Clovis Oncology, Inc.
Form 424B1
April 04, 2012
Table of Contents

Filed Pursuant to Rule 424(b)(1)
Registration No. 333-180293

Prospectus

3,750,000 Shares

COMMON STOCK

We are offering 3,750,000 shares of our common stock.

Our common stock is listed on the NASDAQ Global Select Market under the symbol CLVS . On April 3, 2012, the reported last sale price of our common stock was $20.86 per share.

	Per Share	Total
Public offering price	$ 20.00	$ 75,000,000
Underwriting discounts and commissions	$ 1.20	$ 4,500,000
Proceeds to Clovis, before expenses	$ 18.80	$ 70,500,000

We have granted the underwriters an option to purchase up to 562,500 additional shares of our common stock to cover over-allotments.

Investing in our common stock involves risks. See Risk Factors beginning on page 8.

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 underwriters expect to deliver the shares on or about April 10, 2012.

J.P. Morgan **Credit Suisse**

Leerink Swann

April 3, 2012

Table of Contents

TABLE OF CONTENTS

You should rely only on the information contained in this prospectus or in any free writing prospectus that we may specifically authorize to be delivered or made available to you. **We have not, and the underwriters have not, authorized anyone to provide you with any information other than that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus may only be used where it is legal to offer and sell shares of our common stock. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock.** Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the underwriters are not, making an offer of these securities in any jurisdiction where the offer is not permitted.

For investors outside the United States: We have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

Table of Contents

PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and consolidated financial statements included elsewhere in this prospectus. This summary does not contain all of the information that may be important to you. You should read and carefully consider the following summary together with the entire prospectus, including our consolidated financial statements and the related notes thereto appearing elsewhere in this prospectus and the matters discussed in the sections in this prospectus entitled Risk Factors, Selected Consolidated Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations, before deciding to invest in our common stock. Some of the statements in this prospectus constitute forward-looking statements that involve risks and uncertainties. See Cautionary Note Regarding Forward-Looking Statements and Industry Data. Our actual results could differ materially from those anticipated in such forward-looking statements as a result of certain factors, including those discussed in the Risk Factors and other sections of this prospectus.

Clovis Oncology® and the Clovis logo are trademarks of Clovis Oncology, Inc. in the United States and in other selected countries. All other brand names or trademarks appearing in this prospectus are the property of their respective holders. Except as otherwise indicated herein or as the context otherwise requires, references in this prospectus to Clovis, the Company, we, us, and our, refer to Clovis Oncology, Inc. together with its consolidated subsidiary.

Overview

We are a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the United States, Europe and additional international markets. We target our development programs for the treatment of specific subsets of cancer populations, and seek to simultaneously develop, with partners, companion diagnostics that direct our product candidates to the patients that are most likely to benefit from their use. We are currently developing three product candidates for which we hold global marketing rights: CO-101, a lipid-conjugated form of the anti-cancer drug gemcitabine, which is in a pivotal study in a specific patient population for the treatment of metastatic pancreatic cancer; CO-1686, an orally available, small molecule epidermal growth factor receptor, or EGFR, covalent inhibitor that was the subject of an investigational new drug application, or IND, submitted to the U.S. Food and Drug Administration, or FDA, that became effective in January 2012 and has begun initial Phase I/II clinical development for the treatment of non-small cell lung cancer, or NSCLC, in patients with activating EGFR mutations, including the initial activating mutations, as well as the primary resistance mutation, T790M; and rucaparib, also known as CO-338, an orally available, small molecule poly (ADP-ribose) polymerase, or PARP, inhibitor being developed for various solid tumors that is currently in Phase I/II clinical trials.

We believe that discovery productivity exceeds development capacity in oncology, and we have built our organization to meet the need for innovative patient-specific oncology drug development. To implement our strategy, we have assembled an experienced team with core competencies in global clinical development and regulatory operations in oncology, as well as conducting collaborative relationships with companies specializing in companion diagnostic development. As our product candidates mature, we intend to build our own commercial organizations in major global markets and contract with local distributors in smaller markets.

The most common anti-cancer drug therapies typically address cancers within a specific organ as a single disease as opposed to a collection of different disease subtypes, often resulting in poor response rates and minimal effect on overall survival. We believe the oncology community is increasingly recognizing that tumors in a particular organ have unique pathologic and molecular characteristics that may warrant different treatment strategies. By better understanding differences in tumor biology and underlying disease pathways, researchers are identifying biomarkers to guide development of targeted oncology therapies, with streamlined clinical trials, stratified patient populations and improved patient outcomes. We believe that targeted therapies and companion diagnostics offer a patient-tailored approach to the treatment of cancers with improved diagnosis and outcomes.

We were founded in April 2009 by former executives of Pharmion Corporation, which successfully developed and commercialized novel oncology products in the United States and Europe and was ultimately

Table of Contents

acquired by Celgene Corporation in 2008. Our investors include the following entities or their affiliates: Domain Associates, New Enterprise Associates, Versant Ventures, Aberdare Ventures, Abingworth Bioventures, Frazier Healthcare Ventures, Pfizer Inc., ProQuest Investments and our management team. To date, we have not generated any revenues. Based on our current development plans, we do not expect to generate revenues until 2014 at the earliest. As of December 31, 2011, we had an accumulated deficit of $110.5 million.

Our Strategy

Our strategy is to acquire, develop, and commercialize innovative anti-cancer agents in the United States, Europe and additional international markets in oncology indications with significant unmet medical need. The critical components of our business strategy include the following:

Focus on oncology. The oncology market is characterized by a number of disorders with high rates of recurrence and a limited response from current therapies or treatments.

Focus on compounds where improved outcomes are associated with specific biomarkers. Our strategy to date has been to prioritize opportunities in which a strong biological hypothesis has been established linking a specific characteristic or biological state of a cell, or biomarker, with improved outcomes for the product candidate.

Combine companion diagnostics with drug development efforts to realize superior clinical outcomes. A companion diagnostic is a test or measurement intended to assist physicians in making treatment decisions for their patients. Companion diagnostics do so by evaluating the presence of biomarkers, and physicians use this information to select a specific drug or treatment to which their patient will most likely respond. Our development strategy is based on the premise that we can utilize effective companion diagnostics to identify different patient subsets who we believe will uniquely benefit from our product candidates.

Manage and control global development activities and regulatory operations. We believe our development and regulatory experience enables us to devise time- and cost-efficient strategies to develop and obtain regulatory approvals for new drugs, and to identify the regulatory pathway that allows us to get a product candidate to market as quickly as possible.

Seek and maintain global commercial rights. We believe that it is very important to maintain global rights to our product candidates, and that we can build our own commercial organizations in major pharmaceutical markets as well as a network of third-party distributors in smaller markets.

Table of Contents

Our Product Pipeline

Consistent with our strategy, each of our initial three in-licensed product candidates, for which we hold global marketing rights, is being developed for selected patient subsets. The following table summarizes the status of our product pipeline:

CO-101 a Lipid-Conjugated Form of the Anti-Cancer Drug Gemcitabine

CO-101 is currently in a Phase II clinical study in patients with metastatic pancreatic cancer for use as an initial therapy recommended for treatment of the disease, or a so-called first-line treatment . CO-101 is a novel, patented, lipid-conjugated form of the anti-cancer drug gemcitabine that is designed to treat patients with pancreatic cancer whose tumors express low amounts of a membrane transporter protein on the surface of the cancer cell known as hENT1 and are thus expected to be resistant to standard gemcitabine-based therapy. Based on the published results of multiple studies assessing the correlation of hENT1 expression to survival outcomes in pancreatic cancer patients treated with gemcitabine, as well as the prospective hENT1 classification of the first 250 patients enrolled in our pivotal study of CO-101, we believe that approximately one-half to two-thirds of pancreatic cancer patients express low levels of hENT1, and thus derive little or no benefit from gemcitabine therapy. For example, in 2009, a study published in *Gastroenterology* reported the results of a retrospective analysis of randomized samples collected from 198 pancreatic cancer patients between 1998 and 2002 comparing treatment with gemcitabine versus 5-fluorouracil (5-FU). Patients in this study treated with gemcitabine who had a high level of hENT1 expression had a median overall survival of 21 months, compared to a median overall survival of 16 months for gemcitabine-treated patients with low hENT1 expression and 12 months for gemcitabine-treated patients with no hENT1 expression.

CO-101, which we in-licensed from Clavis Pharma ASA, is currently in an international, randomized and controlled 360-patient Phase II clinical study for the first-line treatment of metastatic pancreatic cancer. This open-label study compares CO-101 to gemcitabine as a first-line treatment in patients with metastatic pancreatic cancer. The primary objective of this study is to compare the overall survival of patients with metastatic pancreatic cancer and low hENT1 expression that are treated with CO-101 versus gemcitabine. Secondary endpoints include overall survival in all patients and in patients with high hENT1 expression, disease response rate, and drug tolerability and toxicity. We completed enrollment for this trial in the first quarter of 2012 and

Table of Contents

expect to report top line results as to overall survival in the prespecified hENT1-low patient subset in the fourth quarter of 2012. While we have not sought a Special Protocol Assessment, or SPA, from the FDA for this trial, for the reasons set forth under *CO-101 Regulatory Strategy*, we believe that if its results are positive, this study will serve as a pivotal trial for CO-101 and enable us to file a New Drug Application, or NDA, with the FDA and a Marketing Approval Application, or MAA, with the European Medicines Agency, or EMA, in mid-2013. We have partnered with Ventana Medical Systems for the development and commercialization of a companion diagnostic for the assessment of hENT1 levels.

CO-1686 an Oral EGFR Mutant-Selective Inhibitor

CO-1686, which we in-licensed from Avila Therapeutics, Inc., is a novel, orally available, small molecule covalent inhibitor of the cancer-causing mutant forms of EGFR for the treatment of NSCLC. Because CO-1686 targets both the initial activating EGFR mutations as well as the primary resistance mutation, T790M, it has the potential to treat NSCLC patients with EGFR mutations, both as a first-line treatment, or as a therapy recommended for patients when a first-line treatment has been ineffective, a so-called second-line treatment. According to a study published in *Clinical Cancer Research* in 2008, such initiating activating mutations occur in approximately 10% to 15% of NSCLC cases in Caucasian patients and approximately 30% to 35% of NSCLC cases in East Asian patients. Based on multiple published reports, including a study in *Nature Reviews Cancer* in 2007, following treatment with approved NSCLC therapies, Tarceva (erlotinib) or Iressa (gefitinib), both known as tyrosine kinase inhibitors, or TKIs, approximately half of these patients develop the T790M mutation.

In January 2012, our IND became effective, permitting us to begin clinical investigation of CO-1686. We commenced an initial Phase I/II study of CO-1686 in the U.S. and Europe in the first quarter of 2012 and expect to commence such a study in Asia during the third quarter of 2012. We have designed an accelerated clinical development program for CO-1686, and if successful, have a goal of filing an NDA for an initial indication within approximately four years of filing our IND. We intend to pursue the development of CO-1686 as both a second-line therapy for EGFR-mutated NSCLC patients who become resistant to TKIs due to the emergence of the T790M secondary mutation and potentially as a first-line treatment for EGFR-mutated NSCLC. We have partnered with Roche Molecular Systems, Inc., or Roche, for the development and commercialization of a companion diagnostic for identification of EGFR mutations.

Rucaparib a PARP Inhibitor

Rucaparib, also known as CO-338, is a novel, orally available, small molecule PARP inhibitor that we intend to develop as both monotherapy and in combination with chemotherapeutic agents for the treatment of patients with cancers predisposed to PARP inhibitor sensitivity. Such cancers include serous ovarian cancer and selected patients with breast cancer. Rucaparib, which we in-licensed from Pfizer Inc., is currently in a Phase I clinical trial to determine the maximum tolerated dose of oral rucaparib that can be combined with intravenous, or IV, platinum chemotherapy in the treatment of solid tumors. This program is supplemented by two ongoing investigator-initiated trials: a Phase I/II monotherapy study in hereditary, or germ-line, BRCA mutant breast and ovarian cancer and a Phase II randomized study of the chemotherapy drug cisplatin, with or without rucaparib, in the adjuvant treatment of high-risk germ-line BRCA mutant and triple-negative breast cancer, a particularly difficult to treat form of breast cancer. In the fourth quarter of 2011, we initiated a Phase I/II monotherapy study of the oral formulation to determine an appropriate dose and schedule for long term administration and to then assess preliminary efficacy in breast and ovarian cancers, including in patients with germ-line mutations in BRCA genes.

Risks Associated with Our Business

Our business and our future results of operations and financial condition are subject to a number of risks and uncertainties. These risks and uncertainties that could adversely affect our actual results and performance, as well as the successful implementation of our business strategy, are discussed more fully in the Risk Factors and Cautionary Note Regarding Forward-Looking Statements and Industry Data sections of this prospectus. You should carefully consider all of the information set forth in this prospectus and, in particular, should evaluate the specific factors set forth under Risk Factors and Cautionary Note Regarding Forward-Looking Statements and

Table of Contents

Industry Data in deciding whether to invest in our common stock. Among these important risks and uncertainties that could adversely affect our results of operations and business condition are the following:

- We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. We are a clinical-stage company with no approved products, and no historical revenues, which makes it difficult to assess our future viability.
- If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates, or continue our development programs.
- We are heavily dependent on the success of our three 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.
- 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.
- The regulatory approval processes of the FDA and similar foreign authorities is 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.
- Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics could harm our drug development strategy.
- Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and major operators of cancer clinics.
- We face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.
- If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.
- Other factors identified elsewhere in this prospectus, including those set forth under Risk Factors .

Our Corporate Information

We were incorporated under the laws of the State of Delaware in April 2009. Our principal executive offices are located at 2525 28th Street, Suite 100, Boulder, Colorado 80301, and our telephone number is (303) 625-5000. Our website address is *www.clovisoncology.com.* Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this prospectus. You should not rely on any such information in making your decision whether to purchase our common stock.

Table of Contents

THE OFFERING

Common stock offered	3,750,000 shares
Common stock to be outstanding immediately following this offering	26,125,757 shares
Over-allotment option	Up to 562,500 shares
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $69.9 million, or approximately $80.5 million if the underwriters exercise their over-allotment option in full, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We expect to use the proceeds of this offering to fund our development programs and for working capital and general corporate purposes. See Use of Proceeds for a more complete description of the intended use of proceeds from this offering.
Risk factors	You should read Risk Factors for a discussion of factors you should carefully consider before deciding to invest in our common stock.
NASDAQ Global Select Market symbol	CLVS

The number of shares of our common stock to be outstanding after this offering set forth above is based on 22,375,757 shares of our common stock outstanding as of December 31, 2011 and excludes:

- 934,816 shares of our common stock issuable upon the exercise of stock options outstanding as of December 31, 2011 at a weighted-average exercise price of $4.88 per share;
- 1,357,258 shares of our common stock reserved for future issuance under our 2011 Equity Incentive Plan, or the 2011 Plan, as of December 31, 2011, plus any annual increases in the number of shares of common stock reserved for future issuance under the 2011 Plan pursuant to an evergreen provision and any other shares that may become issuable under the 2011 Plan pursuant to its terms, as more fully described in Executive and Director Compensation Compensation Decisions Relating to Fiscal Year 2012 2012 Option Grants ; and
- 189,656 shares of our common stock reserved for future issuance under our 2011 Employee Stock Purchase Plan, or the ESPP, as of December 31, 2011, plus any annual increases in the number of shares of our common stock reserved for future issuance under the ESPP pursuant to an evergreen provision and any other shares that may become issuable under the ESPP pursuant to its terms, as more fully described in Executive and Director Compensation Narrative Disclosure Relating to Summary Compensation Table and Grant of Plan Based Awards Table 2011 Employee Stock Purchase Plan.

Unless we specifically state otherwise, the information in this prospectus assumes or gives effect to:

no exercise by the underwriters of their over-allotment option to purchase up to 562,500 additional shares of common stock from us. One of our directors has agreed to purchase 25,000 shares of our common stock in this offering at the public offering price.

Table of Contents

SUMMARY CONSOLIDATED FINANCIAL DATA

The following table sets forth a summary of our historical consolidated financial data at the dates and for the periods indicated. The summary historical financial data presented below for the years ended December 31, 2011 and 2010 and the periods from April 20, 2009 (inception) to December 31, 2009 and 2011 has been derived from our audited financial statements, which are included elsewhere in this prospectus.

The financial information presented from April 20, 2009 (inception) to December 31, 2010 is based solely on the results of Clovis Oncology, Inc. Subsequent to January 1, 2011, the financial information is consolidated and includes the results of our wholly owned subsidiary in the United Kingdom. Our historical results are not necessarily indicative of results expected in any future period.

The summary historical financial data presented below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and the related notes thereto, which are included elsewhere in this prospectus. The summary historical financial data in this section is not intended to replace our financial statements and the related notes thereto.

Statement of Operations Data:

	For the Year Ended December 31,		Period from April 20, 2009 (Inception) to December 31, 2009	Cumulative from April 20, 2009 (Inception) to December 31, 2011
	2011	2010		
	(in thousands, except per share amounts)			
Revenue	$	$	$	$
Operating expenses:				
Research and development	40,726	22,323	1,762	64,811
General and administrative	6,860	4,302	2,209	13,371
Acquired in-process research and development	7,000	12,000	13,085	32,085
Operating loss	(54,586)	(38,625)	(17,056)	(110,267)
Other income (expense), net	(957)	795	(43)	(205)
Loss before income taxes	(55,543)	(37,830)	(17,099)	(110,472)
Income taxes	(27)			(27)
Net loss	$ (55,570)	$ (37,830)	$ (17,099)	(110,499)
Basic and diluted net loss per common share[1]	$ (14.42)	$ (28.55)	$ (15.38)	(51.06)
Common shares used in the computation of basic and diluted net loss per common share	3,854	1,325	1,112	2,164

	As of December 31, 2011	
	Actual	As Adjusted[2] (Unaudited)
	(In thousands)	
Balance sheet data:		
Cash, cash equivalents and available for sale securities	$ 140,248	$ 210,193
Working capital	130,519	200,465
Total assets	143,445	213,390
Common stock and additional paid-in-capital	242,243	312,188
Total stockholders equity	$ 131,793	$ 201,738

(1) See Note 11 within the notes to our consolidated financial statements which are included elsewhere in this prospectus for a description of the method used to compute basic and diluted loss per common share.

(2) As adjusted to reflect the sale of 3,750,000 shares of our common stock offered in this offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Table of Contents

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this prospectus, including our financial statements and the related notes appearing at the end of this prospectus, before making your decision to invest in shares of our common stock. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and cash flows. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.

This prospectus also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below and elsewhere in this prospectus. See Cautionary Note Regarding Forward-Looking Statements and Industry Data for information relating to these forward-looking statements.

Risks Related to Our Financial Position and Capital Requirements

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. We are a clinical-stage company with no approved products, and no historical revenues, which makes it difficult to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have focused primarily on in-licensing and developing our product candidates, CO-101, CO-1686 and rucaparib. We are not profitable and have incurred losses in each year since our inception in April 2009. Because we were only recently formed, we have only a limited operating history upon which you can evaluate our business and prospects. In addition, 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. We have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. Our net loss for the year ended December 31, 2011 was approximately $55.6 million. As of December 31, 2011, we had an accumulated deficit of $110.5 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. As such, we are subject to all of the risks incident in 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. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if any of our product candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders equity and working capital.

We will require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to obtain additional financing, 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 continue to spend substantial amounts to advance the 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 and may also need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate. We will also require funding for our other operating expenses as well as capital expenditures to maintain and improve our facilities, equipment and systems.

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.

Risks Related to Our Business and Industry

We are heavily dependent on the success of our three 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. 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, CO-101, CO-1686 and rucaparib, are currently 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.

Each of our product candidates will require additional clinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, substantial investment 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 FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We believe that, depending on the result of our current CO-101 clinical trial, this trial may serve as a pivotal trial to support our application for approval of CO-101. To the extent that the results of the trial are not satisfactory to the FDA or the EMA for support of an NDA or MAA, respectively, with respect to CO-101, we will be required to expend significant additional resources to conduct additional clinical trials in support of approval of CO-101. 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.

We have not previously submitted an 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 patient subsets that we are targeting 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 United States, 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.

Table of Contents

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. For example, the positive results generated to date in clinical trials for CO-101 and rucaparib do not ensure that later clinical trials will demonstrate similar results. 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. A number of companies in the biopharmaceutical industry have suffered 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.

Although we have clinical trials ongoing for CO-101, CO-1686 and rucaparib, we may experience delays in our ongoing 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;
- developing and validating companion diagnostics on a timely basis;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- 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 rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance.

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

Table of Contents

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.

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;
- we may be unable to demonstrate that a product candidate s clinical and other benefits outweigh its safety risks;
- 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 CO-101, rucaparib and CO-1686, 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.

Table of Contents

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 CO-101 have experienced drug-related side effects including nausea, vomiting, anorexia, fatigue, myelosuppression (an impairment of bone marrow function), neutropenia (a reduction in white blood cells), and thrombocytopenia (a reduction in blood platelet cells) and those treated with rucaparib have experienced drug-related side effects such as nausea and vomiting. While we have only recently initiated clinical trials for CO-1686, 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.

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

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics could harm our drug development strategy.

As one of the key elements of our clinical development strategy, we seek to identify patient subsets within a disease category who may derive selective and meaningful benefit from the product candidates we are developing. In collaboration with partners, we plan to develop companion diagnostics to help us to more accurately identify patients within a particular subset, both during our clinical trials and in connection with the commercialization of our product candidates. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory approval prior to commercialization. We do not develop companion diagnostics internally and thus we are dependent on the sustained cooperation and effort of our third-party collaborators in developing and obtaining approval for these companion diagnostics. We and our collaborators may encounter difficulties in developing and obtaining approval for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation. Any delay or failure by our collaborators to develop or obtain regulatory approval of the companion diagnostics could delay or prevent approval of our product candidates. In addition, our collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community. If such companion diagnostics fail to gain market acceptance, it would have an adverse effect on our ability to derive revenues from sales of our products. In addition, the diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic that we anticipate using in connection with development and commercialization of our product candidates or our

12

Table of Contents

relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

If we established the hENT1 cut-off improperly, or if our LEAP trial results do not support the hENT1 hypothesis, we could jeopardize our potential for success with CO-101.

Retrospective analysis of tissue samples has shown a correlation between hENT1 expression levels and response to gemcitabine therapy such that patients with low levels of hENT1 expression are believed to derive little or no benefit from the drug. Our ongoing pivotal trial will, to our knowledge, be the first clinical trial to prospectively identify patients as hENT1-low and to then correlate their response to CO-101 versus gemcitabine. We utilized both previously published research data, as well as the data we derived from our own retrospective analysis of tissue samples, to reach a judgment as to those pancreatic cancer patients whose level of hENT1 expression we characterize as hENT1-low . Using this definition of hENT1-high and hENT1-low, 65% of the first 250 patients enrolled in the LEAP trial have been classified as hENT1-low. If we have set the cut-off too high (to cover a broader range of patients), we may reduce our chances of being able to show a statistically significant improvement in the rate of survival in the patients classified as hENT1-low, and thereby fail to meet the pre-defined endpoint of the trial. Conversely, if we were overly conservative in our judgment of classifying patients as hENT1-low, we may improve our chance of success in achieving the pre-defined endpoint, but at the cost of limiting the prescribing label on CO-101 to such a small subset of potential patients as to significantly constrain the commercial potential for this product candidate, if approved. Finally, we have established our hENT1 cut-off based on tissue samples that came from primary pancreatic tumors, but are using tissue samples from metastatic cancer sites to define the hENT1 status of the patients in the trial. While there are limited data that suggest that the hENT1 status is generally consistent between metastatic and primary tumors, this may not be the case in the clinical setting, which could adversely affect the outcome of the trial.

There have been multiple publications addressing the relationship between hENT1 levels and gemcitabine treatment outcomes. To date, all of these publications have suggested the same relationship, namely that hENT1-high patients tend to respond better to gemcitabine therapy than hENT1-low patients. For example, in 2009, a study published in *Gastroenterology* reported the results of a retrospective analysis of randomized samples collected from 198 pancreatic cancer patients between 1998 and 2002 comparing treatment with gemcitabine versus 5-FU. Patients in this study treated with gemcitabine who had a high level of hENT1 expression had a median overall survival of 21 months, compared to a median overall survival of 16 months for gemcitabine-treated patients with low hENT1 expression and 12 months for gemcitabine-treated patients with no hENT1 expression. Importantly, the results of this study also demonstrated that there was no correlation between overall survival and hENT1 expression for patients treated with 5-FU. It is possible that other retrospective analyses of tissue samples may be published that do not reflect this correlation. Moreover, none of such studies have attempted to do what our LEAP trial is designed to do, which is to seek to prospectively prove this hENT1 hypothesis. Accordingly, we bear the risk that in a prospective, well controlled clinical trial, we may not be able to prove the hENT1 hypothesis. Our failure to achieve the predefined endpoints of the LEAP trial that support this hENT1 hypothesis would have an adverse impact on our ability to obtain approval for CO-101 and on our business, financial condition and prospects.

We rely on third parties to conduct our preclinical 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 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

Table of Contents

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, 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 cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

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 rely completely 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, Competent Authorities of the Member States of the EEA or comparable 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. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as current good manufacturing practices, or cGMPs, for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and 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

Table of Contents

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.

We rely on our manufacturers to 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. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, 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 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.

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. Later 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.

15

Table of Contents

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 currently have no marketing and sales organization. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues.

We currently do not have a marketing or sales organization for the marketing, sales and distribution of pharmaceutical products. In order to commercialize any product candidates, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we intend to establish our sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. With respect to our product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and major operators of cancer 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;
- the approval, availability, market acceptance and reimbursement for the companion diagnostic;
- acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;
- the potential and perceived advantages of such product candidate over alternative treatments, especially with respect to patient subsets that we are targeting with such product candidate;
- the safety of such product candidate seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;

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

relative convenience and ease of administration;

the prevalence and severity of adverse side effects; and

the effectiveness of our sales and marketing efforts.

Table of Contents

If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, health care payors and patients, we will not be able to generate significant revenues, and we may not become or remain profitable.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. In addition, the competition in the oncology market is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example, there are currently two agents approved for the treatment of metastatic pancreatic cancer: Gemzar®/gemcitabine marketed by Eli Lilly, Teva Pharmaceutical Industries and APP Pharmaceuticals, and Tarceva® (erlotinib) marketed by Astellas Pharma, and there are a number of active clinical trials ongoing in pancreatic cancer, including by AB Science SA, Amgen Inc., Astellas Pharma, BioSante Pharmaceuticals, Inc., Celgene Corporation, Immunomedics, Inc., Lorus Therapeutics, Merrimack Pharmaceuticals, Inc., NewLink Genetics Corporation and Threshold Pharmaceuticals, Inc. Tarceva® and Iressa® are two of the currently approved drugs that are used to treat EGFR mutant NSCLC, and in addition, we are aware of two products in development targeting EGFR for the treatment of NSCLC: Boehringer Ingelheim s BIBW-2992 (afatinib) and Pfizer s PF-299804. Finally, we believe the products in development targeting the PARP pathway consist of Abbott s ABT-888 (velaparib), Merck s MK-4827, Eisai s E-7016, Cephalon s CEP-9722 and Biomarin s BMN-673.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products that are more effective or less costly than any drug candidate that we are currently developing or that we may develop. If approved, our product candidates will face competition from commercially available drugs as well as drugs that are in the development pipelines of our competitors and later enter the market.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA, EMA or other regulatory approval or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business.

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. We intend to seek approval to market our product candidates in the United States, Europe and other selected foreign jurisdictions. Market acceptance and sales of our product candidates in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future health care reform measures.

Table of Contents

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

In both the United States and certain foreign jurisdictions, there have been and we expect there will continue to be a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products under the Medicare program in the United States. This has resulted in lower rates of reimbursement. In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Healthcare Reform Law, was enacted. The Healthcare Reform Law substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of the Healthcare Reform Law of greatest importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, beginning in 2011;
- an increase in the minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new Medicare Part D coverage gap discount program, under which manufacturers must agree to offer 50 percent 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, beginning in 2011;
- extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program, effective January 2010;

a licensure framework for follow-on biologic products; and

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research.

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

the demand for any drug products for which we may obtain regulatory approval;

our ability to set a price for our products;

Table of Contents

- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

In addition, governments may impose price controls, which may adversely affect our future profitability.

In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, especially Patrick J. Mahaffy, our President and Chief Executive Officer, Erle T. Mast, our Executive Vice President and Chief Financial Officer, Andrew R. Allen, our Executive Vice President of Clinical and Pre-Clinical Development and Chief Medical Officer, Steven L. Hoerter, our Senior Vice President of Commercial, and Gillian C. Ivers-Read, our Executive Vice President of Technical Operations and Chief Regulatory Officer, whose services are critical to the successful implementation of our product candidate acquisition, development and regulatory strategies. We are not aware of any present intention of any of these individuals to leave our company. In order to induce valuable employees to continue their employment with us, we have provided stock options that vest over time. The value to employees of stock options that vest over time is significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Pursuant to their employment arrangements, each of our executive officers may voluntarily terminate their employment at any time by providing as little as thirty days advance notice. Our employment arrangements, other than those with our executive officers, provide for at-will employment, which means that any of our employees (other than our executive officers) could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

Table of Contents

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of March 12, 2012, we had 57 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational and finance systems; and
- expanding our facilities.

As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, 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, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Ethics, but 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 governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such 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 and results of operations, including the imposition of significant fines or other sanctions.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to 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, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in

Table of Contents

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 payers that are false or fraudulent;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, 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 may not have the same effect, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

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

decreased demand for our product candidates or products that we may develop;

injury to our reputation;

withdrawal of clinical trial participants;

initiation of investigations by regulators;

costs to defend the related litigation;

a diversion of management s time and our resources;

substantial monetary awards to trial participants or patients;

product recalls, withdrawals or labeling, marketing or promotional restrictions;

loss of revenues from product sales; and

the inability to commercialize our product candidates.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop.

Table of Contents

We currently carry $10.0 million of product liability insurance, which we believe is adequate for our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in 2012 and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We may experience an ownership change as a result of this offering. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2011, we had federal net operating loss carryforwards of approximately $63.6 million that could be limited if we experience an ownership change, which could have an adverse effect on our results of operations.

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

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

We will incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes Oxley Act, as well as rules subsequently adopted by the SEC and the NASDAQ Stock Market, or NASDAQ. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. In addition, on July 21, 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as say on pay and proxy access, and the SEC has since issued final rules implementing say on pay measures. We expect these rules and regulations to substantially increase our legal and financial compliance costs, to make some activities more time-consuming and costly, to result in increased general and administrative expenses and to divert management time and attention from revenue-generating activities. The increased costs will decrease our net income or increase our consolidated net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we are required to perform system and

Table of Contents

process evaluation and testing of our internal controls over financial reporting to allow management to report, commencing in our annual report on Form 10-K for the year ending December 31, 2012, on the effectiveness of our internal controls over financial reporting, if then required by Section 404 of the Sarbanes-Oxley Act. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. 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. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner or if we identify or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

New laws and regulations as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act and rules adopted by the SEC and by NASDAQ, would likely result in increased costs to us as we respond to their requirements.

Risks Related to Our Intellectual Property

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or license may fail to result in issued patents in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold or pursue with respect to our product candidates is threatened, it could threaten our ability to commercialize our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, an interference proceeding can be provoked by a third-party or instituted by the United States Patent and Trademark Office, or the U.S. PTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

With respect to CO-101, we have an exclusive, worldwide license from Clavis to a portfolio of patents directed to the CO-101 composition of matter that expire in 2018. With respect to rucaparib, we have an exclusive, worldwide license from Pfizer to a portfolio of patents and patent applications directed to the rucaparib composition of matter that expire in 2020. While patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend our patent exclusivity for either CO-101 or rucaparib, we cannot provide any assurances that any such patent term extension will be obtained.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have

Table of Contents

access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including interference and reexamination proceedings before the U.S. PTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license, limit our uses, or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

We are aware of a family of patents and patent applications controlled by a third party that claim certain uses of PARP inhibitors that could potentially be asserted against our use of rucaparib in certain indications. We are conducting clinical trials for the treatment of solid tumors, a subset of which are ovarian cancer and breast cancer characterized as having positive germ-line BRCA mutations. Methods for treating such germ-line BRCA mutant positive patients with rucaparib could potentially fall within the scope of the issued or to be issued claims of such patents or patent applications. We are evaluating the validity of the patents and patent applications, including the scope or potential scope of the claims of these patents and patent applications, to determine whether to seek a license under such patents or patent applications, when and if they issue, or alternatively whether to initiate proceedings to challenge such patents. If we are unable to either license or successfully challenge such patents, we may consider shifting our development emphasis among alternative uses, and in so doing we could reduce the size of the aggregate potential market for rucaparib.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us,

Table of Contents

we may have to pay substantial damages, including treble damages and attorneys fees for willful infringement, obtain one or more licenses from third parties, limit our uses, pay royalties or redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

The patent protection and patent prosecution for some of our product candidates is dependent on third parties.

While we normally seek and gain the right to fully prosecute the patents relating to our product candidates, there may be times when platform technology patents that relate to our product candidates are controlled by our licensors. This is the case with our license of CO-1686 from Avila Therapeutics, Inc., in which Avila retained the right to prosecute and maintain the patents and patent applications covering its core discovery technology, including molecular backbones, building blocks and classes of compounds generated by that technology, aspects of which relate to CO-1686. While we have the right to prosecute and maintain the patent rights for the composition of matter for CO-1686, if Avila or any of our future licensing partners fail to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by the U.S. PTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Table of Contents

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

If we breach any of the agreements under which we license commercialization rights to our product candidates from third parties, we could lose license rights that are important to our business.

We license the use, development and commercialization rights for all of our product candidates, and may enter into similar licenses in the future. Under each of our existing license agreements with Clavis (CO-101), Avila (CO-1686) and Pfizer (rucaparib), we are subject to commercialization and development, diligence obligations, milestone payment obligations, royalty payments and other obligations. If we fail to comply with any of these obligations or otherwise breach our license agreements, our licensing partners may have the right to terminate the license in whole or in part. Generally, the loss of any one of our three current licenses or other licenses in the future could materially harm our business, prospects, financial condition and results of operations.

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

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

- Others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- We may not develop additional proprietary technologies that are patentable.
- The patents of others may have an adverse effect on our business.

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

Risks Related to This Offering and Ownership of our Common Stock

There may not be a viable public market for our common stock and as a result it may be difficult for you to sell your shares of our common stock.

Our common stock had not been publicly traded prior to our initial public offering in November 2011. The trading market for our common stock on The NASDAQ Global Select Market has been limited and an active

Table of Contents

trading market for our shares may not be sustained. As a result of these and other factors, you may be unable to resell your shares at a price that is attractive to you or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

The price of our stock has been, and may continue to be, volatile, and you could lose all or part of your investment.

The trading price of our common stock has been, and may continue to be, volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Since our initial public offering in November 2011 the price of our common stock on the NASDAQ Global Select Market has ranged from $11.45 per share to $27.55 per share. In addition to the factors discussed in this Risk Factors section and elsewhere in this prospectus, these factors include:

- our failure to commercialize our product candidates, if approved;
- actual or anticipated adverse results or delays in our clinical trials;