

IMMUNOGEN INC  
Form 10-K  
August 29, 2012

Use these links to rapidly review the document  
[ImmunoGen, Inc. Form 10-K TABLE OF CONTENTS](#)  
[Item 8. Financial Statements and Supplementary Data](#)

[Table of Contents](#)

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-K**

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

For the fiscal year ended June 30, 2012

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission file number 0-17999

**ImmunoGen, Inc.**

**Massachusetts**  
(State or other jurisdiction  
of incorporation or organization)

**04-2726691**  
(I.R.S. Employer  
Identification No.)

**830 Winter Street, Waltham, MA 02451**  
(Address of principal executive offices, including zip code)

**(781) 895-0600**  
(Registrant's telephone number, including area code)  
**Securities registered pursuant to Section 12(b) of the Act:**

| <b>Title of Each Class</b>    | <b>Name of Each Exchange on Which Registered</b> |
|-------------------------------|--|
| Common Stock, \$.01 par value | NASDAQ Global Select Market                      |

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ✓ Yes o No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. o Yes ✓ No

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

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Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  Yes  No

Aggregate market value, based upon the closing sale price of the shares as reported by the NASDAQ Global Market, of voting stock held by non-affiliates at December 31, 2011: \$886,501,851 (excludes shares held by executive officers and directors). Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of management or policies of the registrant, or that such person is controlled by or under common control with the registrant. Common Stock outstanding at August 21, 2012: 84,104,625 shares.

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement to be delivered to shareholders in connection with the Annual Meeting of Shareholders to be held on November 13, 2012 are incorporated by reference into Part III.

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Table of Contents

**ImmunoGen, Inc.**

**Form 10-K**

**TABLE OF CONTENTS**

| Item   | Page<br>Number |
|--|----------------|
| <b>Part I</b>  |                |
| 1. <u>Business</u>   | <u>3</u>       |
| 1A. <u>Risk Factors</u>  | <u>26</u>      |
| 1B. <u>Unresolved Staff Comments</u>   | <u>40</u>      |
| 2. <u>Properties</u>   | <u>41</u>      |
| 3. <u>Legal Proceedings</u>  | <u>41</u>      |
| 3.1 <u>Executive Officers of the Registrant</u>  | <u>41</u>      |
| 4. <u>Mine Safety Disclosures</u>  | <u>42</u>      |
| <b>Part II</b>   |                |
| 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> | <u>43</u>      |
| 6. <u>Selected Financial Data</u>  | <u>43</u>      |
| 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                        | <u>44</u>      |
| 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>  | <u>59</u>      |
| 8. <u>Financial Statements and Supplementary Data</u>  | <u>60</u>      |
| 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>                         | <u>103</u>     |
| 9A. <u>Controls and Procedures</u>   | <u>103</u>     |
| 9B. <u>Other Information</u>   | <u>105</u>     |
| <b>Part III</b>  |                |
| 10. Directors, Executive Officers and Corporate Governance   | 106            |
| 11. Executive Compensation   | 106            |
| 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters                     | 106            |
| 13. Certain Relationships and Related Transactions, and Director Independence  | 106            |
| 14. Principal Accounting Fees and Services   | 106            |
| <b>Part IV</b>   |                |
| 15. <u>Exhibits, Financial Statement Schedules</u>   | <u>107</u>     |
| <u>Signatures</u>  | <u>108</u>     |

Table of Contents

**Item 1. Business**

In this Annual Report on Form 10-K, ImmunoGen, Inc. (ImmunoGen, Inc., together with its subsidiaries, is referred to in this document as "we", "us", "ImmunoGen", or the "Company"), incorporates by reference certain information from parts of other documents filed with the Securities and Exchange Commission. The Securities and Exchange Commission allows us to disclose important information by referring to it in that manner. Please refer to all such information when reading this Annual Report on Form 10-K. All information is as of June 30, 2012 unless otherwise indicated. For a description of the risk factors affecting or applicable to our business, see "Risk Factors," below.

**The Company**

We develop novel, targeted, antibody-based therapeutics for the treatment of cancer using our expertise in cancer biology, monoclonal antibodies, highly potent cytotoxic, or cell-killing, agents, and the design of linkers that enable these agents to remain stably attached to the antibodies while in the blood stream and be released in their fully active form after delivery to a cancer cell. An anticancer compound made using our Targeted Antibody Payload, or TAP, technology consists of a monoclonal antibody that binds specifically to an antigen target found on cancer cells with multiple copies of one of our proprietary cell-killing agents attached using one of our engineered linkers. Its antibody component enables a TAP compound to bind specifically to cancer cells that express its target antigen, the highly potent cytotoxic agent serves to kill the cancer cell and the engineered linker controls the release and activation of the cytotoxic agent inside the cancer cell. With some TAP compounds, the antibody component also has anticancer activity of its own. Our TAP technology is designed to enable the creation of highly effective, well-tolerated anticancer products.

The most advanced compound with our TAP technology is trastuzumab emtansine, often referred to as T-DM1, which is in global development by Roche through our collaboration with Genentech, a member of the Roche Group. Positive findings from the lead T-DM1 Phase III trial have been reported, and, in August 2012, Roche announced that it has submitted the T-DM1 marketing application in the U.S. and will submit it soon in Europe. Under the collaboration agreement, we are entitled to receive royalties on T-DM1 sales, if any, as well as milestone payments on defined regulatory events.

We have three wholly owned clinical-stage product candidates IMGN901, IMGN853, and IMGN529 and other TAP compounds in earlier stages of development. IMGN901 is a potential treatment for small-cell lung cancer, or SCLC, and other cancers that express CD56 and is in Phase II testing for the first-line treatment of SCLC. IMGN853 is a potential treatment for ovarian cancer, non-small cell lung cancer, or NSCLC, and other cancers that over-express its folate receptor target and began Phase I testing in mid-2012. IMGN529 is a potential treatment for non-Hodgkin's lymphoma, or NHL, and chronic lymphocytic leukemia and began Phase I testing in early 2012. We also have earlier stage compounds in development and expect to advance our next wholly owned compound to Investigational New Drug, or IND, application stage in mid-2013. In addition to our product programs, we continue to invest in our TAP technology, including the development of additional cytotoxic agents and engineered linkers, to maintain a leadership position in our field.

Part of our business model is to establish collaborations with other companies in order to provide us with cash and revenue short term and potential significant value long term. Collaborations also help expand the utilization of our TAP technology. Our current collaborative partners are: Amgen Inc., Bayer HealthCare (a subgroup of Bayer AG), Biotest AG, Eli Lilly and Company, or Lilly, Novartis Institutes for BioMedical Research, Inc., or Novartis, Genentech, Inc. and Sanofi. These partners have certain rights to use our TAP technology to development anticancer therapies and have product candidates in clinical and/or preclinical testing. Eight compounds, including T-DM1, are in clinical testing through our collaborations.

Table of Contents

We were organized as a Massachusetts corporation in 1981. Our principal offices are located at 830 Winter Street, Waltham, Massachusetts (MA) 02451, and our telephone number is (781) 895-0600. We maintain a website at [www.immunogen.com](http://www.immunogen.com), where certain information about us is available. Please note that information contained on the website is not a part of this document. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports are available free of charge through the "Investor Information" section of our website as soon as reasonably practicable after those materials have been electronically filed with, or furnished to, the Securities and Exchange Commission. We have adopted a Code of Corporate Conduct that applies to all our directors, officers and employees and a Senior Officer and Financial Personnel Code of Ethics that applies to our senior officers and financial personnel. Our Code of Corporate Conduct and Senior Officer and Financial Personnel Code of Ethics are available free of charge through the "Investor Information" section of our website.

**Product Candidates**

There are eleven compounds in clinical trials through our own programs and our collaborations with other companies; these are listed in the table below. The results in early clinical trials may not be predictive of results obtained in subsequent clinical trials and there can be no assurance that each of our or our collaborators' product candidates will advance or will demonstrate the level of safety and efficacy necessary to obtain regulatory approval.

|  | <b>Current Stage</b> |
|--|----------------------|
| <b>Lead Compound in Development through a Collaborative Partner</b>  |                      |
| Trastuzumab emtansine (T-DM1)  | Registration         |
| <b>Compounds in Development by ImmunoGen</b>                         |                      |
| IMGN901 (lorvotuzumab mertansine)                                    | Phase II             |
| IMGN853  | Phase I              |
| IMGN529  | Phase I              |
| <b>Other Compounds in Development through Collaborative Partners</b> |                      |
| SAR3419  | Phase II             |
| BT-062   | Phase I              |
| SAR650984*   | Phase I              |
| SAR566658  | Phase I              |
| BAY 94-9343  | Phase I              |
| First Amgen TAP compound "Amgen 1"                                   | Phase I              |
| Second Amgen TAP compound "Amgen 2"                                  | Phase I              |

\*

*Non-conjugated or "naked" antibody therapeutic*

***Trastuzumab Emtansine (T-DM1)***

Trastuzumab emtansine, often referred to as T-DM1, is the most advanced compound in development using our TAP technology. T-DM1 consists of trastuzumab, which is the active component of Genentech's antibody therapeutic, Herceptin® (trastuzumab), with our DM1 cell-killing agent attached using our SMCC engineered linker. T-DM1 is in global development by Genentech's parent company, Roche, under a license with us.

T-DM1 is in Phase III testing for the treatment of HER2+ metastatic breast cancer, or mBC, and in June 2012 Roche reported its plans to initiate registration trials evaluating it for early stage HER2+ breast cancer, or eBC. Roche also is initiating a trial evaluating T-DM1 for HER2+ gastric cancer.

Table of Contents

***Evaluation for HER2+ mBC***

For HER2+ mBC previously treated with Herceptin and with a taxane Roche's lead T-DM1 Phase III trial, EMILIA, compares T-DM1, used alone, with Tykerb® (lapatinib) used together with Xeloda® (capecitabine) to treat HER2+ mBC in patients who have previously received Herceptin with a taxane. EMILIA has two co-primary endpoints: progression-free survival, or PFS, and overall survival, or OS. Findings from EMILIA were reported in June 2012 at the American Society of Clinical Oncology, or ASCO, annual meeting. Among the findings reported was that treatment with T-DM1 significantly improved PFS compared to treatment with Tykerb plus Xeloda, with a hazard ratio of 0.65 (p<0.0001). As expected, the OS data were not mature at the time of this analysis. A sufficient number of events (deaths) had occurred to establish median OS in the Tykerb plus Xeloda treatment arm but not in the T-DM1 treatment arm, and longer follow up is required. The EMILIA data reported also included that fewer T-DM1-treated patients experienced Grade 3 or higher adverse events, which are severe adverse events, than the patients treated with Tykerb plus Xeloda. In August 2012, Roche announced that, in updated results, treatment with T-DM1 significantly improved OS compared to treatment with Tykerb plus Xeloda, and thus both of the co-primary endpoints of the EMILIA trial had now been met. Roche also disclosed that it has submitted a Biologics License Application, or BLA, for T-DM1 to the U.S. Food and Drug Administration, or FDA, and that it expects to soon submit a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA.

For first-line treatment of HER2+ mBC In July 2010, Roche began a Phase III trial, MARIANNE, to assess T-DM1 for first-line treatment of HER2+ mBC. Current standard-of-care for this cancer is Herceptin used with a taxane, and MARIANNE compares T-DM1 to this treatment, both when used alone and when used with Roche's Perjeta® (pertuzumab) antibody. Roche intends to use MARIANNE results, if favorable, to apply in 2014 for approval of T-DM1 in the United States and Europe to treat this cancer, both used alone and used together with Perjeta.

For HER2+ mBC previously treated with Herceptin and with Tykerb Roche also has a Phase III trial, TH3RESA, underway assessing T-DM1 for this use. Patient dosing in this trial began in September 2011.

***Evaluation for HER2+ eBC***

In June 2012 Roche presented its three-pronged approach to developing T-DM1 for the treatment of HER2+ eBC: development for neoadjuvant use, for adjuvant use, and for patients with residual invasive disease following surgery. Roche has announced that it plans to initiate registration trials with T-DM1 in each of these uses in 2013.

***Lorvotuzumab mertansine (IMGN901)***

Our most advanced wholly owned product candidate is the TAP compound lorvotuzumab mertansine, which we also call IMGN901. We developed IMGN901 to target CD56, which is found on SCLC, Merkel cell carcinoma, multiple myeloma, ovarian cancers, carcinoid tumors, and other cancers of neuroendocrine origin. In early clinical testing, IMGN901 demonstrated evidence of activity when used alone to treat CD56+ cancers that had recurred after treatment with approved anticancer drugs.

We are evaluating IMGN901 for the first-line treatment of SCLC. Assuming this clinical trial is successful we intend to advance IMGN901 into pivotal clinical testing for this indication. We also are completing a Phase I clinical trial assessing IMGN901 for the treatment of multiple myeloma.

Table of Contents

*Evaluation for SCLC*

In March 2012 we began Phase II evaluation of IMGN901, used in combination with etoposide/carboplatin (E/C), as a treatment for newly diagnosed metastatic SCLC. E/C is a current standard care for this cancer. Patients enrolled in this trial, called NORTH, are randomized to receive either E/C or E/C plus IMGN901, with two patients randomized to the E/C plus IMGN901 group for every one patient randomized to the E/C alone group. The IMGN901 dose being used in the NORTH trial was established in the Phase I part of this trial.

The NORTH trial is designed to assess whether the addition of IMGN901 to E/C meaningfully improves patient outcomes. The primary endpoint of the NORTH trial is PFS. Secondary endpoints include PFS at 6 months, OS at 12 months, time to progression, OS, and overall response rate. An interim analysis focused on PFS at 6 months is planned after enrollment of the first 59 patients. The full NORTH trial is designed to include 120 patients.

*Evaluation for Multiple Myeloma*

IMGN901 is being assessed in a Phase I clinical trial for the treatment of multiple myeloma, used in combination with lenalidomide plus dexamethasone, a standard of care for this cancer. Promising data were presented at the ASCO meeting in June 2011 from the dose-finding portion of this clinical trial. Based on clinical findings to date, we believe IMGN901 is a promising treatment for multiple myeloma. However, because of the significant unmet medical need in SCLC, we have focused development on SCLC and currently have no plans to advance IMGN901 into pivotal testing for the treatment of multiple myeloma.

**IMGN853**

Our IMGN853 TAP compound targets folate receptor 1, or FOLR1, which is over-expressed on many cases of ovarian cancer, or OC, and also on other types of solid tumors, including NSCLC. IMGN853 consists of a FOLR1-targeting antibody with one of our potent cell-killing agents attached using one of our linkers engineered to counteract the multi-drug resistance that many cancers develop.

In July 2012 we advanced IMGN853 into clinical testing in a Phase I clinical trial intended to enable us to establish the path(s) to potential regulatory approval for IMGN853. The maximum-tolerated dose, or MTD, of IMGN853 will be established in the dose-escalation portion of this trial, which allows for single-patient cohorts at the initial, lower dose levels. Once the MTD is established, we plan to evaluate IMGN853 in patients with previously treated epithelial OC and in patients with previously treated adenocarcinoma NSCLC.

**IMGN529**

Our IMGN529 TAP compound targets CD37, which is expressed on B-cell malignancies such as NHL and chronic lymphocytic leukemia. Scientists have found the expression profile of CD37 on NHL subtypes to be similar to that of CD20, the target of Rituxan® (rituximab).

IMGN529 comprises an antibody that, in preclinical testing, has demonstrated meaningful anticancer activity, our DM1 cell-killing agent, and our SMCC engineered linker, thus paralleling T-DM1 in design. We believe IMGN529 is a highly differentiated product candidate for B-cell malignancies because it combines the anticancer activity of its antibody component with the actions of our potent cell-killing agent. In April 2012, we began Phase I clinical testing of IMGN529 for the treatment of NHL.

Table of Contents

***Compounds in Development by Our Partners***

In addition to T-DM1, seven other compounds are in clinical testing through our collaborations with other companies. Several of our collaborative partners also have TAP compounds in earlier stages of development, including our newest partners Novartis and Lilly.

***SAR3419***

We created the SAR3419 TAP compound and licensed it to Sanofi from our preclinical pipeline as part of a broader collaboration. SAR3419 targets CD19 and is a potential new treatment for CD19-expressing B-cell malignancies including NHL and B-cell acute lymphoblastic leukemia, or B-ALL. In Phase I clinical testing, SAR3419 showed encouraging efficacy and tolerability in the treatment of NHL previously treated with approved anticancer agents. Sanofi initiated Phase II clinical testing of SAR3419 in October 2011 and is evaluating it for both diffuse large B-cell lymphoma, a type of NHL, and in B-ALL.

***BT-062***

BT-062 was created by Biotest under a license agreement with us that grants Biotest rights to use our TAP technology with antibodies that target CD138, an antigen found on multiple myeloma and certain solid tumors. We have opt-in rights with respect to BT-062 in the United States. Encouraging early stage clinical data have been reported with BT-062 used as a single agent to treat multiple myeloma that had recurred after treatment with approved anticancer agents. In July 2012 Biotest began patient dosing in an early stage trial assessing BT-062 used as part of a combination regimen for this cancer. Biotest also is assessing BT-062 preclinically for the treatment of CD138-expressing solid tumors.

***SAR650984 and SAR566658***

These compounds also were licensed to Sanofi preclinically as part of a broader collaboration, and both are in early stage clinical testing. SAR650984 is a CD38-targeting therapeutic antibody for hematological malignancies. SAR566658 is a TAP compound for DS6-expressing solid tumors, including ovarian cancers. DS6 is also known as CA6.

***BAY 94-9343***

BAY 94-9343 was created by Bayer under a license agreement with us that grants Bayer rights to use our TAP technology with antibodies that target mesothelin. BAY 94-9343 advanced into Phase I clinical testing for the treatment of mesothelin-expressing solid tumors in September 2011.

***Amgen 1 and Amgen 2***

Two TAP compounds that we refer to as Amgen 1 and Amgen 2 advanced into clinical testing in early 2012 through our collaboration with Amgen. Both compounds were created by Amgen under license agreements with us granting Amgen rights to use our TAP technology with antibodies binding to the targets of Amgen 1 and Amgen 2.

**Incidence of Relevant Cancers**

Cancer remains a leading cause of death worldwide, and is the second leading cause of death in the U.S. The American Cancer Society estimates that in 2012 approximately 1.6 million new cases of cancer will be diagnosed in the U.S. and that approximately 577,000 people will die from the disease. The total number of people living with cancer significantly exceeds the number of patients diagnosed with cancer in a given year as patients can live with cancer for a year or longer. Additionally, the potential market for anticancer drugs exceeds the number of patients treated as many types of cancer typically are treated with multiple compounds at the same time and because patients often receive a number of drug regimens sequentially.



Table of Contents

T-DM1 Based on American Cancer Society and Roche estimates, we believe approximately 57,000 new cases of HER2+ breast cancer will be diagnosed in the U.S. in 2012. These include diagnoses for both early stage, or localized, disease and advanced, or metastatic, disease.

The first approvals of T-DM1 are expected to be for metastatic disease. Based on information reported by Roche in late 2011, we believe that the metastatic HER2+ breast cancer market in the U.S. consists of approximately 21,100 patients: 7,800 eligible for first-line treatment; 5,900 eligible for second-line treatment; 4,300 eligible for third-line treatment; and 3,100 eligible for fourth-line treatment.

IMGN901 We are assessing this compound in the clinic for the treatment of CD56+ SCLC and multiple myeloma. Based on our own studies and scientific literature, we believe that CD56 is expressed on approximately 89% of SCLC and 76% of multiple myeloma cases. Based on American Cancer Society estimates and other sources, we believe that approximately 29,400 new cases of SCLC will be diagnosed in the U.S. in 2012. SCLC tends to spread broadly through the body quite early in the course of the disease, and according to the American Cancer Society approximately two-thirds of SCLC patients have extensive disease at the time of diagnosis. Based on American Cancer Society estimates, we also believe that approximately 21,700 new cases of multiple myeloma will be diagnosed in the U.S. in 2012.

IMGN853 We are assessing our IMGN853 compound for the treatment of epithelial ovarian cancer and adenocarcinoma NSCLC. Based on American Cancer Society estimates, we believe approximately 19,000 and 90,000 new cases of these cancers will be diagnosed in the U.S. in 2012, respectively.

IMGN529 We are assessing our IMGN529 compound for the treatment of NHL. Based on American Cancer Society estimates, we believe approximately 70,000 new cases of NHL will be diagnosed in the U.S. in 2012.

**Out-licenses and Collaborations**

We selectively out-license restricted access to our TAP technology to other companies to provide us with cash to fund our own product programs and to expand the utilization of our technology. These agreements typically provide the licensee with rights to use our TAP technology with any of its antibodies and apply them to a defined target to develop products. The licensee is generally responsible for the development, clinical testing, manufacturing, registration and commercialization of any resulting product candidate. As part of these agreements, we are generally entitled to receive upfront fees, potential milestone payments, royalties on the sales of any resulting products and research and development funding based on activities performed at our collaborative partner's request. We are also compensated for preclinical and clinical materials supplied to our partners.

We will not receive royalty payments from a TAP technology out-license until a product candidate developed under the license is approved for marketing and commercialized, nor do we expect to receive significant individual milestones payments under our existing collaborations prior to the commencement of pivotal clinical trials or, in some cases, product approval. Achievement of product approval requires, at a minimum, favorable completion of preclinical development and evaluation, assessment of early-stage clinical trials, advancement into pivotal Phase II and/or Phase III clinical testing, completion of this later-stage clinical testing with favorable results, and completion of regulatory submissions and review. The only collaboration that may provide us with royalty revenue and significant milestone payments in the foreseeable future is our collaboration with Roche relating to

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### Table of Contents

T-DM1. Below is a table setting forth our active collaborations, the number of targets licensed and current status of the product candidates being developed thereunder:

| <b>Collaborator</b>   | <b>Agreement Type</b>            | <b>Effective Date(s)</b> | <b>Development Status<sup>1</sup></b> |
|-----------------------|----------------------------------|--------------------------|---------------------------------------|
| Roche <sup>2</sup>    | Multiple single-targets          | 2000                     | Registration                          |
| Amgen <sup>3</sup>    | Right-to-test and single-targets | 2000                     | Phase I                               |
| Sanofi                | Multiple single-targets          | 2003                     | Phase II                              |
| Sanofi <sup>4</sup>   | Right-to-test                    | 2006                     | Research/Preclinical                  |
| Biotest               | Single-target                    | 2006                     | Phase I                               |
| Bayer HealthCare      | Single-target                    | 2008                     | Phase I                               |
| Novartis <sup>4</sup> | Right-to-test                    | 2010                     | Research/Preclinical                  |
| Lilly <sup>4</sup>    | Right-to-test                    | 2011                     | Research/Preclinical                  |

<sup>1</sup> For collaborations involving multiple targets, development status denotes the most advanced program under the collaboration.

<sup>2</sup> Roche has five single-target licenses. Pursuant to the license covering the target HER2, which was entered into in 2000, a product candidate, T-DM1, has been developed and Roche has submitted a marketing application for the compound. The remaining four licenses were entered into between 2005 and 2008, and the development status of product candidates under each of those licenses is research/preclinical.

<sup>3</sup> Amgen has multiple outstanding exclusive and non-exclusive options providing it with the right to take single-target licenses, on pre-negotiated terms, to specified targets during the respective option periods. As of June 30, 2012, Amgen has taken two single-target licenses pursuant to the terms of its right-to-test agreement.

<sup>4</sup> Sanofi, Novartis and Lilly each has the right to take multiple exclusive options providing it with the right to take single-target licenses, on pre-negotiated terms, to specified targets during the respective option periods.

### ***Roche***

In May 2000, we granted Roche, through its Genentech unit, an exclusive development and commercialization license to our maytansinoid TAP technology for use with antibodies or other proteins that target HER2, such as trastuzumab. The product candidate T-DM1 is currently in development under this agreement. We received a \$2 million upfront payment from Roche upon execution of the agreement. We are also entitled to receive up to a total of \$44 million in milestone payments, plus tiered royalties in the mid-single digits on the commercial sales of any resulting products. On an individual country basis, royalties on commercial sales will be reduced to the low-single digits at any time during the applicable royalty period that the product is not covered by ImmunoGen patent rights in that country.

Roche may terminate this agreement for convenience at any time upon 90 days' prior written notice to us. The agreement may also be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, the agreement will continue in effect until the expiration of Roche's royalty obligations. For each product and country, Roche's royalty obligations commence with the first commercial sale of that product in that country, and extend for a period of 10 years from the date of that first commercial sale in that country, although if the product

Table of Contents

(or its manufacture, use or sale) is covered by an ImmunoGen patent in that country on such tenth anniversary, then the period during which royalties are payable is extended until 12 years from the date of the first commercial sale in that country.

Through June 30, 2012, we have received and recognized a total of \$13.5 million in milestone payments under this agreement. The next potential milestone we will be entitled to receive will be a regulatory milestone for marketing approval of T-DM1. As this could occur first in either the U.S. or Europe, the next potential milestone due will be either \$10.5 million with first approval in the U.S. or \$5 million with first approval in Europe.

***Amgen***

In September 2000, we entered into a ten-year right-to-test agreement with Abgenix, Inc. which was later acquired by Amgen. The agreement provides Amgen with the right to (a) test our maytansinoid TAP technology with Amgen's antibodies under a right-to-test, or research, license, (b) take options, with certain restrictions, to individual targets selected by Amgen on either an exclusive or non-exclusive basis for specified option periods and (c) upon exercise of those options, take exclusive or non-exclusive licenses to use our maytansinoid TAP technology to develop and commercialize products directed to the specified targets on previously agreed-upon terms. Amgen no longer has the right to take additional options under the right-to-test agreement, although multiple outstanding options remain in effect for the remainder of their respective option periods.

For each exclusive development and commercialization license taken, we are entitled to receive an exercise fee of \$1 million and up to a total of \$34 million in milestone payments, plus royalties on the commercial sales of any resulting products.

Amgen may terminate each development and commercialization license for convenience upon prior notice to us. Each license may also be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, each license will continue in effect until the expiration of Amgen's royalty obligations, which are determined on a product-by-product and country-by-country basis. For each product and country, Amgen's royalty obligations commence with the first commercial sale of that product in that country, and extend until the later of either the expiration of the last-to-expire ImmunoGen patent covering that product in that country or the expiration for that country of the minimum royalty period specified in each development and commercialization license.

Under the right-to-test agreement, in September 2009 and November 2009, we entered into two development and commercialization licenses with Amgen and received an exercise fee of \$1 million with each license taken. In November 2011, the Investigational New Drug (IND) applications for two compounds developed under the separate development and commercialization licenses became active, which triggered two \$1 million milestone payments to us. The next potential milestone we will be entitled to receive under either of these development and commercialization licenses will be a development milestone for the first dosing of a patient in a Phase II clinical trial, which will result in a \$3 million payment being due.

***Sanofi***

*Collaboration Agreement*

In July 2003, we entered into a broad collaboration agreement with Sanofi (formerly Aventis) to discover, develop and commercialize antibody-based products. The collaboration agreement provides Sanofi with worldwide development and commercialization rights to new antibody-based products directed to targets that are included in the collaboration, including the right to use our TAP technology and our humanization technology in the creation of products directed to these targets. The product

Table of Contents

candidates (targets) currently in development under the collaboration include SAR3419 (CD19), SAR650984 (CD38), SAR566658 (DS6, also known as CA6) and at least one earlier-stage compound that has yet to be disclosed. For each of the targets included in the collaboration at this time, we are entitled to receive up to a total of \$21.5 million in milestone payments, plus royalties on the commercial sales of any resulting products.

The agreement may be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, the agreement will continue in effect until the expiration of Sanofi's royalty obligations, which are determined on a product-by-product and country-by-country basis. For each product and country, Sanofi's royalty obligations commence upon first commercial sale of that product in that country, and extend until the later of either the expiration of the last-to-expire ImmunoGen patent covering that product in that country or the expiration for that country of the minimum royalty period specified in the agreement.

The collaboration agreement also provides us an option to certain co-promotion rights in the U.S. on a product-by-product basis. The terms of the collaboration agreement allow Sanofi to terminate our co-promotion rights if there is a change in control of our company.

Through June 30, 2012, we have received and recognized a total of \$16 million in milestone payments related to compounds covered under this agreement now and in the past, including a total of \$8 million in milestone payments related to two product candidates previously in the collaboration that have been returned to us along with the rights to the respective targets. The next potential milestone we will be entitled to receive with respect to each of SAR566658 and for SAR650984 will be a development milestone for initiation of a Phase IIB clinical trial (as defined in the agreement), which will result in each case in a \$3 million payment being due. The next potential milestone we will be entitled to receive with respect to SAR3419 will be for initiation of a Phase III clinical trial, which will result in a \$3 million payment being due. The next potential milestone we will be entitled to receive for each of the unidentified targets will be a development milestone for commencement of a Phase I clinical trial, which will result in a \$1 million payment being due, or a preclinical milestone which will result in a \$500,000 payment being due.

*Right-to-Test Agreement*

In December 2006, we entered into a separate right-to-test agreement with Sanofi. The agreement provides Sanofi with the right to (a) test our maytansinoid TAP technology with Sanofi's antibodies to targets that were not included in the collaboration agreement described above under a right-to-test, or research, license, (b) take exclusive options, with certain restrictions, to individual targets selected by Sanofi for specified time periods and (c) upon exercise of those options, take exclusive licenses to use our maytansinoid TAP technology to develop and commercialize products directed to the specified targets on terms agreed upon at the inception of the right-to-test agreement. The right-to-test agreement had a three-year original term from the activation date that was extended on a one-time basis by Sanofi in August 2011 for an additional three years by payment of a \$2 million extension fee.

For each development and commercialization license taken, we are entitled to receive an exercise fee of \$2 million and up to a total of \$30 million in milestone payments, plus royalties on the commercial sales of any resulting products.

Each development and commercialization license may be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, each license will continue in effect until the expiration of Sanofi's royalty obligations, which are determined on a product-by-product and country-by-country basis. For each product and country, Sanofi's royalty obligations commence with the first commercial sale of that product in that country, and extend until the later of either the expiration of the last-to-expire ImmunoGen patent covering that product in that country or the expiration for that country of the minimum royalty period specified in each development

Table of Contents

and commercialization license. No development and commercialization license has yet been taken under the right-to-test agreement.

***Biotest***

In July 2006, we granted Biotest an exclusive development and commercialization license to our maytansinoid TAP technology for use with antibodies that target CD138. The product candidate BT-062 is currently in development under this agreement. We received a \$1 million upfront payment from Biotest upon execution of the agreement. We are also entitled to receive up to a total of \$35.5 million in milestone payments, plus royalties on the commercial sales of any resulting products.

The agreement also provides us with the right to elect, at specific stages during the clinical evaluation of any compound created under the agreement, to participate in the United States development and commercialization of that compound in lieu of receiving the milestone payments not yet earned and royalties on sales in the United States. We can exercise this right during an exercise period specified in the agreement by notice and payment to Biotest of an agreed upon opt-in fee of \$5 million or \$15 million, depending on the stage of development. Upon exercise of this right, we would share equally with Biotest the associated costs of product development and commercialization in the United States along with the profit, if any, from product sales in the United States.

Biotest may terminate the agreement for convenience at any time prior to our election to participate in the U.S. development and commercialization of a compound created under this agreement upon prior notice to us. The agreement may also be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, the agreement will continue in effect until the expiration of Biotest's royalty obligations, which are determined on a product-by-product and country-by-country basis. For each product and country, Biotest's royalty obligations commence upon first commercial sale of that product in that country, and extend until the later of either the expiration of the last-to-expire ImmunoGen patent covering that product in that country or the expiration for that country of the minimum royalty period specified in the agreement.

Through June 30, 2012, we have received and recognized a total of \$500,000 in milestone payments under this agreement. The next potential milestone we will be entitled to receive will be a development milestone for commencement of a Phase IIb clinical trial (as defined in the agreement) which will result in a \$2 million payment being due.

***Bayer HealthCare***

In October 2008, we granted BayerHealthCare an exclusive development and commercialization license to our maytansinoid TAP technology for use with antibodies or other proteins that target mesothelin. The product candidate BAY 94-9343 is currently in development under this agreement. We received a \$4 million upfront payment upon execution of the agreement. We are also entitled to receive, for each product developed and marketed by Bayer HealthCare under this agreement, up to a total of \$170.5 million in milestone payments, plus royalties on the commercial sales of any resulting products.

Bayer HealthCare may terminate the agreement for convenience at any time upon prior written notice to us. The agreement may also be terminated by either party for a material breach by the other, subject to notice and cure provisions. We may also terminate the agreement upon the occurrence of specified events. Unless earlier terminated, the agreement will continue in effect until the expiration of Bayer HealthCare's royalty obligations, which are determined on a product-by-product and country-by-country basis. For each product and country, Bayer HealthCare's royalty obligations commence upon first commercial sale of that product in that country, and extend until the later of

Table of Contents

either the expiration of the last-to-expire ImmunoGen patent covering that product in that country or the expiration for that country of the minimum royalty period specified in the agreement.

Through June 30, 2012, we have received and recognized a total of \$3 million in milestone payments under this agreement. The next potential milestone we will be entitled to receive will be a development milestone for commencement of a non-pivotal Phase II clinical trial, which will result in a \$4 million payment being due.

*Novartis*

In October 2010, we entered into a right-to-test agreement with Novartis Institutes for BioMedical Research, Inc. (Novartis). The agreement provides Novartis with a right to (a) test our TAP technology with Novartis' antibodies directed to individual targets selected by Novartis under a right-to-test, or research, license, (b) take exclusive options, with certain restrictions, to individual targets selected by Novartis for specified option periods, and (c) upon exercise of those options take exclusive licenses to use our TAP technology to develop and commercialize products for a specified number of individual targets on terms agreed upon at the inception of the right-to-test agreement. The initial term of the right-to-test agreement is three years, which may be extended by Novartis for up to two additional one-year periods by the payment of additional consideration. Novartis must exercise its options for the development and commercialization licenses by the end of the term of the right-to-test agreement, after which any then outstanding options will lapse.

We received a \$45 million upfront payment in connection with the execution of the right-to-test agreement, and we are also entitled to receive additional payments under the agreement for research and development activities performed on behalf of Novartis during the term of the agreement. For each development and commercialization license taken, we are entitled to receive an exercise fee of \$1 million and up to a total of \$199.5 million in milestone payments, plus royalties on the commercial sales of any resulting products.

Novartis may terminate any development and commercialization license for convenience upon prior notice to us. Each license may also be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, each development and commercialization license will continue in effect until the expiration of Novartis' royalty obligations, which are determined on a product-by-product and country-by-country basis. For each product and country, Novartis' royalty obligations commence upon first commercial sale of that product in that country, and extend until the later of either the expiration of the last-to-expire ImmunoGen patent covering that product in that country or the expiration for that country of the minimum royalty period specified in each license. No development and commercialization license has yet been taken under the right-to-test agreement.

*Lilly*

In December 2011, the Company entered into a three-year right-to-test agreement with Eli Lilly and Company (Lilly). The agreement provides Lilly with the right to (a) take exclusive options, with certain restrictions, to individual targets selected by Lilly for specified option periods, (b) test our maytansinoid TAP technology with Lilly's antibodies directed to the optioned targets under a right-to-test, or research, license, and (c) upon exercise of those options take exclusive licenses to use our maytansinoid TAP technology to develop and commercialize products for a specified number of individual targets on terms agreed upon at the inception of the right-to-test agreement. Lilly must exercise its options for the development and commercialization licenses by the end of the term of the right-to-test agreement, after which any then outstanding options will lapse.

We received a \$20 million upfront payment in connection with the execution of the agreement, and we are also entitled to receive additional payments under the agreement for research and development

Table of Contents

activities performed under the agreement on behalf of Lilly during the term of the research license. For the first development and commercialization license taken, we are entitled to receive up to a total of \$200.5 million in milestone payments, plus tiered royalties in the mid-single to low-double digits on the commercial sales of any resulting products. For each subsequent development and commercialization license taken, we are entitled to receive an exercise fee of \$2 million and up to a total of \$199 million in milestone payments, plus royalties on the commercial sales of any resulting products.

Lilly may terminate any development and commercialization license for convenience upon prior notice to us. Each license may also be terminated by either party for a material breach by the other, subject to notice and cure provisions. We may also terminate the agreement upon the occurrence of specified events. Unless earlier terminated, each development and commercialization license will continue in effect until the expiration of Lilly's royalty obligations, which are determined on a product-by-product and country-by-country basis. For each product and country, Lilly's royalty obligations commence upon first commercial sale of that product in that country, and extend until the later of either the expiration of the last-to-expire ImmunoGen patent covering that product in that country or the expiration for that country of the minimum royalty period specified in each license. No development and commercialization license has yet been taken under the right-to-test agreement.

**In-Licenses**

From time to time we may in-license certain rights to targets or technologies for use in conjunction with our internal efforts to develop TAP compounds and related technologies. These licenses include rights to certain antibodies. In exchange, we may be obligated to pay upfront fees, potential milestone payments and royalties on any product sales.

**Patents, Trademarks and Trade Secrets**

Our intellectual property strategy centers on obtaining patent protection for our proprietary technologies and product candidates. As of June 30, 2012, our patent portfolio had a total of 381 issued patents worldwide and 438 pending patent applications worldwide that we own or license from third parties. We seek to protect our TAP technology and our product candidates through a multi-pronged approach. In this regard, we have patents and patent applications covering antibodies and other cell-binding agents, linkers, maytansinoid and other cell-killing agents, and complete antibody-drug conjugates, or immunoconjugates, comprising these components and methods of making and using each of the above. Typically, multiple issued patents and pending patent applications cover various aspects of each product candidate.

We consider our maytansinoid technology to be a key component of our overall corporate strategy. We currently own 34 issued U.S. patents covering various embodiments of our maytansinoid technology including claims directed to certain maytansinoids, antibody-maytansinoid conjugates and other cell-binding agents used with maytansinoids, and methods of making and using the same. In all cases, we have received or are applying for comparable patents in other jurisdictions including Europe and Japan. We have issued patents that cover numerous aspects of the manufacture of both our DM1 and DM4 cell-killing agents. These issued patents remain in force until various times between 2020 and 2026. We also have several composition of matter patents covering various aspects of our DM4 cell-killing agent and antibody-maytansinoid conjugates incorporating DM4 that are expected to remain in force until 2024-2025.

Our intellectual property strategy also includes pursuing patents directed to linkers, antibodies, conjugation methods, immunoconjugate formulations and the use of specific antibodies and immunoconjugates to treat certain diseases. In this regard, we have issued patents and pending patent applications related to many of our linker technologies. These issued patents, expiring in 2021-2027, and any patents which may issue from the patent applications, cover antibody-maytansinoid conjugates

Table of Contents

using these linkers. We also have issued U.S. patents and pending patent applications covering methods of assembling immunoconjugates from their constituent antibody, linker and cell-killing agent moieties. These issued patents will expire in 2021-2027, while any patents that may issue from pending patent applications also covering various aspects of these technologies will, if issued, expire between 2021 and 2032. We also have issued patents and pending patent applications related to monoclonal antibodies that may be a component of a TAP compound or may be developed as a therapeutic, or "naked," antibody anticancer compound. Among these patents is an issued U.S. patent claiming a method of humanizing murine antibodies to avoid their detection by the human immune system. We have received patents in other jurisdictions, including Europe and Japan, that correspond to our antibody humanization U.S. patent. These patents will expire between 2013 and 2014.

We expect our continued work in each of these areas will lead to other patent applications. In all such cases, we will either be the assignee or owner of such patents or have an exclusive license to the technology covered by the patents. For example, we also own issued patents covering proprietary derivatives of non-maytansinoid cell-killing molecules. However, we do not currently consider these additional patent families to be material to our business.

We have in-licensed intellectual property relating to our IMG901 product candidate from Dana-Farber Cancer Institute. We do not believe that the terms of this license are material to our business or prospects.

We cannot provide assurance that the patent applications will issue as patents or that any patents, if issued, will provide us with adequate protection against competitors with respect to the covered products, technologies or processes. Defining the scope and term of patent protection involves complex legal and factual analyses and, at any given time, the result of such analyses may be uncertain. In addition, other parties may challenge our patents in litigation or administrative proceedings resulting in a partial or complete loss of certain patent rights owned or controlled by ImmunoGen, Inc. Furthermore, as a patent does not confer any specific freedom to operate, other parties may have patents that may block or otherwise hinder the development and commercialization of our technology.

In addition, many of the processes and much of the know-how that are important to us depend upon the skills, knowledge and experience of our key scientific and technical personnel, which skills, knowledge and experience are not patentable. To protect our rights in these areas, we require that all employees, consultants, advisors and collaborators enter into confidentiality agreements with us. Further, we require that all employees enter into assignment of invention agreements as a condition of employment. We cannot provide assurance, however, that these agreements will provide adequate or any meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure of such trade secrets, know-how or proprietary information. Further, in the absence of patent protection, we may be exposed to competitors who independently develop substantially equivalent technology or otherwise gain access to our trade secrets, know-how or other proprietary information.

**Competition**

We focus on highly competitive areas of product development. Our competitors include major pharmaceutical companies and other biotechnology firms. For example, Pfizer, Seattle Genetics, Roche and Bristol-Myers Squibb have programs to attach a proprietary cell-killing small molecule to an antibody for targeted delivery to cancer cells. Pharmaceutical and biotechnology companies, as well as other institutions, also compete with us for promising targets for antibody-based therapeutics and in recruiting highly qualified scientific personnel. Many competitors and potential competitors have substantially greater scientific, research and product development capabilities, as well as greater financial, marketing and human resources than we do. In addition, many specialized biotechnology



Table of Contents

firms have formed collaborations with large, established companies to support the research, development and commercialization of products that may be competitive with ours.

In particular, competitive factors within the antibody and cancer therapeutic market include:

the safety and efficacy of products;

the timing of regulatory approval and commercial introduction;

special regulatory designation of products, such as Orphan Drug designation; and

the effectiveness of marketing, sales, and reimbursement efforts.

Our competitive position depends on our ability to develop effective proprietary products, implement clinical development programs, production plans and marketing plans, including collaborations with other companies with greater marketing resources than ours, and to obtain patent protection and secure sufficient capital resources.

Continuing development of conventional and targeted chemotherapeutics by large pharmaceutical companies and biotechnology companies may result in new compounds that may compete with our product candidates. In addition, antibodies developed by certain of these companies have been approved for use as cancer therapeutics. In the future, additional antibodies may compete with our product candidates. In addition, other companies have created or have programs to create potent cell-killing agents for attachment to antibodies. These companies may compete with us for technology out-license arrangements.

Because of the acceptance of combination therapy for the treatment of cancer and the variety of genes and targets implicated in cancer incidence and progression, we believe that products resulting from applications of new technologies may be complementary to our own.

Such new technologies include, but are not limited to:

the use of genomics technology to identify new gene-based targets for the development of anticancer drugs;

the use of high-throughput screening to identify and optimize lead compounds;

the use of gene therapy to deliver genes to regulate gene function; and

the use of therapeutic vaccines.

**Regulatory Matters**

*Government Regulation and Product Approval*

Government authorities in the U.S., at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. A new drug must be approved by the FDA through the new drug application, or NDA, process and a new biologic must be approved by the FDA through the biologics license application, or BLA, process before it may be legally marketed in the U.S.

Table of Contents

*U.S. Drug Development Process*

In the U.S., the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act, or FDCA, and in the case of biologics, also under the Public Health Service Act, or PHSA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug or biologic may be marketed in the U.S. generally involves the following:

completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices or other applicable regulations;

submission to the FDA of an IND which must become effective before human clinical trials may begin;

performance of adequate and well-controlled human clinical trials according to Good Clinical Practices to establish the safety and efficacy of the proposed drug for its intended use;

submission to the FDA of an NDA or BLA;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and

FDA review and approval of the NDA or BLA.

Once a pharmaceutical candidate is identified for development it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during studies due to safety concerns or non-compliance.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with good clinical practice regulations. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the results of the clinical trials must be submitted at least annually. In addition, timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. An institutional review board, or IRB, at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be

Table of Contents

provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

**Phase I:** The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

**Phase II:** This phase involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

**Phase III:** Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Phase I, Phase II, and Phase III testing may not be completed successfully within any specified period, if at all.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA or BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and FDA to reach agreement on the next phase of development. Sponsors typically use the End of Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support approval of the new drug. If this type of discussion occurred, a sponsor may be able to request a Special Protocol Assessment, or SPA, the purpose of which is to reach agreement with the FDA on the design of the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim.

According to FDA guidance for industry on the SPA process, a sponsor which meets the prerequisites may make a specific request for a special protocol assessment and provide information regarding the design and size of the proposed clinical trial. The FDA is supposed to evaluate the protocol within 45 days of the request to assess whether the proposed trial is adequate, and that evaluation may result in discussions and a request for additional information. A SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the record. The agreement will be binding on the FDA and may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the sponsor and the FDA or if the FDA determines that a substantial scientific issue essential to determining the safety or efficacy of the drug was identified after the testing began. Also, if the sponsor makes any unilateral changes to the approved protocol, the agreement will be invalidated.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP

Table of Contents

requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

*U.S. Review and Approval Processes*

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances. The FDA reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept a NDA or BLA for filing. In this event, the NDA or BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA or BLA, or an approved letter following satisfactory completion of all aspects of the review process. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. Before approving an NDA or BLA, the FDA will inspect the facility or facilities where the product is manufactured.

NDAs or BLAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. Priority review for an NDA for a new molecular entity and original BLAs will be 6 months from the date that the NDA or BLA is filed. In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Priority review and accelerated approval do not change the standards for approval, but may expedite the approval process.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the

Table of Contents

commercial value of the product. In addition, the FDA may require us to conduct Phase IV testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA or BLA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized.

The recently enacted Food and Drug Administration Safety and Innovation Act, or FDASIA, made permanent the Pediatric Research Equity Act, or PREA, which requires a sponsor to conduct pediatric studies for most drugs and biologicals, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs, BLAs and supplements thereto, must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data needs to be collected before the pediatric studies begin. After April 2013, the FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

*Patent Term Restoration and Marketing Exclusivity*

Depending upon the timing, duration and specifics of FDA approval of our drugs, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA or BLA, plus the time between the submission date of an NDA or BLA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by FDA to be essential to the approval of the application, for example, for new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical

Table of Contents

investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the U.S. The FDASIA made permanent the Best Pharmaceuticals for Children Act, or BPCA, which provides for an additional six months of marketing exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA, or a Written Request. If the Written Request does not include studies in neonates, the FDA is required to include its rationale for not requesting those studies. The FDA may request studies on approved or unapproved indications in separate Written Requests. The issuance of a Written Request does not require the sponsor to undertake the described studies. To date, we have not received any Written Requests.

*Biologics Price Competition and Innovation Act of 2009*

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act which included the Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA amended the PHSA to create an abbreviated approval pathway for two types of "generic" biologics: biosimilars and interchangeable biologic products, and provides for a twelve-year exclusivity period for the first approved biological product, or reference product, against which a biosimilar or interchangeable application is evaluated; however if pediatric studies are performed and accepted by the FDA, the twelve-year exclusivity period will be extended for an additional six months. A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. An interchangeable product is a biosimilar product that may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

An application for a biosimilar product may not be submitted until four years after the date on which the reference product was first approved. The first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed, but the exclusivity period may be shortened under certain circumstances.

In February 2012, the FDA issued 3 draft guidance documents on biosimilar product development. The draft guidance documents are: "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product," "Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product," and "Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009." The guidance documents provide FDA's current thinking on approaches to demonstrating that a proposed biological product is biosimilar to a reference product. The FDA received public comments on the draft documents and intends to issue final guidance

Table of Contents

documents in the future. Nevertheless, the absence of a final guidance document does not prevent a sponsor for seeking licensure of a biosimilar under the BPCIA.

*Orphan Drug Designation*

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for this type of disease or condition will be recovered from sales in the U.S. for that drug. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years. Orphan drug exclusivity, however, also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease.

The FDA also administers a clinical research grants program, whereby researchers may compete for funding to conduct clinical trials to support the approval of drugs, biologics, medical devices, and medical foods for rare diseases and conditions. A product does not have to be designated as an orphan drug to be eligible for the grant program. An application for an orphan grant should propose one discrete clinical study to facilitate FDA approval of the product for a rare disease or condition. The study may address an unapproved new product or an unapproved new use for a product already on the market.

The FDA granted Orphan Drug designation to our lorvotuzumab mertansine compound when used for the treatment of Merkel cell carcinoma (MCC), small-cell lung cancer (SCLC) and multiple myeloma (MM). Orphan drug designation provides ImmunoGen with seven years of market exclusivity that begins once lorvotuzumab mertansine receives FDA marketing approval for the use for which the orphan drug status was granted. Also, through a separate process, lorvotuzumab mertansine has been granted orphan medicinal product designation for the treatment of MCC, SCLC and MM in the European Union. Orphan medicinal product designation provides ImmunoGen with ten years of market exclusivity that begins once lorvotuzumab mertansine receives European approval for the use for which it was granted. We may pursue these designations for other indications for lorvotuzumab mertansine, and for other product candidates intended for qualifying patient populations.

*Expedited Review and Approval*

The FDA has various programs, including Fast Track, priority review, and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis of surrogate endpoints. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. Generally, drugs that may be eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development, and expedite the review of drugs to treat serious diseases and fill an unmet medical need. Priority review is designed to give drugs that offer

Table of Contents

major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of 10 months. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval provides an earlier approval of drugs to treat serious diseases, and that fill an unmet medical need based on a surrogate endpoint, which is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trials.

*Post-Approval Requirements*

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws and regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

*Foreign Regulation*

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, before we may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.



Table of Contents

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines, and optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the European Medicines Agency where it will be evaluated by the Committee for Medicinal Products for Human Use and a favorable opinion typically results in the grant by the European Commission of a single marketing authorization that is valid for all European Union member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period. The decentralized procedure provides for approval by one or more "concerned" member states based on an assessment of an application performed by one member state, known as the "reference" member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

As in the United States, we may apply for designation of a product as an orphan drug for the treatment of a specific indication in the European Union before the application for marketing authorization is made. Orphan drugs in Europe enjoy economic and marketing benefits, including up to 10 years of market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan-designated product.

*Reimbursement*

Sales of pharmaceutical products depend in significant part on the availability of third-party reimbursement. Third-party payors include government healthcare programs, managed care providers, private health insurers and other organizations. We anticipate third-party payors will provide reimbursement for our products. However, these third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Our product candidates may not be considered cost-effective. It is time consuming and expensive for us to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries, and included a major expansion of the prescription drug benefit under Medicare Part D. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a

Table of Contents

Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee.

It is not clear what effect the MMA has had on the prices paid for currently approved drugs and the pricing options for future approved drugs. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

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

We expect that there will continue to be a number of federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, ACA) enacted in March 2010, is expected to have a significant impact on the health care industry. ACA is expected to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. We cannot predict the impact of ACA on pharmaceutical companies as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions which has not yet occurred. In addition, although the United States Supreme Court recently upheld the constitutionality of most of the ACA, some states have stated their intentions to not implement certain sections of ACA and some members of Congress are still working to repeal ACA. These challenges add to the uncertainty of the changes enacted as part of ACA.

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

Table of Contents

**Research and Development Spending**

During each of the three years ended June 30, 2012, 2011 and 2010, we spent approximately \$69.2 million, \$63.5 million and \$50.3 million, respectively, on research and development activities.

**Raw Materials and Manufacturing**

We procure certain raw material components of finished conjugate, including antibodies, DM1, DM4, and linker, for ourselves and on behalf of our collaborators. In order to meet our commitments to our collaborators as well as our own needs, we are required to enter into agreements with third parties to produce these components well in advance of our production needs. Our principal suppliers for these components include Boehringer Ingelheim, Cytovance Biologics LLC, SAFC, Inc. and Società Italiana Corticosteroidi S.r.l.

In addition, we operate a conjugate manufacturing facility. A portion of the cost of operating this facility, including the cost of manufacturing personnel, is reimbursed by our collaborators based on the number of batches of preclinical and clinical materials produced on their behalf. Over the past few years, we have expanded and upgraded the capabilities of our manufacturing facility.

**Employees**

As of June 30, 2012, we had 245 full-time employees, of whom 205 were engaged in research and development activities. Ninety-seven research and development employees hold post-graduate degrees, of which 45 hold Ph.D. degrees and six hold M.D. degrees. We consider our relations with our employees to be good. None of our employees is covered by a collective bargaining agreement.

We have entered into confidentiality agreements with all of our employees, members of our board of directors and consultants. Further, we have entered into assignment of invention agreements with all of our employees.

**Third-Party Trademarks**

Herceptin® and Perjeta® are registered trademarks of Genentech. Xeloda® is a registered trademark of Hoffman-La Roche Inc. Tykerb® is a registered trademark of the GlaxoSmithKline group. Rituxan® is a registered trademark of Biogen Idec Inc.

**Item 1A. Risk Factors**

*THE RISKS AND UNCERTAINTIES DESCRIBED BELOW ARE THOSE THAT WE CURRENTLY BELIEVE MAY MATERIALLY AFFECT OUR COMPANY. ADDITIONAL RISKS AND UNCERTAINTIES THAT WE ARE UNAWARE OF OR THAT WE CURRENTLY DEEM IMMATERIAL ALSO MAY BECOME IMPORTANT FACTORS THAT AFFECT OUR COMPANY.*

**We have a history of operating losses and expect to incur significant additional operating losses.**

We have generated operating losses since our inception. As of June 30, 2012, we had an accumulated deficit of \$504.0 million. For the years ended June 30, 2012, 2011, and 2010, we generated losses of \$73.3 million, \$58.3 million and \$50.9 million, respectively. We may never be profitable. We expect to incur substantial additional operating expenses over the next several years as our research, development, preclinical testing, clinical trials and collaborator support activities continue. We intend to continue to invest significantly in our product candidates. Further, we expect to invest significant resources supporting our existing collaborators as they work to develop, test and commercialize TAP and other antibody compounds. We or our collaborators may encounter technological or regulatory difficulties as part of this development and commercialization process that we cannot overcome or remedy. We may also incur substantial marketing and other costs in the future if we decide to establish

Table of Contents

marketing and sales capabilities to commercialize our product candidates. None of our or our collaborators' product candidates has generated any commercial revenue and our only revenues to date have been primarily from upfront and milestone payments, research and development support and clinical materials reimbursement from our collaborative partners. We do not expect to generate revenues from the commercial sale of our internal product candidates in the near future, and we may never generate revenues from the commercial sale of internal products. Even if we do successfully develop products that can be marketed and sold commercially, we will need to generate significant revenues from those products to achieve and maintain profitability. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis.

**If we are unable to obtain additional funding when needed, we may have to delay or scale back some of our programs or grant rights to third parties to develop and market our product candidates.**

We will continue to expend substantial resources developing new and existing product candidates, including costs associated with research and development, acquiring new technologies, conducting preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing products as well as providing certain support to our collaborators in the development of their products. We believe that our current working capital, including \$94 million of net proceeds resulting from a public stock offering in July 2012, and expected future payments from our existing collaboration arrangements will be sufficient to meet our current and projected operating and capital requirements through fiscal 2015. However, we cannot provide assurance that such collaborative agreement funding will, in fact, be received. Should such future collaborator payments not be earned and paid as currently anticipated, we expect we could seek additional funding from other sources. We may need additional financing sooner due to a number of other factors as well, including:

if either we incur higher than expected costs or we or any of our collaborators experience slower than expected progress in developing product candidates and obtaining regulatory approvals;

acquisition of technologies and other business opportunities that require financial commitments.

Additional funding may not be available to us on favorable terms, or at all. We may raise additional funds through public or private financings, collaborative arrangements or other arrangements. Debt financing, if available, may involve covenants that could restrict our business activities. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, scale back or eliminate expenditures for some of our development programs or grant rights to develop and market product candidates that we would otherwise prefer to internally develop and market. If we are required to grant such rights, the ultimate value of these product candidates to us may be reduced.

**If our TAP technology does not produce safe, effective and commercially viable products, our business will be severely harmed.**

Our TAP technology yields novel product candidates for the treatment of cancer. To date, no TAP product candidate has obtained regulatory approval. Our TAP product candidates and/or our collaborators' TAP product candidates may not prove to be safe, effective or commercially viable treatments for cancer and our TAP technology may not result in any future meaningful benefits to us or for our current or potential collaborative partners. Furthermore, we are aware of only two compounds that are a conjugate of an antibody and a cytotoxic small molecule that have obtained approval by the FDA and are based on technology similar to our TAP technology. One of these products was later taken off the market by its owner due to toxicity concerns. If our TAP technology fails to generate product candidates that are safe, effective and commercially viable treatments for cancer, or fails to obtain FDA approval, our business will be severely harmed.

Table of Contents

**Clinical trials for our and our collaborative partners' product candidates will be lengthy and expensive and their outcome is uncertain.**

Before obtaining regulatory approval for the commercial sale of any product candidates, we and our collaborative partners must demonstrate through clinical testing that our product candidates are safe and effective for use in humans. Conducting clinical trials is a time-consuming, expensive and uncertain process and typically requires years to complete. The most advanced product candidate incorporating our TAP technology is in Phase III clinical testing. In our industry, the results from preclinical studies and early clinical trials often are not predictive of results obtained in later-stage clinical trials. Some compounds that have shown promising results in preclinical studies or early clinical trials subsequently fail to establish sufficient safety and efficacy data necessary to obtain regulatory approval. At any time during the clinical trials, we, our collaborative partners, or the FDA might delay or halt any clinical trials of our product candidates for various reasons, including:

occurrence of unacceptable toxicities or side effects;

ineffectiveness of the product candidate;

insufficient drug supply;

negative or inconclusive results from the clinical trials, or results that necessitate additional studies or clinical trials;

delays in obtaining or maintaining required approvals from institutions, review boards or other reviewing entities at clinical sites;

delays in patient enrollment;

insufficient funding or a reprioritization of financial or other resources; or

other reasons that are internal to the businesses of our collaborative partners, which they may not share with us.

Any failure or substantial delay in successfully completing clinical trials and obtaining regulatory approval for our product candidates or our collaborative partners' product candidates could severely harm our business.

**We and our collaborative partners are subject to extensive government regulations and we and our collaborative partners may not be able to obtain necessary regulatory approvals.**

We and our collaborative partners may not receive the regulatory approvals necessary to commercialize our product candidates, which would cause our business to be severely harmed. Pharmaceutical product candidates, including those in development by us and our collaborative partners, are subject to extensive and rigorous government regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products. If our potential products or our collaborators' potential products are marketed abroad, they will also be subject to extensive regulation by foreign governments. None of our product candidates has been approved for sale in the U.S. or any foreign market. The regulatory review and approval process, which includes preclinical studies and clinical trials of each product candidate, is lengthy, complex, expensive and uncertain. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each indication to establish the product candidate's safety and efficacy. Data obtained from preclinical studies and clinical trials are susceptible to varying interpretation, which may delay, limit or prevent regulatory approval. The approval process may take many years to complete and may involve ongoing requirements for post-marketing studies. In light of the limited regulatory history of monoclonal antibody-based therapeutics, regulatory approvals for our or our collaborative

Table of Contents

partners' product candidates may not be obtained without lengthy delays, if at all. Any FDA or other regulatory approvals of our or our collaborative partners' product candidates, once obtained, may be withdrawn. The effect of government regulation may be to:

delay marketing of potential products for a considerable period of time;

limit the indicated uses for which potential products may be marketed;

impose costly requirements on our activities; and

place us at a competitive disadvantage to other pharmaceutical and biotechnology companies.

We may encounter delays or rejections in the regulatory approval process because of additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. Failure to comply with FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other regulatory action against our product candidates or us. Outside the U.S., our ability to market a product is contingent upon receiving clearances from the appropriate regulatory authorities. The foreign regulatory approval process includes similar risks to those associated with the FDA approval process. In addition, we are, or may become, subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work. If we fail to comply with the laws and regulations pertaining to our business, we may be subject to sanctions, including the temporary or permanent suspension of operations, product recalls, marketing restrictions and civil and criminal penalties.

**Our and our collaborative partners' product candidates will remain subject to ongoing regulatory review even if they receive marketing approval. If we or our collaborative partners fail to comply with continuing regulations, we could lose these approvals and the sale of our products could be suspended.**

Even if we or our collaborative partners receive regulatory approval to market a particular product candidate, the approval could be conditioned on us or our collaborative partners conducting costly post-approval studies or could limit the indicated uses included in product labeling. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, force us or our collaborative partners to withdraw it from the market or impede or delay our or our collaborative partners' ability to obtain regulatory approvals in additional countries. In addition, the manufacturer of the product and its facilities will continue to be subject to FDA review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping related to the product remain subject to extensive regulatory requirements. We or our collaborative partners may be slow to adapt, or we or our collaborative partners may never adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements.

If we or our collaborative partners fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, or if previously unknown problems with our or our partners' products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

restrictions on the products, manufacturers or manufacturing processes;

warning letters;

civil or criminal penalties;

Table of Contents

finest;

injunctive;

product seizures or detentions;

import bans;

voluntary or mandatory product recalls and publicity requirements;

suspension or withdrawal of regulatory approvals;

total or partial suspension of production; and

refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

Any one of these could have a material adverse effect on our business or financial condition.

**If our collaborative partners fail to perform their obligations under our agreements with them, or determine not to continue with clinical trials for particular product candidates, our business could be severely impacted.**

Our strategy for the development and commercialization of our product candidates depends, in large part, upon the formation and maintenance of collaborative arrangements. Collaborations provide an opportunity for us to:

generate cash flow and revenue;

fund some of the costs associated with our internal research and development, preclinical testing, clinical trials and manufacturing;

seek and obtain regulatory approvals faster than we could on our own;

successfully commercialize existing and future product candidates; and

secure access to targets which, due to intellectual property restrictions, would otherwise be unavailable to our technology.

If we fail to secure or maintain successful collaborative arrangements, the development and marketing of compounds that use our technology may be delayed, scaled back or otherwise may not occur. In addition, we may be unable to negotiate other collaborative arrangements or, if necessary, modify our existing arrangements on acceptable terms. We cannot control the amount and timing of resources our collaborative partners may devote to our product candidates. Our collaborative partners may separately pursue competing product candidates, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our collaborative efforts, or may decide, for reasons not known to us, to discontinue development of product candidates under our agreements with them. Any of our collaborative partners may slow or discontinue the development of a product candidate covered by a collaborative arrangement for reasons that can include, but are not limited to:

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a change in the collaborative partner's strategic focus as a result of merger, management changes, adverse business events, or other causes;

a change in the priority of the product candidate relative to other programs in the collaborator's pipeline;

a reassessment of the patent situation related to the compound or its target;

a change in the anticipated competition for the product candidate;

preclinical studies and clinical trial results; and



Table of Contents

a reduction in the financial resources the collaborator can or is willing to apply to the development of new compounds.

Even if our collaborative partners continue their collaborative arrangements with us, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Also, our collaborative partners may fail to perform their obligations under the collaborative agreements or may be slow in performing their obligations. Our collaborative partners can terminate our collaborative agreements under certain conditions. The decision to advance a product that is covered by a collaborative agreement through clinical trials and ultimately to commercialization is in the discretion of our collaborative partners. If any collaborative partner were to terminate or breach our agreements, fail to complete its obligations to us in a timely manner, or decide to discontinue its development of a product candidate, our anticipated revenue from the agreement and from the development and commercialization of the products would be severely limited. If we are not able to establish additional collaborations or any or all of our existing collaborations are terminated and we are not able to enter into alternative collaborations on acceptable terms, or at all, our continued development, manufacture and commercialization of our product candidates could be delayed or scaled back as we may not have the funds or capability to continue these activities. If our collaborators fail to successfully develop and commercialize TAP compounds, our business prospects would be severely harmed.

**We depend on a small number of collaborators for a substantial portion of our revenue. The loss of, or a material reduction in activity by, any one of these collaborators could result in a substantial decline in our revenue.**

We have and will continue to have collaborations with a limited number of companies. As a result, our financial performance depends on the efforts and overall success of these companies. Also, the failure of any one of our collaborative partners to perform its obligations under its agreement with us, including making any royalty, milestone or other payments to us, could have an adverse effect on our financial condition. Further, any material reduction by any one of our collaborative partners in its level of commitment of resources, funding, personnel, and interest in continued development under its agreement with us could have an adverse effect on our financial condition. To date, we have recorded \$13.5 million in milestone payments with the advancement of T-DM1. Our agreement with Roche, through its Genentech unit, entitles us to receive up to \$44 million in milestone payments and also royalties on commercial sales, if any. Failure of Roche to continue to advance T-DM1 would have an adverse effect on our financial outlook. Also, if consolidation trends in the healthcare industry continue, the number of our potential collaborators could decrease, which could have an adverse impact on our development efforts. If a present or future collaborator of ours were to be involved in a business combination, the collaborator's continued pursuit and emphasis on our product development program could be delayed, diminished or terminated.

**If our collaborative partners' requirements for clinical materials to be manufactured by us are significantly lower than we have estimated, our financial results and condition could be adversely affected.**

We procure certain components of finished conjugate, including DM1, DM4, and linker, on behalf of several of our collaborators. In order to meet our commitments to our collaborative partners, we are required to enter into agreements with third parties to produce these components well in advance of our production of clinical materials on behalf of our collaborative partners. If our collaborative partners do not require as much clinical material as we have contracted to produce and we are unable to use these materials for our own products, we may not be able to recover our investment in these components and we may suffer significant losses. Collaborators have discontinued development of

Table of Contents

product candidates in the past and in the periods subsequent to these discontinuations, we had significantly reduced demand for conjugated material which adversely impacted our financial results.

In addition, we operate a conjugate manufacturing facility. A portion of the cost of operating this facility, including the cost of manufacturing personnel, is reimbursed by our collaborators based on the number of batches of preclinical and clinical materials produced on their behalf. If we produce fewer batches of clinical materials for our collaborators, a smaller amount of the cost of operating the conjugate manufacturing facility will be charged to our collaborative partners and our financial condition could be adversely affected.

**If our product requirements for clinical trials are significantly higher than we estimated, the inability to procure additional antibody or fill/finish services in a timely manner could impair our ability to initiate or advance our clinical trials.**

We rely on third-party suppliers to manufacture antibodies used in our own proprietary compounds. Due to the specific nature of the antibody and availability of production capacity, there is significant lead time required by these suppliers to provide us with the needed materials. If our antibody requirements for clinical materials to be manufactured are significantly higher than we estimated, we may not be able to readily procure additional antibody which would impair our ability to advance our clinical trials currently in process or initiate additional trials. We also rely on third parties to convert the bulk drug substance we manufacture into filled and finished vials of drug product for clinical use. Unanticipated difficulties or delays in the fill/finish process could impair our ability to advance our clinical trials currently in process or initiate additional trials. There can be no assurance that we will not have supply problems that could delay or stop our clinical trials or otherwise could have a material adverse effect on our business.

**We currently rely on one third-party manufacturer with commercial production experience to produce our cell-killing agents, DM1 and DM4.**

We rely on a third-party supplier to manufacture materials used to make TAP compounds. Our cell-killing agents DM1 and DM4, collectively DMx, are manufactured from a precursor, ansamitocin P3. As part of preparing to produce TAP compounds for later-stage clinical trials and commercialization, we currently use a single supplier, Società Italiana Corticosteroidi S.r.l., that converts ansamitocin P3 to DMx. Any delay or interruption in our supply of DMx could lead to a delay or interruption in our manufacturing operations, preclinical studies and clinical trials of our product candidates and our collaborators' product candidates, which could negatively affect our business.

**We may be unable to establish the manufacturing capabilities necessary to develop and commercialize our and our collaborative partners' potential products.**

Currently, we have only one conjugate manufacturing facility that we use to manufacture conjugated compounds for us and our collaborative partners for preclinical studies and early-stage clinical testing. Two of our partners have contracted for separate, large-scale manufacturing capacity to make materials to support potential future commercialization of their TAP compounds. We do not currently have the manufacturing capacity needed to make our product candidates for commercial sale. In addition, our manufacturing capacity may be insufficient to complete all clinical trials contemplated by us and our collaborative partners over time. We intend to rely in part on third-party contract manufacturers to produce sufficiently large quantities of drug materials that are and will be needed for later-stage clinical trials and commercialization of our potential products. We are currently in the process of developing relationships with third-party manufacturers that we believe will be necessary to continue the development of our product candidates. Third-party manufacturers may not be able to meet our needs with respect to timing, quantity or quality of materials. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or

Table of Contents

difficulties in our relationships with manufacturers, our clinical trials may be delayed, thereby delaying the submission of product candidates for regulatory approval and the market introduction and subsequent commercialization of our potential products. Any such delays may lower our revenues and potential profitability.

**We have only one conjugate manufacturing facility and any prolonged and significant disruption at that facility could impair our ability to manufacture our and our collaborative partners' product candidates for clinical testing.**

Currently, in certain cases, we are contractually obligated to manufacture Phase I and non-pivotal Phase II clinical products for companies licensing our TAP technology. We manufacture this material, as well as material for our own product candidates, in our conjugate manufacturing facility. We have only one such manufacturing facility in which we can manufacture clinical products. Our current manufacturing facility contains highly specialized equipment and utilizes complicated production processes developed over a number of years that would be difficult, time-consuming and costly to duplicate. Any prolonged disruption in the operations of our manufacturing facility would have a significant negative impact on our ability to manufacture products for clinical testing on our own and would cause us to seek additional third-party manufacturing contracts, thereby increasing our development costs. Even though we carry business interruption insurance policies, we may suffer losses as a result of business interruptions that exceed the coverage available or any losses may be excluded under our insurance policies. Certain events, such as natural disasters, fire, political disturbances, sabotage or business accidents, which could impact our current or future facilities, could have a significant negative impact on our operations by disrupting our product development efforts until such time as we are able to repair our facility or put in place third-party contract manufacturers to assume this manufacturing role.

**Unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives applicable to our product candidates could limit our potential product revenue.**

Antibody-based anticancer products are often much more costly to produce than traditional chemotherapeutics and tend to have significantly higher prices. Factors that help justify the price include the high mortality associated with many types of cancer and the need for more and better treatment options.

Regulations governing drug pricing and reimbursement vary widely from country to country. Some countries require approval of the sales price of a drug before it can be marketed. Some countries restrict the physicians that can authorize the use of more expensive medications. Some countries establish treatment guidelines to help limit the use of more expensive therapeutics and the pool of patients that receive them. In some countries, including the U.S., third-party payers frequently seek discounts from list prices and are increasingly challenging the prices charged for medical products. Because our product candidates are in the development stage, we do not know the level of reimbursement, if any, we will receive for any products that we are able to successfully develop. If the reimbursement for any of our product candidates is inadequate in light of our development and other costs, our ability to achieve profitability would be affected.

We believe that the efforts of governments and third-party payors to contain or reduce the cost of healthcare will continue to affect the business and financial condition of pharmaceutical and biopharmaceutical companies. A number of legislative and regulatory proposals to change the healthcare system in the U.S. and other major healthcare markets have been proposed and adopted in recent years. For example, the U.S. Congress enacted a limited prescription drug benefit for Medicare recipients as part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. While the program established by this statute may increase demand for any products that we are able to successfully develop, if we participate in this program, our prices will be negotiated with drug

Table of Contents

procurement organizations for Medicare beneficiaries and are likely to be lower than prices we might otherwise obtain. Non-Medicare third-party drug procurement organizations may also base the price they are willing to pay on the rate paid by drug procurement organizations for Medicare beneficiaries. The PPACA will also require discounts under the Medicare drug benefit program and increased rebates on drugs covered by Medicaid. In addition, the PPACA imposes an annual fee, which will increase annually, on sales by branded pharmaceutical manufacturers starting in 2011. The financial impact of these discounts, increased rebates and fees and the other provisions of the PPACA on our business is unclear and there can be no assurance that our business will not be materially adversely affected by the PPACA. In addition, ongoing initiatives in the U.S. have increased and will continue to increase pressure on drug pricing. The announcement or adoption of any such initiative could have an adverse effect on potential revenues from any product candidate that we may successfully develop.

**We may be unable to establish sales and marketing capabilities necessary to successfully commercialize our potential products.**

We currently have no direct sales or marketing capabilities. We anticipate relying on third parties to market and sell most of our primary product candidates or we may outlicense these products prior to the time when these capabilities are needed. If we decide to market our potential products through a direct sales force, we would need either to hire a sales force with expertise in pharmaceutical sales or to contract with a third party to provide a sales force which meets our needs. We may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for our potential products and be competitive. In addition, co-promotion or other marketing arrangements with third parties to commercialize potential products could significantly limit the revenues we derive from these potential products, and these third parties may fail to commercialize our compounds successfully.

**If our product candidates or those of our collaborative partners do not gain market acceptance, our business will suffer.**

Even if clinical trials demonstrate the safety and efficacy of our and our collaborative partners' product candidates and the necessary regulatory approvals are obtained, our and our collaborative partners' product candidates may not gain market acceptance among physicians, patients, healthcare payors and other members of the medical community. The degree of market acceptance of any product candidates that we or our collaborative partners develop will depend on a number of factors, including:

their degree of clinical efficacy and safety;

their advantage over alternative treatment methods;

our/the marketer's and our collaborative partners' ability to gain acceptable reimbursement and the reimbursement policies of government and third- party payors; and

the quality of the distribution capabilities for product candidates, both ours and our collaborative partners.

Physicians may not prescribe any of our future products until such time as clinical data or other factors demonstrate the safety and efficacy of those products as compared to conventional drug and other treatments. Even if the clinical safety and efficacy of therapies using our products is established, physicians may elect not to recommend the therapies for any number of other reasons, including whether the mode of administration of our products is effective for certain conditions, and whether the physicians are already using competing products that satisfy their treatment objectives. Physicians, patients, third-party payors and the medical community may not accept and use any product candidates that we, or our collaborative partners, develop. If our products do not achieve significant market

Table of Contents

acceptance and use, we will not be able to recover the significant investment we have made in developing such products and our business will be severely harmed.

**We may be unable to compete successfully.**

The markets in which we compete are well established and intensely competitive. We may be unable to compete successfully against our current and future competitors. Our failure to compete successfully may result in lower volume sold, pricing reductions, reduced gross margins and failure to achieve market acceptance for our potential products. Our competitors include research institutions, pharmaceutical companies and biotechnology companies, such as Pfizer, Seattle Genetics, Roche and Bristol-Myers Squibb. Many of these organizations have substantially more experience and more capital, research and development, regulatory, manufacturing, human and other resources than we do. As a result, they may:

develop products that are safer or more effective than our product candidates;

obtain FDA and other regulatory approvals or reach the market with their products more rapidly than we can, reducing the potential sales of our product candidates;

devote greater resources to market or sell their products;

adapt more quickly to new technologies and scientific advances;

initiate or withstand substantial price competition more successfully than we can;

have greater success in recruiting skilled scientific workers from the limited pool of available talent;

more effectively negotiate third-party licensing and collaboration arrangements; and

take advantage of acquisition or other opportunities more readily than we can.

A number of pharmaceutical and biotechnology companies are currently developing products targeting the same types of cancer that we target, and some of our competitors' products have entered clinical trials or already are commercially available.

Our product candidates, if approved and commercialized, will also compete against well-established, existing, therapeutic products that are currently reimbursed by government healthcare programs, private health insurers and health maintenance organizations. In addition, if our product candidates are approved and commercialized, we may face competition from generic products if the product candidate is a small molecule drug, or biosimilars if the product candidate is a biologic. The route to market for generic versions of small molecule drugs was established with the passage of the Hatch-Waxman Amendments in 1984 and for biosimilars with the passage of the PPACA in March 2010. The PPACA establishes a pathway for the FDA approval of follow-on biologics and provides twelve years exclusivity for reference products and an additional six months exclusivity period if pediatric studies are conducted. In Europe, the European Medicines Agency has issued guidelines for approving products through an abbreviated pathway, and biosimilars have been approved in Europe. If a biosimilar version of one of our potential products were approved in the United States or Europe, it could have a negative effect on sales and gross profits of the potential product and our financial condition.

We face and will continue to face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for relationships with academic and research institutions and for licenses to proprietary technology. In addition, we anticipate that we will face increased competition in the future as new companies enter our markets and as scientific developments surrounding antibody-based therapeutics for cancer continue to accelerate. While we will seek to expand our technological capabilities to remain competitive, research and development by



Table of Contents

others may render our technology or product candidates obsolete or noncompetitive or result in treatments or cures superior to any therapy developed by us.

**If we are unable to protect our intellectual property rights adequately, the value of our technology and our product candidates could be diminished.**

Our success depends in part on obtaining, maintaining and enforcing our patents and other proprietary rights and our ability to avoid infringing the proprietary rights of others. Patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving, is surrounded by a great deal of uncertainty and involves complex legal, scientific and factual questions. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology patents. Accordingly, our pending patent applications may not result in issued patents. Although we own numerous patents, the issuance of a patent is not conclusive as to its validity or enforceability. Through litigation, a third party may challenge the validity or enforceability of a patent after its issuance.

Also, patents and applications owned or licensed by us may become the subject of interference, opposition, nullity, or other proceedings in a court or patent office in the United States or in a foreign jurisdiction to determine validity, enforceability or priority of invention, which could result in substantial cost to us. An adverse decision in such a proceeding may result in our loss of rights under a patent or patent application. It is unclear how much protection, if any, will be given to our patents if we attempt to enforce them or if they are challenged in court or in other proceedings. A competitor may successfully invalidate our patents or a challenge could result in limitations of the patents' coverage. In addition, the cost of litigation or interference proceedings to uphold the validity of patents can be substantial. If we are unsuccessful in these proceedings, third parties may be able to use our patented technology without paying us licensing fees or royalties. Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement claims, which are expensive and time-consuming. In an infringement proceeding, a court may decide that a patent of ours is not valid. Even if the validity of our patents were upheld, a court may refuse to stop the other party from using the technology at issue on the ground that its activities are not covered by our patents.

The Leahy-Smith America Invents Act was signed into law on September 16, 2011, but will not fully take effect until March 16, 2013. In general, the legislation attempts to address issues surrounding the enforceability of patents and the increase in patent litigation by, among other things, moving to a first-inventor-to-file system, establishing new procedures for challenging patents and establishing different methods for invalidating patents. While we cannot predict what form any new patent reform regulations ultimately may take, final governmental rule-making and case law interpreting the new statute could introduce new substantive rules, procedures and case law bases for challenging patents, and certain reforms that make it easier for competitors to challenge our patents could have a material adverse effect on our business and prospects.

Policing unauthorized use of our intellectual property is difficult, and we may not be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

In addition to our patent rights, we also rely on unpatented technology, trade secrets, know-how and confidential information. Third parties may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose our technology. We may not be able to effectively protect our rights in unpatented technology, trade secrets, know-how and confidential information. We require each of our employees, consultants and corporate partners to execute a confidentiality agreement at the commencement of an employment, consulting or collaborative relationship with us. Further, we require that all employees enter into assignment of invention agreements as a condition of employment. However, these agreements may not provide effective

Table of Contents

protection of our information or, in the event of unauthorized use or disclosure, they may not provide adequate remedies.

**Any inability to license proprietary technologies or processes from third parties which we use in connection with the development and manufacture of our product candidates may impair our business.**

Other companies, universities and research institutions have or may obtain patents that could limit our ability to use, manufacture, market or sell our product candidates or impair our competitive position. As a result, we would have to obtain licenses from other parties before we could continue using, manufacturing, marketing or selling our potential products. Any necessary licenses may not be available on commercially acceptable terms, if at all. If we do not obtain required licenses, we may not be able to market our potential products at all or we may encounter significant delays in product development while we redesign products or methods that are found to infringe on the patents held by others.

**We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights held by third parties and we may be unable to protect our rights to, or to commercialize, our product candidates.**

Patent litigation is very common in the biotechnology and pharmaceutical industries. Third parties may assert patent or other intellectual property infringement claims against us with respect to our technologies, products or other matters. From time to time, we have received correspondence from third parties alleging that we infringe their intellectual property rights. Any claims that might be brought against us alleging infringement of patents may cause us to incur significant expenses and, if successfully asserted against us, may cause us to pay substantial damages and limit our ability to use the intellectual property subject to these claims. Even if we were to prevail, any litigation would be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. Furthermore, as a result of a patent infringement suit, we may be forced to stop or delay developing, manufacturing or selling potential products that incorporate the challenged intellectual property unless we enter into royalty or license agreements. There may be third-party patents, patent applications and other intellectual property relevant to our potential products that may block or compete with our products or processes. In addition, we sometimes undertake research and development with respect to potential products even when we are aware of third-party patents that may be relevant to our potential products, on the basis that such patents may be challenged or licensed by us. If our subsequent challenge to such patents were not to prevail, we may not be able to commercialize our potential products after having already incurred significant expenditures unless we are able to license the intellectual property on commercially reasonable terms. We may not be able to obtain royalty or license agreements on terms acceptable to us, if at all. Even if we were able to obtain licenses to such technology, some licenses may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations, which could severely harm our business.

**We use hazardous materials in our business, and any claims relating to improper handling, storage or disposal of these materials could harm our business.**

Our research and development and manufacturing activities involve the controlled use of hazardous materials, chemicals, biological materials and radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by applicable laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from



Table of Contents

these materials. In the event of such an accident, we could be held liable for any resulting damages, and any liability could exceed our resources. We may be required to incur significant costs to comply with these laws in the future. Failure to comply with these laws could result in fines and the revocation of permits, which could prevent us from conducting our business.

**We face product liability risks and may not be able to obtain adequate insurance.**

While we secure waivers from all participants in our clinical trials, the use of our product candidates during testing or after approval entails an inherent risk of adverse effects, which could expose us to product liability claims. Regardless of their merit or eventual outcome, product liability claims may result in:

- decreased demand for our product;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial volunteers;
- costs of litigation;
- distraction of management; and
- substantial monetary awards to plaintiffs.

We may not have sufficient resources to satisfy any liability resulting from these claims. We currently have \$5 million of product liability insurance for products which are in clinical testing. This coverage may not be adequate in scope to protect us in the event of a successful product liability claim. Further, we may not be able to maintain our current insurance or obtain general product liability insurance on reasonable terms and at an acceptable cost if we or our collaborative partners begin commercial production of our proposed product candidates. This insurance, even if we can obtain and maintain it, may not be sufficient to provide us with adequate coverage against potential liabilities.

**We depend on our key personnel and we must continue to attract and retain key employees and consultants.**

We depend on our key scientific and management personnel. Our ability to pursue the development of our current and future product candidates depends largely on retaining the services of our existing personnel and hiring additional qualified scientific personnel to perform research and development. We will also need to hire personnel with expertise in clinical testing, government regulation, manufacturing, marketing and finance. Attracting and retaining qualified personnel will be critical to our success. We may not be able to attract and retain personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. Failure to retain our existing key management and scientific personnel or to attract additional highly qualified personnel could delay the development of our product candidates and harm our business.

**Our stock price can fluctuate significantly and results announced by us and our collaborators can cause our stock price to decline.**

Our stock price can fluctuate significantly due to business developments announced by us and by our collaborators, as a result of market trends and daily trading volume. The business developments that could impact our stock price include disclosures related to clinical findings with compounds that make use of our TAP technology, new collaborations and clinical advancement or discontinuation of product candidates that make use of our TAP technology. Our stock price can also fluctuate significantly with the level of overall investment interest in small-cap biotechnology stocks.

Table of Contents

Our operating results have fluctuated in the past and are likely to continue to do so in the future. Our revenue is unpredictable and may fluctuate due to the timing of non-recurring licensing fees, decisions of our collaborative partners with respect to our agreements with them, reimbursement for manufacturing services, the achievement of milestones and our receipt of the related milestone payments under new and existing licensing and collaboration agreements. Revenue historically recognized under our prior collaboration agreements may not be an indicator of revenue from any future collaborations. In addition, our expenses are unpredictable and may fluctuate from quarter to quarter due to the timing of expenses, which may include obligations to manufacture or supply product or payments owed by us under licensing or collaboration agreements. It is possible that our quarterly and/or annual operating results will not meet the expectations of securities analysts or investors, causing the market price of our common stock to decline. We believe that quarter-to-quarter and year-to-year comparisons of our operating results are not good indicators of our future performance and should not be relied upon to predict the future performance of our stock price.

**The potential sale of additional shares of our common stock may cause our stock price to decline.**

Pursuant to shelf registration statements filed with the Securities and Exchange Commission, in July 2012, we sold 6,250,000 shares of our common stock at \$16.00 per share in a public offering resulting in gross proceeds of \$100 million; in fiscal 2011, we sold 7,800,000 shares of our common stock at \$12.00 per share in a public offering resulting in gross proceeds of \$93.6 million; in fiscal 2010, we sold 10,350,000 shares of our common stock at \$8.00 per share in a public offering resulting in gross proceeds of \$82.8 million; and in fiscal 2009, we sold 5,750,000 shares of our common stock at \$7.00 per share in a public offering resulting in gross proceeds of \$40.3 million. Additionally, in fiscal 2008, a private investor purchased 7,812,500 shares of our common stock at \$3.20 per share resulting in gross proceeds of \$25 million. The potential sale of additional shares of our common stock may be dilutive to our shares outstanding and may cause our stock price to decrease.

**We do not intend to pay cash dividends on our common stock.**

We have not paid cash dividends since our inception and do not intend to pay cash dividends in the foreseeable future. Therefore, shareholders will have to rely on appreciation in our stock price, if any, in order to achieve a gain on an investment.

Table of Contents

**A WARNING ABOUT FORWARD-LOOKING STATEMENTS**

This report includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to analyses and other information which are based on forecasts of future results and estimates of amounts that are not yet determinable. These statements also relate to our future prospects, developments and business strategies.

These forward-looking statements are identified by their use of terms and phrases, such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will" and other similar terms and phrases, including references to assumptions. These statements are contained in the "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections, as well as other sections of this Annual Report on Form 10-K.

Forward-looking statements in this report include, but are not limited to:

successfully finding and managing the relationships with collaborative partners;

the uncertainty as to whether our TAP compounds or those of our collaborators will succeed in entering human clinical trials and uncertainty as to the results of such trials;

the risk that we and/or our collaborators may not be able to obtain regulatory approvals necessary to commercialize product candidates;

the potential development of competing products and technologies; uncertainty whether our TAP technology will produce safe, effective and commercially viable products;

our ability to successfully protect our intellectual property;

our reliance on third-party manufacturers to supply our maytansinoid cell-killing agents, DM1 and DM4, linkers, antibodies and perform fill/finish services;

the risk that we may be unable to establish the manufacturing capabilities necessary to develop and commercialize our potential products;

the adequacy of our liquidity and capital resources;

government regulation of our activities, facilities, products and personnel; the dependence on key personnel;

uncertainties as to the extent of reimbursement for the costs of our potential products and related treatments by government and private health insurers and other organizations; the potential adverse impact of government- directed health care reform; and

the risk of product liability claims; and economic conditions, both generally and those specifically related to the biotechnology industry.

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These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from those contemplated by our forward-looking statements. These known and unknown risks, uncertainties and other factors are described in detail in the "Risk Factors" section and in other sections of this Annual Report on Form 10-K. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

### **Item 1B.** *Unresolved Staff Comments*

None.

Table of Contents

**Item 2. *Properties***

We lease approximately 89,000 square feet of laboratory and office space in a building located at 830 Winter Street, Waltham, MA. The initial term of the 830 Winter Street lease expires on March 31, 2020, with an option for us to extend the lease for two additional five-year terms. In December 2009, we entered into a sublease, as sublessor, to rent 14,100 square feet of our original office and laboratory space at 830 Winter Street, Waltham, MA through January 2015. Due to space requirements, in April 2012, we entered into a sublease agreement for the rental of 7,310 square feet of additional laboratory and office space at 830 Winter Street, Waltham, MA for an initial term of three years with a conditional option to extend through October 2017. We also lease approximately 43,850 square feet of space in Norwood, MA, which serves as our conjugate manufacturing facility and office space. The Norwood lease expires on June 30, 2018, with an option for us to extend the lease for an additional five-year term.

**Item 3. *Legal Proceedings***

From time to time we may be a party to various legal proceedings arising in the ordinary course of our business. We are not currently subject to any material legal proceedings.

**Item 3.1. *Executive Officers of the Registrant***