements.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers, or ASU 2014-09. ASU 2014-09 supersedes the revenue recognition requirements of ASC-605, Revenue Recognition, and most industry-specific guidance throughout the ASC, resulting in the creation of ASC-606, Revenue from Contracts with Customers. ASU 2014-09 requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. This ASU provides alternative methods of adoption. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers, Deferral of the Effective Date, or ASU 2015-14. ASU 2015-14 defers the effective date of ASU 2014-09 by one year to December 15, 2017 for fiscal years, and interim periods within those years, beginning after that date and permits early adoption of the standard, but not before the original effective date for fiscal years beginning after December 15, 2016. In March 2016, the FASB issued ASU 2016-08, Revenue from Contracts with Customers, Principal versus Agent Considerations (Reporting Revenue Gross versus Net), or ASU 2016-08, clarifying the implementation guidance on principal versus agent considerations. Specifically, an entity is required to determine whether the nature of a promise is to provide the specified good or service itself (that is, the entity is a principal) or to arrange for the good or service to be provided to the customer by the other party (that is, the entity is an agent). The

determination influences the timing and amount of revenue recognition. In April 2016, the FASB issued ASU 2016-10, Revenue from Contracts with Customers, Identifying Performance Obligations and Licensing, clarifying the implementation guidance on identifying performance obligations and licensing. Specifically, the amendments reduce the cost and complexity of identifying promised goods or services and improves the guidance for determining whether promises are separately identifiable. The amendments also provide implementation guidance on determining whether an entity's promise to grant a license provides a customer with either a right to use the entity's intellectual property (which is satisfied at a point in time) or a right to access the entity's intellectual property (which is satisfied over time). The effective date and transition requirements for ASU 2016-08 and ASU 2016-10 are the same as the effective date and transition requirements for ASU 2014-09. The Company is currently assessing the potential impact of adopting ASU 2014-09, ASU 2016-08 and ASU 2016-10 on its financial statements and related disclosures.

2. License agreements

Specific information pertaining to each of our significant license agreements is discussed in our audited financial statements for the years ending December 31, 2015 and 2014, including their nature and purpose, the significant rights and obligations of the parties, and specific accounting policy elections. The following represents updates for the nine months ended September 30, 2016, if applicable, to the Company's significant license agreements:

(a) Titan Pharmaceuticals

In February 2016, the Company entered into a supply agreement with Titan Pharmaceuticals to purchase Probuphine implants at a fixed cost per implant. The term of the agreement is for six months, with an automatic renewal of an additional six months, unless (i) the Company provides written notice to Titan wishing to terminate, or (ii) the Company enters into a separate supply agreement with another manufacturer.

In May 2016, the Company received regulatory approval of Probuphine by the FDA and triggered a $15 million regulatory milestone, which the Company paid in June 2016 and capitalized the payment as an intangible asset.

(b) Cascadian Therapeutics (formerly known as Oncothyreon Inc.)

In September 2016, following unsuccessful pre-clinical studies, the Company determined to discontinue all research activities associated with ATI-9242, licensed from Cascadian Therapeutics (f/k/a Oncothyreon Inc.) and therefore, does not expect to incur any expenses related to this asset moving forward.

(c) Knight Therapeutics Inc.

In February 2016, the Company entered into a distribution and sublicense agreement, or the Knight Agreement, with Knight Therapeutics Inc. for the exclusive rights to commercialize Probuphine in Canada. Pursuant to the Knight Agreement, the Company is entitled to receive tiered royalty payments from Knight on net sales of Probuphine ranging from low double-digit percentages to percentages in the mid-thirties. In addition, the Company will be the exclusive supplier of Probuphine to Knight, subject to a supply agreement to be negotiated between Knight and the Company.

Pursuant to the Knight Agreement, the Company granted Knight an exclusive license to (i) certain patents and know-how controlled by the Company and (ii) certain trademarks owned by the Company and the Probuphine trademark the Company licensed from Titan to commercialize Probuphine in Canada. The Company has retained the right to commercialize Probuphine in the United States and its territories, including Puerto Rico. The Company also granted to Knight a right of first negotiation in the event the

Company intends to license its right to commercialize any of its other products in Canada. During the term of the Knight Agreement, the Company may not commercialize any product containing buprenorphine that is intended for a treatment duration of six months or more in Canada. Pursuant to the Knight Agreement, Knight must use commercially reasonable efforts to commercialize Probuphine in Canada.

Unless earlier terminated, the initial term of the Knight Agreement will expire on the 15th anniversary of the date of the first commercial sale of Probuphine for opioid addition in Canada. If Probuphine is approved for another indication in Canada after the fifth anniversary of the first commercial sale of Probuphine for opioid addition in Canada, the Company must negotiate in good faith whether to extend the initial term. After the initial term, the Knight Agreement will automatically renew for two-year periods until either party provides the other party with written notice of its intent not to renew at least 180 days prior to the expiration of the initial term or then-current term. The Company or Knight may terminate the Knight Agreement in the event that (i) the NDA for Probuphine has not been transferred to the Company by Titan within six months of the date of the Knight Agreement, (ii) either party determines in good faith that it is not advisable for Knight to continue to commercialize Probuphine in Canada as a result of a bona fide safety issue, (iii) the other party has filed for bankruptcy, reorganization, liquidation or receivership proceedings, or (iv) the other party materially breached the agreement and has not cured such breach within a specified time period. In addition, subject to certain exceptions and requirements, the Company may terminate the Knight Agreement (i) if Knight discontinues the commercial sale of Probuphine for a period of at least three months and fails to resume sales within the specified cure period, (ii) in the event that Knight commences any legal proceedings seeking to challenge the validity or ownership of any of the Company's patents related to Probuphine, or (iii) if the Company determines, in its sole discretion, to terminate the Titan Agreement.

In the event of termination, among other things, Knight shall (i) cease commercialization of Probuphine in Canada, (ii) transfer title to all current and pending regulatory submissions and regulatory approvals for Probuphine to the Company and (iii) pay any royalty payments generated by Knight's sales of Probuphine in Canada due to the Company.

(d) Lubrizol Advanced Materials, Inc.

In September 2016, the Company triggered a developmental milestone to Lubrizol of $109,000, which the Company paid in November 2016. The milestone payment was charged to research and development expense in September 2016.

3. Earnings per share

The computation of basic and diluted net loss per share for the nine months ended September 30, 2016 and 2015 is as follows:

	September 30, 2016	September 30, 2015
Numerator:		
Net loss	$ (76,816,095)	$(22,624,289)
Net loss available to all shareholders	$ (76,816,095)	$(22,624,289)
Net loss attributable to common shareholders		$(19,994,154)
Net loss attributable to preferred shareholders	$ (76,816,095)	$ (2,630,135)
Denominator:		
Weighted-average common shares, basic and diluted		76,019,503
Weighted-average preferred shares, basic and dilued	170,923,700	10,000,000
Net loss per common share, basic and diluted		$ (0.26)
Net loss per preferred share, basic and diluted	$ (0.45)	$ (0.26)

The Company's preferred stock is participating and accumulates an 8% dividend that is not included in the earnings per share calculation above. Prior to and subsequent of the Company's dissolution of Braeburn BVBA, the Company's equity is owned solely by ATP IV and its subsidiaries. As of September 30, 2016 and 2015, the cumulative preferred dividend was $14.7 million and $2.4 million, respectively, as the Company's preferred shares were issued by Braeburn Pharmaceuticals Inc. to Braeburn BVBA and eliminated upon consolidation.

The following table sets forth the potential common shares that could potentially dilute basic income per share in the future that were not included in the computation of diluted income / (loss) per share because to do so would have been anti-dilutive (for the nine months ended):

	September 30, 2016	September 30, 2015
Conversion of employee equity awards	1,112,808	829,659
Total potential dilutive effect	1,112,808	829,659

The following table illustrates the unaudited pro forma net loss and basic and diluted net loss per common share assuming the following pro forma adjustments, reflected in the table below: (i) the effects of incremental time-based vesting for the share-based compensation for restricted stock units and non-qualified stock options granted under the 2015 Equity Incentive Plan that were now only subject to time-based vesting criteria during the nine months ending September 30, 2016, assuming the initial public offering occurred on January 1, 2015. Due to the current performance criteria of a liquidity event, no share-based compensation expense has been recognized in the historical financial statements in the nine months ended September 30, 2016; (ii) the conversion of all outstanding issued convertible preferred stock as it became outstanding throughout the year into shares of common stock at the applicable conversion rate of 13.5 preferred shares for one common share, assuming the transaction occurred at the date of the first issuance; and (iii) the incremental issuance and vesting of restricted stock units during the nine months ended September 30, 2016, assuming that the initial public offering occurred on January 1, 2015.

The pro forma net loss per share does not include the shares expected to be sold and related proceeds to be received from the Company's proposed initial public offering.

	Nine Months Ended September 30, 2016
	(Unaudited)
Net loss—as reported	$(76,816,095)
Share-based compensation expense	(4,499,739)
Pro forma net loss, including the effect of share-based compensation expense	$ (81,315,834)
Pro forma net loss per common share, basic and diluted	$ (5.66)
Pro forma weighted average basic and diluted common shares outstanding	14,355,563

4. Fair value measurement

Fair value of certain investments is based upon market prices using quoted prices in active markets for identical assets quoted on the measurement date. The Company reviews its investments on a periodic basis for other-than-temporary impairments. This review is subjective, as it requires management to evaluate whether an event or change in circumstances has occurred in that period that may have a significant adverse effect on the fair value of the investment. For the nine months ended September 30, 2016 and 2015, the Company did not recognize any other-than-temporary impairments.

The following represents the fair value using the hierarchy described in Note 1 for the Company's financial assets that are required to be measured at fair value on a recurring basis as of September 30, 2016 and December 31, 2015:

	As of September 30, 2016			
	Level 1	Level 2	Level 3	Total
Equity investments, classified as available-for-sale	$–	$–	$–	$–
Total assets	$–	$–	$–	$–

	As of December 31, 2015			
	Level 1	Level 2	Level 3	Total
Equity investments, classified as available-for-sale	$–	$ 5,045,455	$–	$ 5,045,455
Total assets	$–	$ 5,045,455	$–	$ 5,045,455

As of December 31, 2015, the Company classified its available-for-sale securities as Level 2 in the fair value hierarchy, due to the relatively low trading volume and percentage of shares held by insiders. During the nine months ended September 30, 2016, the Company sold all shares classified as available-for-sale, netting proceeds of $6.2 million and realizing a gain of $1.2 million. During the nine months ended September 30, 2015, the Company did not have any sales of marketable securities.

Unrealized gains and losses are reported as a component of accumulated other comprehensive (loss) income in shareholders' equity. During the nine months ended September 30, 2016 and 2015, the Company had gross unrealized gains of $0 and $0.5 million, respectively.

5. Prepaid expenses and other current assets

Prepaid expenses and other current assets as of September 30, 2016 and December 31, 2015 consists of the following:

	September 30, 2016	December 31, 2015
Prepaid research and development	$ 1,822,370	$ 2,455,721
Prepaid general and administrative	1,215,092	125,807
Prepaid insurance	165,601	44,737
Deferred initial public offering costs	167,965	–
Prepaid rent	84,340	81,618
Other	140,959	53,382
Total prepaid expenses and other current assets	$ 3,596,326	$ 2,761,265

6. Inventory

Inventories are stated at the lower of cost or net realizable value. Inventories are recorded at the actual cost per lot determined using the specific identification method. Inventories as of September 30, 2016 and December 31, 2015 consists of the following:

	September 30, 2016	December 31, 2015
Finished goods	$ 188,682	$–
Work in process	15,942	–
Raw materials	569,324	–
Inventory, gross	773,948	–
Less: Write-downs of obsolete inventory	–	–
Inventory, net	$ 773,948	$–

The Company did not record any write-downs of inventory as of September 30, 2016 and December 31, 2015.

7. Plant, property, and equipment

Property and equipment is recorded at cost and consists of the following:

	September 30, 2016	December 31, 2015
Leasehold Improvements	$ 228,835	$ 185,018
Computer Equipment	218,442	120,188
Furniture and Office Equipment	233,006	207,283
Construction in Process	11,008,230	95,718
Total Fixed Assets	11,688,513	608,207
Less: Accumulated Depreciation	(281,035)	(184,973)
Total Property and Equipment	$ 11,407,478	$ 423,234

In 2016, the Company began capitalizing construction costs related to its build-to-suit lease for its manufacturing facility in Durham, North Carolina. See Note 9. As of September 30, 2016, the Company capitalized $4.6 million for the fair value of the building in its build-to-suit lease and $6.3 million to construction-in-process related to design and construction costs, as well as machinery and equipment.

Depreciation expense was approximately $96,000 and $54,000 for the nine months ended September 30, 2016 and 2015, respectively.

8. Deposits and Other Assets

Deposits and other assets as of September 30, 2016 and December 31, 2015 consists of the following:

	September 30, 2016	December 31, 2015
Escrow of construction funds for North Carolina facility build-out	$1,500,000	$ –
Other	112,709	97,813
Total deposits and other assets	$ 1,612,709	$ 97,813

9. Leases

Princeton, NJ operating lease

The Company has a non-cancelable operating lease of approximately 4,600 square feet of office space for its corporate headquarters in Princeton, New Jersey that expires in 2018.

North Carolina build-to-suit lease

In December 2015, the Company entered into a lease agreement for approximately 33,900 square feet of manufacturing and office space in Durham, North Carolina, commencing in 2016. The lease agreement expires in 2026, with the Company's option to extend to 2031 or 2036. The Company intends to modify the space to meet its manufacturing and supply chain needs, and will be reimbursed for construction costs of up to $3.9 million from the landlord. As a result of the nature and involvement in the construction period of the leased space, the Company is determined to be the ''deemed owner'', for accounting purposes only, of the construction project, and is required to capitalize the fair value of the building and construction costs incurred by the Company, pursuant to *ASC-840, Leases*, and the accounting policy described in Note 1.

In February 2016, the Company capitalized the fair value of the building, excluding land, of $4.5 million, as commencement of the construction period began, with a corresponding financing obligation of $4.5 million. The Company recorded the fair value of the building, excluding land, based on its portion of the space, calculated by square footage. Construction costs as well as interest are capitalized to construction-in-process during the construction period. Further, the Company's tenant improvement allowance of $3.9 million is reimbursable in equal installments upon 50% project completion and 100% project completion. The Company will record an increase in lease obligation upon reimbursement, upon which rental payments will be applied, with the difference being recorded as interest expense. In regards to the land upon which the building sits, in accordance with *ASC-840, Leases*, the Company recognizes rental expense on a straight-line basis over the life of the lease for the imputed ground lease.

In May 2016, the Company entered into a short-term lease agreement with the same landlord for approximately 5,799 square feet of additional office space in the Durham, North Carolina for a term of 8 months.

Rent-free periods and other incentives granted under the leases and scheduled rent increases are charged to rent expense on a straight-line basis over the related terms of the lease. Rental expense for operating leases was approximately $187,000 and $128,000 for the nine months ended September 30, 2016 and 2015, respectively.

The future lease payments under non-cancelable operating leases as of September 30, 2016 are as follows:

	Princeton, NJ operating lease	North Carolina build-to-suit lease
2016 (October - December)	$ 47,074	$ 138,077
2017	188,296	784,523
2018	156,913	808,055
2019	–	832,265
2020	–	857,155
Thereafter	–	5,535,501
Total	$ 392,283	$ 8,955,576

10. Intangible assets

Intangible assets as of September 30, 2016 consist of the following:

		As of September 30, 2016			
	Weighted average life	Gross carrying amount	Impairment	Accumulated amortization	Net carrying amount
Amortized intangible assets:					
Probuphine Approval Milestone	7.7 years	$15,000,000	$–	$(657,804)	$14,342,196
Total amortized intangible assets:		$15,000,000	$–	$(657,804)	$14,342,196

As of September 30, 2016, the weight average remaining life for definite-lived intangible assets was approximately 7.7 years.

In connection with the Titan license agreement described in Note 2, the Company capitalized the milestone related to the regulatory approval of Probuphine and recorded an intangible asset valued at $15.0 million that is being amortized over the patent life on a straight-line basis.

The Company did not have any intangible assets as of December 31, 2015.

Estimated remaining amortization expense related to intangible assets with definite lives for each of the five succeeding years and thereafter is as follows:

	Amount
2016 (October - December)	$ 471,340
2017	1,890,538
2018	1,890,538
2019	1,890,538
2020	1,895,718
Thereafter	6,303,524
Total	$14,342,196

Amortization expense was $0.7 million and $0 for the nine months ended September 30, 2016 and 2015, respectively.

11. Accounts payable, accrued expenses, and other current liabilities

Accounts payable, accrued expenses, and other current liabilities at September 30, 2016 and December 31, 2015 consists of the following:

	September 30, 2016	December 31, 2015
Accounts Payable	$ 8,757,475	$ 1,319,296
Accrued Research and Development Expense	5,604,958	4,436,875
Accrued General and Administrative Expense	1,057,679	540,689
Accrued Inventory	583,972	–
Accrued Fixed Assets	698,929	46,144
Accrued Bonuses	1,325,485	901,407
Deferred Revenue	219,407	–
Other	221,320	69,664
	$ 18,469,225	$7,314,076

12. Stock plans

2015 Equity Incentive Plan

In June 2015, the Board of Directors approved the 2015 Equity Incentive Plan, or the 2015 Plan, pursuant to which 1,426,840 shares of common stock were authorized for issuance to employees, directors, officers, and other parties as determined by the Board of Directors. Shares may be issued as restricted stock units, stock appreciation rights, non-qualified stock options, and incentive stock options. Equity shares generally vest over a 4-year period, with 25% vesting on the first anniversary of the vesting start date, and 2.08% vesting every month thereafter. However, vesting of these equity shares are subject to the occurrence of certain performance criteria. Equity shares will not become exercisable until the occurrence of a liquidation event, defined as 180 days after an initial public offering or certain change of control transactions. Upon termination of service, the grantee will remain eligible to vest in the number of equity shares in which the grantee was otherwise eligible to vest in upon a liquidation event or certain change of control transactions at the date of termination. The 2015 Plan also provides that, in the event of certain change of control transactions prior to termination of service, all outstanding, unvested equity shares shall automatically

vest. Equity shares granted under the 2015 Plan expire on the tenth anniversary of the date they were granted.

As of September 30, 2016, 1,036,882 restricted stock units to purchase 1,036,882 shares of common stock were outstanding, and 75,925 non-qualified stock options to purchase 75,925 shares of common stock were outstanding. As of the nine months ended September 30, 2016 and 2015, the Company recognized $0 and $0 compensation expense, respectively, as none of the performance criteria has been satisfied, and such performance criteria is not deemed probable of occurring.

The Company uses a third-party valuation specialist to assist in the estimation of the fair value of its common stock. The Company utilizes significant estimates and assumptions in determining the fair value of its common stock. Management has determined the estimated fair value of the Company's common stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector, discounted cash flows and the likelihood of achieving a liquidity event, such as an IPO of common stock or a sale of the Company.

The Company utilized various valuation methodologies in accordance with the framework of the 2013 American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, to estimate the fair value of its common stock. The methodologies included a probability-weighted expected return methodology that determined an estimated value under an IPO scenario and a sale scenario based upon an assessment of the probability of occurrence of each scenario. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates include assumptions regarding future performance, including the successful completion of preclinical studies and clinical trials and the time to complete an IPO or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

The following table summarizes information on the Company's restricted stock and non-qualified stock options:

	Restricted stock		Non-qualified stock options	
	Number of shares	Weighted average grant date fair value	Number of shares	Weighted average grant date fair value
January 1, 2015	—	—	—	—
Granted	989,465	$2.73	—	$ —
Vested	—	—	—	—
Forfeited	—	—	—	—
Unvested at December 31, 2015	989,465	$2.73	—	$ —
Granted	47,524	$2.73	77,777	$2.35
Vested	—	—	—	—
Forfeited	107	$2.73	1,852	$1.65
Unvested at September 30, 2016	1,036,882	$2.73	75,925	$2.38

As of September 30, 2016, there was approximately $3.0 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the 2015 Plan. This cost is expected to be recognized as compensation expense over the weighted average remaining service period of approximately 1.24 years.

The weighted average fair value of stock options granted during the periods and the assumptions used to estimate those values using the Black-Scholes option pricing model were as follows:

	Nine months ended September 30, 2016
Weighted average expected stock price volatility	67.1%
Estimated dividend yield	0%
Risk-free interest rate	1.2%
Expected life of option (in years)	6.11
Weighted average grant date fair value per option	$ 0.88

The expected stock price volatility for the stock options is based on historical volatility of comparable peer companies. The Company does not anticipate paying cash dividends, and therefore, the expected dividend rate is assumed to be 0%. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected life assumption. The expected life of the stock options was estimated based on the vesting pattern of the awards.

13. Common stock

Since founding, the Company has received funding directly or indirectly from ATP IV and its subsidiaries and they were the only holders of the outstanding equity. The consolidated statements of shareholders' equity / (deficit) for the nine months ended September 30, 2016 and 2015 reflect the class of stock held by ATP IV and its subsidiaries that were not eliminated in consolidation.

During 2015, the Company had the following capitalization events:

- In May 2015, Braeburn Pharmaceuticals entered into three separate agreements with Braeburn BVBA, in which Braeburn BVBA contributed the Probuphine license agreement, Camurus license agreement, and Endo license agreement to Braeburn Pharmaceuticals in exchange for 57,370,000, 21,910,000, and 9,200,000 series A preferred shares with a fair market value of $1 per share. See Note 2 for discussion of license agreements and Note 14 for preferred stock.
- In June 2015, Braeburn Pharmaceuticals exchanged all outstanding common shares (2,073,262 shares) for 2,073,262 series A preferred shares ($1.00 per share) with Braeburn BVBA.
- In September 2015, the investment of shares in Titan was transferred from Braeburn BVBA to Braeburn Pharmaceuticals, Inc.
- In November 2015, Braeburn BVBA was voluntarily dissolved, with resulting investment in Braeburn Pharmaceuticals, Inc. transferring to ATP IV and its subsidiaries. All Braeburn BVBA common shares were retired by ATP IV and its subsidiaries upon dissolution. See Note 15.

As of September 30, 2016 and December 31, 2015, the Company is authorized to issue 90,000,000 shares of common stock, $0.0001 par value per share, with 0 shares issued and outstanding. The voting, dividend and liquidation rights of the holders of the common stock are subject to and qualified by the rights, power and preferences of the holder of the preferred stock. The holders of the common stock are entitled to one vote for each share of common stock.

14. Preferred stock

As of September 30, 2016, the Company is authorized to issue 351,000,000 shares of preferred stock, $0.0001 par value per share, of which 350,000,000 are designated as Convertible Series A preferred stock and the remaining 1,000,000 to be designated by the Board of Directors from time to time in one or more additional series. During the nine months ended September 30, 2016, the Company sold 103,750,000 convertible Series A preferred shares to ATP IV and its subsidiaries in exchange for $103.8 million. As of September 30, 2016, 222,803,262 shares of Series A preferred stock were outstanding, which can be converted at the holders' discretion into 16,503,945 shares of common stock.

Liquidation preferences

In the event of any voluntary or involuntary liquation, dissolution, or winding up of the Company, the holders of shares of Series A preferred stock then outstanding are entitled to be paid out of the assets of the Company available for distribution to its shareholders before any payment shall be made to the holders of the common stock, an amount per share equal to the greater of (i) the Series A original issue price plus any accruing dividends accrued but unpaid or (ii) the amount per share as would have been payable had all shares of Series A preferred stock been converted to common stock immediately prior to such liquidation.

Voting rights

Each holder of outstanding shares of Series A preferred stock is entitled to one-fifth of a vote for each outstanding share.

Dividends

The holders of the convertible preferred stock are entitled to receive, when, as, and if declared by the Board of Directors, cumulative dividends at a rate of 8% of the original base amount per annum from the date of issuance. The base amount for a share of Series A preferred stock is an amount equal to the Series A original issue price plus the amount of any previously accrued but unpaid dividends. Accruing dividends accrue from day to day, and are cumulative.

Conversion rights

Each share of Series A preferred stock is convertible, at the option of the holder, at any time, at a rate of 13.5 preferred shares for one fully paid and non-assessable share of common stock.

15. Dissolution of Braeburn BVBA

In November 2015, Braeburn BVBA was voluntarily legally dissolved. As discussed in Note 1, this transaction represents a transaction among entities under common control and has been accounted for in a manner similar to the pooling of interests' method, which requires that the merged entities be combined at their historical cost. The Company's consolidated financial statements and related footnotes are presented as if the transaction occurred at the beginning of the earliest date presented. All remaining net assets of Braeburn BVBA, which consisted solely of cash, transferred to ATP IV and its subsidiaries. The transfer was accounted for as a liquidating cash dividend of $754,000. At time of dissolution, Braeburn BVBA had no additional paid-in capital, as common shares of Braeburn BVBA were issued at par. Therefore, the Company accounted for the liquidating dividend as an increase in accumulated deficit. Upon dissolution, the remaining Braeburn BVBA common shares were cancelled. The preferred shares held by Braeburn BVBA of

Braeburn Inc. were transferred to ATP IV and its subsidiaries. As of September 30, 2016, all equity of the Company was held by ATP IV and its subsidiaries.

16. Income taxes

Income taxes have been accounted for using the asset and liability method in accordance with *ASC 740—Income Taxes*. The Company computes its interim provision for income taxes by applying the estimated annual effective tax rate method. The Company's effective tax rate for the nine months ending September 30, 2016 and 2015 is 0.0% and (7.6%), respectively.

The Company has incurred cumulative losses since its inception and is forecasting additional losses through the year, resulting in an estimated net loss for both financial statement and tax purposes for the year ending December 31, 2016. Due to the Company's history of losses, there is not sufficient evidence to record a net deferred tax asset, and accordingly, a full valuation allowance has been recorded related to the net deferred tax asset.

The Company had no unrecognized tax benefits that would affect the Company's effective tax rate as of September 30, 2016 and 2015.

17. Commitments and contingencies

Legal proceedings

The Company may become involved in or subject to, routine litigation, claims, disputes, proceedings and investigations in the ordinary course of business, which in management's opinion will not have a material effect on its financial condition, cash flows or results of operations.

18. Other Comprehensive Income

The following table illustrates the tax effects allocated to each component of other comprehensive income for the nine months ended September 30, 2016:

	For the nine months ended September 30, 2016		
	Before-Tax Amount	Tax (Expense) or Benefit	Net-of-Tax Amount
Unrealized gains on available-for-sale securities			
Unrealized holding gains arising during period	$1,189,061	$—	$1,189,061
Less: reclassification adjustment for gains included in net income	(1,216,716)	—	(1,216,716)
Other comprehensive income	$ (27,655)	$—	$ (27,655)

19. Related party transactions

Transactions with affiliates of common parent (ATP IV)

The Company transacts with certain affiliates of its parent, ATP IV. Transactions involving related parties cannot be presumed to be carried out on an arm's-length basis, as the requisite conditions of competitive, free-market dealings may not exist.

As of September 30, 2016 and December 31, 2015, due to affiliates were comprised of the following:

	September 30, 2016	December 31, 2015
Due to Apple Tree Life Sciences	$–	$ 64,582
Total due to affiliates	$–	$ 64,582

Apple Tree Life Sciences

During the nine months ended September 30, 2015, the Company received certain services from Apple Tree Life Sciences, or ATLS, a subsidiary of ATP IV. These included administrative services relating to accounting, finance, legal, human resources, and other administrative services. As well, these services also included research and development services including regulatory and clinical support. ATLS charged the Company a service fee consisting of allocated internal time incurred on its projects by their employees, plus a pre-determined mark-up. Further, the Company paid or reimbursed ATLS at cost for any expenses incurred by third parties on its behalf. Beginning January 1, 2016, the Company no longer receives services from ATLS. Expenses from services rendered by ATLS, inclusive of the mark-up, for the nine months ended September 30, 2016 and 2015 are as follows:

	September 30, 2016	September 30, 2015
Expenses from services by ATLS, inclusive of markup	$–	$ 671,669

During the nine months ended September 30, 2015, the Company provided certain accounting and finance services to ATLS, consisting of allocated internal time by its employees on ATLS projects, of which were reimbursed to the Company. Beginning January 1, 2016, the Company no longer provides these services. The amounts reimbursed to the Company by ATLS for the nine months ended September 30, 2016 and 2015 are as follows:

	September 30, 2016	September 30, 2015
Reimbursement from services provided to ATLS	$–	$ 48,581

ATP IV—Advocates for Opioid Recovery, Inc. agreement

In June 2016, the Company entered into an agreement with ATP IV to pay $900,000, payable in three installments ending on January 1, 2017, towards a charitable contribution to Advocates for Opioid Recovery Inc., or AOR, a Delaware 501(c)(4) corporation. The $900,000 will be remitted by ATP IV on behalf of the Company to AOR. As of September 30, 2016, the Company paid $675,000 to ATP IV and recorded expenses in June and September as a charitable contribution in selling, general and administrative expense, respectively.

Female Opioid-Addiction Research and Clinical Experts (FORCE)

In July 2016, the Company entered into a charitable contribution agreement with Female Opioid-Addiction Research and Clinical Experts, or FORCE, a non-profit charitable organization of which certain Company employees, including the Chief Executive Officer, are members of the FORCE Board of Directors. The Company agreed to provide $200,000 to FORCE, of which the Company will receive no benefit. In August 2016, the Company paid $200,000 to FORCE and recorded the amount in selling, general and administrative expense. As well, during the nine months ended September 30, 2016, the Company paid

certain expenses on behalf of FORCE totaling $33,000. All amounts were recorded in selling, general and administrative expense. The Company does not expect any additional future payments on behalf of FORCE.

20. Subsequent events

The Company has evaluated events that have occurred subsequent to September 30, 2016 through the date the financial statements were originally available to be issued, December 9, 2016 and as it relates to the last four paragraphs below through the re-issuance date December 30, 2016.

In October 2016, the Company announced that Marshall Woodworth, Chief Financial Officer and Treasurer, is no longer with the Company, and appointed David McIntyre as Chief Financial Officer.

In October 2016, the Company entered into the first amendment to the Camurus license agreement. The amendment granted the Company the exclusive rights to develop and commercialize BB0417, a combination product containing buprenorphine and granisetron for the treatment of pain. The amendment obligates the Company to reimburse Camurus for up to $1.5 million of a Camurus-led Phase 1 clinical trial for BB0417. As well, the amendment adds an additional $7 million in one-time, non-refundable regulatory milestones. Further, the amendment adds BB0417 towards the aggregate sales milestones, as well as the aforementioned royalty in the licensed territory, included in the original Camurus agreement.

In October 2016, the Company granted 83,672 non-qualified stock options to new employees under the 2015 Equity Incentive Plan with one quarter of these options vesting on the first anniversary of the grant date, and the remainder vesting in twelve equal quarterly installments. At the same time, the Company also granted an additional 1,105,799 restricted stock units and 192,823 non-qualified stock options to various individuals, with these equity grants vesting in forty-eight monthly installments with effect from the relevant vesting commencement dates, ranging from January 2016 through November 2016.

In October 2016, the Company received a $22 million capital contribution from ATP IV and its subsidiaries in exchange for 22,000,000 preferred shares with a par value of $0.0001.

In October 2016, the Company triggered a $2.0 million milestone payment under the original Camurus license agreement as a result of the first dosing of CAM2038 reaching a Phase 3 clinical trial for a pain indication. During the fourth quarter of 2016 the Company paid the $2.0 million to Camurus and recorded the milestone payment as research and development expense.

In November 2016, the Company terminated its license agreement with Cascadian Therapeutics.

In November 2016, the Company paid Camurus $1.5 million under the first amendment to the Camurus license agreement for reimbursement of costs related to a Camurus-led Phase 1 clinical trial for BB0417. The Company expensed the $1.5 million in research and development in the same period.

In December 2016, the Company's Board of Directors approved an amendment to the 2015 Equity Incentive Plan to increase the share limit of employee awards granted under the plan from 1,426,840 to 4,444,444, with an effective date of October 24, 2016. The amendment is subject to further approval by the Company's shareholder.

In December 2016, the Company received a $22 million capital contribution from ATP IV and its subsidiaries in exchange for 22,000,000 preferred shares with a par value of $0.0001.

In December 2016, the Company granted 240,254 non-qualified stock options to new employees under the 2015 Equity Incentive Plan with one quarter of these options vesting on the first anniversary of the grant date, and the remainder vesting in twelve equal quarterly installments. The Company also granted an additional 101,849 restricted stock units and 45,578 non-qualified stock options to various individuals, with these equity grants vesting in forty-eight monthly installments with a vesting start date of January 1, 2017.

7,692,308 shares

Braeburn Pharmaceuticals, Inc.

Common stock

J.P. Morgan **BofA Merrill Lynch**

Deutsche Bank Securities

Canaccord Genuity

Through and including , 2017 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.