

Sorrento Therapeutics, Inc.
Form S-8
April 25, 2014
Table of Contents

As filed with the Securities and Exchange Commission on April 25, 2014

Registration No. _____

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

FORM S-8
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Sorrento Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

33-0344842
(I.R.S. Employer
Identification No.)

Edgar Filing: Sorrento Therapeutics, Inc. - Form S-8

6042 Cornerstone Ct. West, Suite B

San Diego, California 92121

(Address of principal executive offices) (Zip Code)

2008 Equity Compensation Incentive Plan

(Full title of the plans)

Dr. Henry Ji

Chief Executive Officer

Sorrento Therapeutics, Inc.

6042 Cornerstone Ct. West, Suite B

San Diego, CA 92121

(Name and Address of agent for service)

(858) 210-3700

(Telephone number, including area code, of agent for service)

With a copy to:

Jeffrey Fessler, Esq.

Sichenzia Ross Friedman Ference LLP

61 Broadway, 32nd Floor

New York, NY 10006

Phone (212) 930-9700

Fax (212) 930-9725

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

Large accelerated filer

Accelerated filer

Table of Contents

2

Non-accelerated filer Smaller Reporting Company **CALCULATION OF REGISTRATION FEE**

Title of Securities to be Registered	Amount to be Registered (1)	Proposed	Proposed	Amount of Registration Fee
		Maximum Offering Price Per Share	Maximum Aggregate Offering Price	
Common Stock, \$.0001 par value	1,560,000	\$10.07 (2)	\$15,709,200	\$2,023.34
TOTAL	1,560,000		\$15,709,200	\$2,023.34

- (1) Pursuant to Rule 416(a) under the Securities Act of 1933, as amended, this Registration Statement shall also cover any additional shares of the Registrant's common stock that become issuable under the Company's Amended and Restated 2009 Stock Incentive Plan, as amended, by reason of any stock dividend, stock split, recapitalization or other similar transaction that increases the number of the outstanding shares of the Registrant's common stock.
- (2) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(c) of the Securities Act of 1933, as amended, using the last sale price reported on The NASDAQ Capital Market on April 24, 2014.

Table of Contents

EXPLANATORY NOTE

This registration statement on Form S-8 (the **Registration Statement**) relates to 1,560,000 shares of the common stock of Sorrento Therapeutics, Inc., a Delaware corporation (the **Registrant**, the **Company**, **we**, **us** or **our**), \$0.0001 per share par value per share (the **Common Stock**), which are issuable pursuant to, or upon exercise of, options that may be granted under the Sorrento Therapeutics 2009 Stock Incentive Plan, as amended and restated (the **Plan**). Under the Plan, a total of 1,560,000 shares of Common Stock have been reserved for issuance upon the grant and exercise of options. In addition, this amount will be automatically increased annually on the first day of each fiscal year, beginning in 2014, by the lesser of: (i) 1% of the aggregate number of shares of our common stock outstanding on the last day of the immediately preceding fiscal year, (ii) 200,000 shares, or (iii) an amount approved by the Plan administrator. However, in no event will the aggregate number of shares available for issuance under the Amended Plan exceed 3,360,000 during the ten-year term of the Plan.

This Registration Statement also includes a reoffer prospectus prepared in accordance with General Instruction C of Form S-8 and in accordance with the requirements of Part I of Form S-3, which may be utilized for reofferings and resales on a continuous or a delayed basis in the future related to the following:

750,900 shares of common stock (the **Shares**) which are issuable upon exercise of options that have been granted under the Plan, with respect to which the reoffer prospectus relates are being registered for reoffers and resales by certain stockholders listed (the **Selling Stockholders**), who are our officers and directors and may be deemed to be our **affiliates** , as defined in Rule 405 of the Securities Act. The Selling Stockholders may acquire the Shares upon exercise of options granted under the Plan. We do not know whether any of such Selling Stockholders will use this reoffer prospectus in connection with the offer or sale of the Shares, or, if this reoffer prospectus is so used, how many shares of Common Stock will be offered or sold. Such Selling Stockholders may resell all, a portion, or none of the shares that they may acquire pursuant to the Plan.

The reoffer prospectus does not contain all of the information included in the Registration Statement, certain items of which are contained in schedules and exhibits to the Registration Statement, as permitted by the rules and regulations of the Securities and Exchange Commission (the **SEC** or the **Commission**). Statements contained in this reoffer prospectus as to the contents of any agreement, instrument or other document referred to herein are not necessarily complete. With respect to each such agreement, instrument or other document filed as an exhibit to the Registration Statement, we refer you to the exhibit for a more complete description of the matter involved, and each such statement shall be deemed qualified in its entirety by this reference.

PART I

INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS

Item 1. Plan Information.

The Company will provide each recipient of a grant under the Plan (the **Recipients**) with documents that contain information related to the Plans, and other information including, but not limited to, the disclosure required by Item 1 of Form S-8, which information is not required to be and are not being filed as a part of this Registration Statement on Form S-8 (the **Registration Statement**) or as prospectuses or prospectus supplements pursuant to Rule 424 under the Securities Act. The foregoing information and the documents incorporated by reference in response to Item 3 of Part II of this Registration Statement, taken together, constitute a prospectus that meets the requirements of Section 10(a)

of the Securities Act. A Section 10(a) prospectus will be given to each Recipient who receives common stock covered by this Registration Statement, in accordance with Rule 428(b)(1) under the Securities Act.

Item 2. Registrant Information and Employee Plan Annual Information.

We will provide to each Recipient a written statement advising of the availability of documents incorporated by reference in Item 3 of Part II of this Registration Statement (which documents are incorporated by reference in this Section 10(a) prospectus) and of documents required to be delivered pursuant to Rule 428(b) under the Securities Act without charge and upon written or oral request by contacting:

Dr. Henry Ji

Chief Executive Officer and President

Sorrento Therapeutics, Inc.

6042 Cornerstone Ct. West, Suite B

San Diego, CA 92121

Table of Contents

REOFFER PROSPECTUS

Sorrento Therapeutics, Inc.

750,900 Shares of

Common Stock

This reoffer prospectus relates to the sale of up to 750,900 shares (the "Shares") of our common stock, \$.0001 par value per share (the "Common Stock") on The NASDAQ Capital Market, or such other stock market or exchange on which our common stock may be listed or quoted, in negotiated transactions or otherwise, at market prices prevailing at the time of the sale or at prices otherwise negotiated (see "Plan of Distribution" starting on page 39 of this prospectus). We will receive no part of the proceeds from sales made under this reoffer prospectus. The selling stockholders will bear all sales commissions and similar expenses. Any other expenses incurred by us in connection with the registration and offering and not borne by the selling stockholders will be borne by us.

This reoffer prospectus has been prepared for the purposes of registering the common shares under the Securities Act to allow for future sales by selling stockholders on a continuous or delayed basis to the public without restriction.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 8 of this reoffer prospectus. These are speculative securities.

Our common stock is quoted on The NASDAQ Capital Market under the symbol "SRNE" and the last reported sale price of our common stock on April 24, 2014 was \$10.07 per share.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is April 25, 2014

Table of Contents

SORRENTO THERAPEUTICS, INC.

TABLE OF CONTENTS

	Page
<u>Prospectus Summary</u>	4
<u>Risk Factors</u>	6
<u>Cautionary Note Regarding Forward-Looking Statements</u>	32
<u>Use of Proceeds</u>	32
<u>Selling Stockholders</u>	33
<u>Plan of Distribution</u>	36
<u>Legal Matters</u>	38
<u>Experts</u>	38
<u>Incorporation of Certain Documents by Reference</u>	38
<u>Disclosure of Commission Position on Indemnification For Securities Act Liabilities</u>	38
<u>Additional Information Available to You</u>	39

NO PERSON HAS BEEN AUTHORIZED TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATIONS, OTHER THAN THOSE CONTAINED IN THIS PROSPECTUS, IN CONNECTION WITH THE OFFERING MADE HEREBY, AND, IF GIVEN OR MADE, SUCH INFORMATION OR REPRESENTATION MUST NOT BE RELIED UPON AS HAVING BEEN AUTHORIZED BY THE COMPANY OR ANY OTHER PERSON. NEITHER THE DELIVERY OF THIS PROSPECTUS NOR ANY SALE MADE HEREUNDER SHALL UNDER ANY CIRCUMSTANCES CREATE ANY IMPLICATION THAT THERE HAS BEEN NO CHANGE IN THE AFFAIRS OF THE COMPANY SINCE THE DATE HEREOF. THIS PROSPECTUS DOES NOT CONSTITUTE AN OFFER TO SELL OR A SOLICITATION OF AN OFFER TO BUY ANY SECURITIES OFFERED HEREBY BY ANYONE IN ANY JURISDICTION IN WHICH SUCH OFFER OR SOLICITATION IS NOT AUTHORIZED OR IN WHICH THE PERSON MAKING SUCH OFFER OR SOLICITATION IS NOT QUALIFIED TO DO SO OR TO ANY PERSON TO WHOM IT IS UNLAWFUL TO MAKE SUCH OFFER OR SOLICITATION.

Table of Contents

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere or incorporated by reference into this prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our securities. You should read this entire prospectus and the accompanying prospectus carefully, including the Risk Factors section contained in this prospectus and our consolidated financial statements and the related notes and the other documents incorporated by reference into this prospectus and in the accompanying prospectus. Unless we have indicated otherwise or the context otherwise requires, references in this prospectus or the documents incorporated by reference herein and therein to the Company, we, us and our refer to Sorrento Therapeutics, Inc. and its subsidiaries.

Business Overview

We are a biopharmaceutical company engaged in the discovery, acquisition, development and commercialization of proprietary drug therapeutics for addressing significant unmet medical needs in the U.S., Europe and additional international markets. Our primary therapeutic focus is oncology, including the treatment of chronic cancer pain, but we are also developing therapeutic products for other indications, including immunology and infectious diseases. We currently have two clinical development programs underway: (i) our lead oncology drug product candidate Cynviloq, a micellar diblock copolymeric paclitaxel formulation, and (ii) resiniferatoxin, a non-opiate, ultra potent and selective agonist of the TRPV-1 receptor for intractable pain in end-stage disease.

Our pipeline also includes preclinical fully human therapeutic antibodies, including our fully human anti-PD-L1 and anti-PD-1 monoclonal antibodies, or Abs, derived from our proprietary G-MAB[®] library platform, antibody drug conjugates, or ADCs, and recombinant intravenous immunoglobulin, or rIVIG. Our objective is to develop two classes of antibody drug products, therapeutic antibodies and ADCs: (i) First in Class, or FIC, and/or (ii) Best in Class, or BIC, which may offer greater efficacy and/or fewer adverse events or side effects as compared to existing drugs.

Although we intend to retain ownership and control of some product candidates by advancing their development, we will also consider partnerships with pharmaceutical or biopharmaceutical companies in order to balance the risks associated with drug discovery and development and maximize our stockholders' returns. Our partnering objectives include generating revenue through license fees, milestone-related development fees and royalties by licensing rights to our product candidates.

Our goal is to deliver innovative, highly effective and safe treatment options to patients throughout the world. By working closely with scientists, doctors, patient organizations and other health care specialists, we are committed to improving the lives of patients and assisting their caregivers in their fight against serious diseases.

Recent Developments

On March 31, 2014, we announced that the first patient has been dosed in the pivotal clinical trial designed to support Cynviloq for the treatment of metastatic breast cancer and non-small cell lung cancer. The registration trial is an open-label, randomized, multi-center, single-dose, crossover registration study being conducted at clinical sites across the U.S., EU, and Singapore. A projected 100 patients with metastatic or locally recurrent breast cancer will be administered 260 mg/m² of Cynviloq or 260 mg/m² of Abraxane[®] using a 30 minute infusion in a crossover design to compare the bioequivalence of both drugs. Based on the End-of-Phase II meeting with the U.S. Food and Drug Administration, or FDA, in July 2013, this trial was designed to gain marketing approval for Cynviloq under the 505(b)(2) regulatory pathway in the U.S. We expect to file a New Drug Application with the FDA in the first half of 2015.

On March 31, 2014, we entered into an amended and restated loan and security agreement with Oxford Finance LLC and Silicon Valley Bank, increasing the September 2013 facility from \$5,000,000 to \$12,500,000, with two banks. The amended and restated loan bears interest at 7.95% per annum. We will make interest only payments on the outstanding amount of the loan on a monthly basis until October 1, 2014, after which equal monthly payments of principal and interest are due until the loan maturity date of September 30, 2017. In the event we raise \$30 million of net equity or proceeds from a collaboration, if any, the interest only period will be extended by six months. Such loan is secured by a security interest in substantially all of our assets, excluding intellectual property, which is subject to a negative pledge. In connection with the amended and restated loan and security agreement, the Lenders received a warrant to purchase an aggregate 34,642 shares of our common stock at an exercise price of \$12.99 per share, which is exercisable for seven years from the date of issuance.

Table of Contents

Corporate Information

On September 21, 2009, QuikByte Software, Inc., a shell company, or QuikByte, acquired Sorrento Therapeutics, Inc., a privately held Delaware corporation, or STI, in a reverse merger, or Merger. Pursuant to the Merger, all of the issued and outstanding shares of STI common stock were exchanged into shares of QuikByte common stock and STI became a wholly owned subsidiary of QuikByte. STI and QuikByte reincorporated in Delaware in December 2009, and on December 4, 2009, STI merged with and into QuikByte, the separate corporate existence of STI ceased and QuikByte continued as the surviving corporation. Contemporaneously, QuikByte Software, Inc. changed its name to Sorrento Therapeutics, Inc. Our principal executive office is located at 6042 Cornerstone Ct. West, Suite B, San Diego, California 92121. Our telephone number is (858) 210-3700 and our website address is www.sorrentotherapeutics.com. The information on our website is not a part of, and should not be construed as being incorporated by reference into, this prospectus supplement or the accompanying prospectus.

Table of Contents

RISK FACTORS

You should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks we are not presently aware of or that we currently believe are immaterial may also impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained or incorporated by reference into this prospectus, including our financial statements and related notes.

Risks Related to Our Financial Position and Capital Requirements

We are a development-stage company subject to all of the risks and uncertainties of a new business, including the risk that we or our partners may never develop, complete development or market any of our product candidates or generate product related revenues.

We are a development-stage biopharmaceutical company that began operating and commenced research and development activities in 2009. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. There is no assurance that our libraries of fully-human mAbs will be suitable for diagnostic or therapeutic use, or that we will be able to identify and isolate therapeutics product candidates, or develop, market and commercialize these candidates. We do not expect any of our fully-human mAb, ADC, RTX, Cynviloq or related companion diagnostic product candidates to be commercially available for a few years, if at all. Even if we are able to commercialize our product candidates, there is no assurance that these candidates would generate revenues or that any revenues generated would be sufficient for us to become profitable or thereafter maintain profitability.

We do not have any products that are approved for commercial sale and therefore do not expect to generate any revenues from product sales in the foreseeable future, if ever.

We have not generated any product related revenues to date, and do not expect to generate any such revenues for at least the next several years, if at all. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing products with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future.

As of December 31, 2013 and 2012, we had an accumulated deficit of \$32.9 million and \$11.0 million, respectively. We have incurred operating losses since our inception, expect to continue to incur significant operating losses for the foreseeable future, and we expect these losses to increase as we: (i) conduct our BE registration trial related to Cynviloq and prepare for our New Drug Application filing anticipated in 2015, (ii) advance RTX into clinical trials and potentially pursue other human or veterinary indications, (iii) continue to identify and advance a number of potential mAb and ADC drug candidates into preclinical and clinical development activities, (iv) continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products, and (v) expand our corporate infrastructure, including the costs associated with being a NASDAQ public company. As such, we are subject to all risks incidental to the development of new biopharmaceutical products and related companion diagnostics, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Our prior losses, combined with expected future losses,

have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates, or continue our development programs.

Our operations have consumed substantial amounts of cash since inception. We expect to significantly increase our spending to advance the preclinical and clinical development of our product candidates and launch and commercialize any product candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets. We will require additional capital for the further development and commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures.

Table of Contents

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. We may also seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

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

the progress of the development of our fully-human mAb, ADC, RTX, Cynviloq or related companion diagnostic product candidates;

the number of product candidates we pursue;

the time and costs involved in obtaining regulatory approvals;

the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims;

our plans to establish sales, marketing and/or manufacturing capabilities;

the effect of competing technological and market developments;

the terms and timing of any collaborative, licensing and other arrangements that we may establish;

general market conditions for offerings from biopharmaceutical companies;

our ability to establish, enforce and maintain selected strategic alliances and activities required for product commercialization; and

our revenues, if any, from successful development and commercialization of our product candidates.

In order to carry out our business plan and implement our strategy, we anticipate that we will need to obtain additional financing from time to time and may choose to raise additional funds through strategic collaborations, licensing arrangements, public or private equity or debt financing, bank lines of credit, asset sales, government grants, or other arrangements. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us or at all. Furthermore, any additional equity or equity-related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to

certain of our product candidates or marketing territories.

Further, there is uncertainty related to future NIH grant funding, and the NIH plans for new grants or cooperative agreements may be re-scoped, delayed, or canceled depending on the nature of the work and the availability of resources. As a result, we cannot assure you that we will receive any additional funding under our existing NIH grants, and we may not be successful in securing additional grants from the NIH in the future.

Our inability to raise capital when needed would harm our business, financial condition and results of operations, and could cause our stock price to decline or require that we wind down our operations altogether.

Risks Related to Our Business and Industry

We are heavily dependent on the success of our technologies and product candidates, and we cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.

To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates. We have not demonstrated our ability to perform the functions necessary for the successful acquisition, development or commercialization of the technologies we are seeking to develop. As an early stage company, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize such product candidates. Our product candidates are currently in preclinical development or in clinical trials. Our business depends entirely on the successful development and commercialization of our product candidates, which may never occur. We currently generate no revenues from sales of any drugs, and we may never be able to develop or commercialize a marketable drug.

The successful development, and any commercialization, of our technologies and any product candidates would require us to successfully perform a variety of functions, including:

developing our technology platform;

identifying, developing, manufacturing and commercializing product candidates;

Table of Contents

entering into successful licensing and other arrangements with product development partners;

participating in regulatory approval processes;

formulating and manufacturing products; and

conducting sales and marketing activities.

Our operations have been limited to organizing our company, acquiring, developing and securing our proprietary technology and identifying and obtaining early preclinical data or clinical data for various product candidates. These operations provide a limited basis for you to assess our ability to continue to develop our technology, identify product candidates, develop and commercialize any product candidates we are able to identify and enter into successful collaborative arrangements with other companies, as well as for you to assess the advisability of investing in our securities. Each of these requirements will require substantial time, effort and financial resources.

Each of our product candidates will require additional preclinical or clinical development, management of preclinical, clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the U.S. Food and Drug Administration, or FDA, or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. In addition, our product development programs contemplate the development of companion diagnostics by our third-party collaborators. Companion diagnostics are subject to regulation as medical devices and must themselves be approved for marketing by the FDA or certain other foreign regulatory agencies before we may commercialize our product candidates.

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. It is not uncommon for companies in the biopharmaceutical industry to suffer significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful.

This drug candidate development risk is heightened by any changes in the planned clinical trials compared to the completed clinical trials. As product candidates are developed through preclinical to early and late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for late stage clinical trials, approval and commercialization, such changes do carry the risk that they will not achieve these intended objectives.

We have not previously initiated or completed a corporate-sponsored clinical trial. Consequently, we may not have the necessary capabilities, including adequate staffing, to successfully manage the execution and completion of any

clinical trials we initiate, including our planned clinical trials of Cynviloq and RTX, in a way that leads to our obtaining marketing approval for our product candidates in a timely manner, or at all.

In the event we are able to conduct a pivotal clinical trial of a product candidate, the results of such trial may not be adequate to support marketing approval. Because our product candidates are intended for use in life-threatening diseases, in some cases we ultimately intend to seek marketing approval for each product candidate based on the results of a single pivotal clinical trial. As a result, these trials may receive enhanced scrutiny from the FDA. For any such pivotal trial, if the FDA disagrees with our choice of primary endpoint or the results for the primary endpoint are not robust or significant relative to control, are subject to confounding factors, or are not adequately supported by other study endpoints, including possibly overall survival or complete response rate, the FDA may refuse to approve a BLA based on such pivotal trial. The FDA may require additional clinical trials as a condition for approving our product candidates.

In some of our future trials, we may combine Cynviloq with other therapies such as chemotherapy or immunotherapy. We have not yet tested these combinations.

Table of Contents

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

Although we are planning for certain clinical trials relating to Cynviloq and RTX, there can be no assurance that the FDA will accept our proposed trial designs. We may experience delays in our clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

obtaining regulatory approval to commence a trial;

reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

obtaining institutional review board, or IRB, approval at each site;

recruiting suitable patients to participate in a trial;

clinical sites deviating from trial protocol or dropping out of a trial;

having patients complete a trial or return for post-treatment follow-up;

developing and validating companion diagnostics on a timely basis, if required;

adding new clinical trial sites; or

manufacturing sufficient quantities of product candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we intend to have agreements governing their committed activities, we will have limited influence over their actual performance.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols,

inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Competition for patients in conducting clinical trials may prevent or delay product development and strain our limited financial resources.

Many pharmaceutical companies are conducting clinical trials in patients with the disease indications that our potential drug products target. As a result, we must compete with them for clinical sites, physicians and the limited number of patients who fulfill the stringent requirements for participation in clinical trials. Also, due to the confidential nature of clinical trials, we do not know how many of the eligible patients may be enrolled in competing studies and who are consequently not available to us for our clinical trials. Our clinical trials may be delayed or terminated due to the inability to enroll enough patients. Patient enrollment depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites and the eligibility criteria for the study. The delay or inability to meet planned patient enrollment may result in increased costs and delays or termination of the trial, which could have a harmful effect on our ability to develop products.

Table of Contents

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

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

we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

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

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

the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;

the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and

the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

We have not previously submitted a biologics license application, or BLA, or a New Drug Application, or NDA, to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon our collaborators' ability to obtain regulatory approval of the companion diagnostics to be used with our product candidates, as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patients that we are targeting for our product candidates are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates both in the U.S., the European Union and in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

Our most rapid and cost effective access to market approval for Cynviloq depends on meeting the conditions for approval under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FFDCA.

We are seeking approval for Cynviloq under Section 505(b)(2) of the FFDCA, enacted as part of the Drug Price Competition and Patent Restoration Act of 1984, otherwise known as the Hatch-Waxman Act, which permits applicants to rely in part on preclinical and clinical data generated by third parties.

Table of Contents

Specifically, with respect to Cynviloq, we are relying in part on third party data on paclitaxel, which is the active ingredient in Cynviloq and the previously approved products Abraxane and Taxol. There can be no assurance that the FDA will not require us to conduct additional preclinical or clinical studies or otherwise obtain new supplementary data with respect to some or all of the data upon which we may rely prior to approving a Cynviloq NDA.

Our NDA also relies on prior FDA findings of safety and effectiveness of previously approved products, and we will make certifications in our NDA under Section 505(b)(2) requirements based on the listed patents in the FDA publication *Approved Drug Products with Therapeutics Equivalence Evaluations*, or the Orange Book, for certain of these referenced products. In the event that one or more patents is listed in the Orange Book for the referenced product after our submission of additional information in support of our NDA for Cynviloq, we may also be required to evaluate the applicability of these patents to Cynviloq and submit additional certifications. A paragraph III certification, stating that a listed patent has not expired, but will expire on a particular date, may delay the approval of Cynviloq until the expiration of the patent. A paragraph IV certification, stating that a listed patent is invalid, unenforceable, or not infringed by Cynviloq may require us to notify the patent owner and the holder of the NDA for the referenced product of the existence of the Cynviloq NDA, and may result in patent litigation against us and the entry of a 30-month stay of FDA ability to issue final approval of the 505(b)(2) NDA for Cynviloq.

Our success also relies, in part, on obtaining Hatch-Waxman marketing exclusivity in connection with any approval of our NDA for Cynviloq. Such exclusivity protection would preclude the FDA from approving a marketing application for a duplicate of Cynviloq, a product candidate that the FDA views as having the same conditions of approval as Cynviloq (for example, the same indication, the same route of delivery and/or other conditions of use), or a 505(b)(2) NDA submitted to the FDA with Cynviloq as the reference product, for a period of three years from the date of Cynviloq approval, although the FDA may accept and commence review of such applications. This form of exclusivity may not prevent FDA approval of an NDA that relies only on its own data to support the change or innovation. Similarly, if, prior to approval of the Cynviloq NDA, another company obtains approval for a product candidate under, in the view of the FDA, the same conditions of approval that we are seeking for Cynviloq, Cynviloq could be blocked until the other company's three-year Hatch-Waxman marketing exclusivity expires.

Our approach to the discovery and development of product candidates that target ADCs and rIVIG is unproven, and we do not know whether we will be able to develop any products of commercial value.

ADCs and rIVIG are emerging technologies and, consequently, it is conceivable that such technologies may ultimately fail to identify commercially viable drugs to treat human patients with cancer or other diseases.

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

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. To date, patients treated with Cynviloq have experienced drug-related side effects such as neutropenia, leukopenia, anemia, thrombocytopenia, peripheral neuropathy, myalgia, nausea, vomiting, diarrhea, alopecia, rash, pruritus and hypersensitivity reactions. The clinical evaluation of Cynviloq is still in the early stages, but as is the case with all oncology drugs, it is likely that there may be side effects associated with its use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to

complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

regulatory authorities may withdraw approvals of such product;

regulatory authorities may require additional warnings on the label;

we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;

we could be sued and held liable for harm caused to patients; and

our reputation may suffer.

Table of Contents

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate or for particular indications of a product candidate, if approved, and could significantly harm our business, results of operations and prospects.

We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully perform their contractual legal and regulatory 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 have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with current good clinical practices, or cGCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the European Medicines Agency, or EMA, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practices, or cGMP, regulations. Our failure 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 CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, 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 revenues could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays 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, financial condition and prospects.

We expect to rely on third parties to manufacture our clinical drug supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical drug supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the cGMP regulatory requirements for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Table of Contents

Material necessary to manufacture our product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidates.

We rely on our manufacturers to produce or purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Except for the manufacture and supply of Cynviloq, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

We expect to continue to depend on third-party contract manufacturers for the foreseeable future. We have not entered into long-term agreements with all of our current contract manufacturers or with any alternate fill/finish suppliers, and though we intend to do so prior to commercial launch in order to ensure that we maintain adequate supplies of finished drug product, we may be unable to enter into such an agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. We currently obtain our supplies of finished drug product through individual purchase orders.

We may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates.

We are dependent on our third party manufacturers to conduct process development and scale-up work necessary to support greater clinical development and commercialization requirements for our product candidates. Carrying out these activities in a timely manner, and on commercially reasonable terms, is critical to the successful development and commercialization of our product candidates. We expect our third-party manufacturers are capable of providing sufficient quantities of our product candidates to meet anticipated clinical and full-scale commercial demands, however if third parties with whom we currently work are unable to meet our supply requirements, we will need to secure alternate suppliers. While we believe that there are other contract manufacturers having the technical capabilities to manufacture our product candidates, we cannot be certain that identifying and establishing relationships with such sources would not result in significant delay or material additional costs.

We currently have no sales and marketing organization. If we are unable to establish a direct sales force in the U.S. to promote our products, the commercial opportunity for our products may be diminished.

We currently have no sales and marketing organization. If any of our product candidates are approved by the FDA, we intend to market that product through our own sales force. We will incur significant additional expenses and commit significant additional management resources to establish our sales force. We may not be able to establish these capabilities despite these additional expenditures. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire and train sales and marketing personnel. If we elect to rely on third parties to sell our product candidates in the U.S., we may receive less revenue than if we sold our products directly. In addition, although we would intend to use due diligence in monitoring their activities, we may have little or no control over the sales efforts of those third parties. In the event we are unable to develop our own sales force or collaborate with a third

party to sell our product candidates, we may not be able to commercialize our product candidates which would negatively impact our ability to generate revenue.

We may need others to market and commercialize our product candidates in international markets.

In the future, if appropriate regulatory approvals are obtained, we may commercialize our product candidates in international markets. However, we have not decided how to commercialize our product candidates in those markets. We may decide to build our own sales force or sell our products through third parties. If we decide to sell our product candidates in international markets through a third party, we may not be able to enter into any marketing arrangements on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed our product candidates entirely on our own. If we are unable to enter into a marketing arrangement for our product candidates in international markets, we may not be able to develop an effective international sales force to successfully commercialize those products in international markets. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenue would be limited.

Table of Contents

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. The future discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;

fines, warning letters or holds on clinical trials;

refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;

product seizure or detention, or refusal to permit the import or export of products; and

injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.

A pharmaceutical product cannot be marketed in the U.S. or other countries until we have completed rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or the PTO. The FDA typically conducts a review of

proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if we believe the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

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

As part of our growth strategy, we intend to develop and market additional products and product candidates. We are pursuing various therapeutic opportunities through our pipeline. We may spend several years completing our development of any particular current or future internal product candidate, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products. Failure of this strategy would impair our ability to grow.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

Table of Contents

In addition, future acquisitions may entail numerous operational and financial risks, including:

disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;

incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;

higher than expected acquisition and integration costs;

difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;

increased amortization expenses;

impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership;

inability to motivate key employees of any acquired businesses; and

assumption of known and unknown liabilities.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

Our commercial success depends upon us attaining significant market acceptance of our product candidates, if approved for sale, among physicians, patients, healthcare payors and major operators of cancer and other clinics.

Even if we obtain regulatory approval for our product candidates, the product may not gain market acceptance among physicians, health care payors, patients and the medical community, which are critical to commercial success. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

the efficacy and safety as demonstrated in clinical trials;

the timing of market introduction of such product candidate as well as competitive products;

the clinical indications for which the drug is approved;

acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;

the safety of such product candidate seen in a broader patient group, including its use outside the approved indications;

the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;

the availability of adequate reimbursement and pricing by third-party payors and government authorities;

the relative convenience and ease of administration of Cynviloq for clinical practices;