OncoMed Pharmaceuticals Inc Form 10-K March 12, 2015 Table of Contents

# **UNITED STATES**

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2014

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-35993

**OncoMed Pharmaceuticals, Inc.** 

(Exact name of registrant as specified in its charter)

Delaware	38-3572512
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	Identification No.)
800 Chesapeake Drive	
Redwood City, California	94063
(Address of principal executive offices)	(Zip Code)
(650) 995-82	00

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

# Title of each className of each exchange on which registeredCommon stock, par value \$0.001 per shareThe NASDAQ Global Select MarketSecurities registered pursuant to Section 12(g) of the Act: None

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

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

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 x No  $\ddot{}$ 

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the 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
 x

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

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

The number of shares outstanding of the registrant s common stock as of March 6, 2015 was 29,941,886. The aggregate market value of the voting stock held by non-affiliates of the registrant as of June 30, 2014, was \$441,941,375. There is no non-voting stock outstanding.

## **DOCUMENTS INCORPORATED BY REFERENCE:**

Portions of the registrant s Proxy Statement for the registrant s 2015 Annual Meeting of Stockholders will be filed with the Commission within 120 days after the close of the registrant s 2014 fiscal year and are incorporated by reference in Part III.

# **OncoMed Pharmaceuticals, Inc.**

## Annual Report on Form 10-K

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# PART I

#### Forward-Looking Statements and Market Data

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report on Form 10-K are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as may, could, will. believe, estimate, intend, would. should, expect, plan, anticipate, predict, seek, contemplate, the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs;

our ability to advance drug candidates into, and successfully complete, clinical trials;

our receipt of future milestone payments and/or royalties, and the expected timing of such payments;

our collaborators exercise of their license options;

the commercialization of our product candidates;

the implementation of our business model, strategic plans for our business, drug candidates and technology;

the scope of protection we are able to establish and maintain for intellectual property rights covering our drug candidates and technology;

estimates of our expenses, future revenues, capital requirements and our needs for additional financing;

the timing or likelihood of regulatory filings and approvals;

our ability to maintain and establish collaborations or obtain additional government grant funding;

our financial performance; and

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developments relating to our competitors and our industry.

These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Risk Factors and elsewhere in this Annual Report on Form 10-K.

Any forward-looking statement in this Annual Report on Form 10-K reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, industry and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

Unless the context requires otherwise, in this Annual Report on Form 10-K the terms OncoMed, we, us and our ref to OncoMed Pharmaceuticals, Inc.

# ITEM 1. BUSINESS.

OncoMed is a clinical development-stage biopharmaceutical company focused on discovering and developing novel protein therapeutics targeting cancer stem cells, or CSCs. CSCs, also known as tumor-initiating cells, are the subpopulation of cells in a tumor responsible for driving growth and metastasis of the tumor. CSCs exhibit certain properties which include the capacity to divide and give rise to new CSCs via self-renewal and the capacity to differentiate or change into the other cells that form the bulk of the tumor. Common cancer drugs target bulk tumor cells but have limited impact on CSCs, thereby providing a path for recurrence of the tumor. Our product candidates target CSCs by blocking self-renewal and driving differentiation of CSCs toward a non-tumorigenic state, and also impact bulk tumor cells. We believe our product candidates are distinct from the current generations of anti-cancer drugs and have the potential to significantly impact cancer treatment and the clinical outcome of patients with cancer.

We utilize our proprietary technologies to (1) identify, isolate and evaluate CSCs, (2) identify and/or validate multiple potential targets and pathways critical to CSC self-renewal and differentiation, and (3) develop targeted antibody and other protein-based therapeutics that are designed to modulate these CSC targets and inhibit the growth of CSCs. These targets are in pathways implicated in cancer biology and stem cell biology, including the Notch, Wnt and other fundamental CSC pathways. We are also actively discovering multiple potential product candidates that target fundamental biological pathways in immuno-oncology. We believe our suite of proprietary CSC and antibody platform technologies provides a competitive advantage in cancer drug discovery. All of our product candidates were discovered internally in our own research laboratories.

We have six anti-CSC product candidates in clinical development and have treated over 500 patients across all of our clinical trials. We have an additional antibody product candidate, anti-RSPO3 (OMP-131R10) in preclinical development with an Investigational New Drug, or IND, application filing with the U.S. Food and Drug Administration, or FDA, planned for the first half of 2015. We are also pursuing discovery of novel anti-CSC and immuno-oncology product candidates. The following summarizes the status of our product candidates and preclinical programs, each of which will be described and discussed in further detail below under Our Product Candidates and Preclinical Programs.

Demcizumab (Anti-DLL4, OMP-21M18). Demcizumab is a humanized monoclonal antibody that inhibits Delta Like Ligand 4, or DLL4, in the Notch signaling pathway. It is currently in two randomized Phase II clinical trials and one Phase Ib/II clinical trial. We completed a single-agent Phase Ia trial in advanced solid tumor patients in 2011, which showed promising evidence of single-agent activity in heavily pretreated patients, with a partial response in one patient with recurrent pancreatic adenocarcinoma and 17 of 55 (31%) patients with stable disease for at least three months. Adverse events, including hypertension and a few reversible cardiopulmonary events were observed. Enrollment has recently been completed in two ongoing Phase Ib combination trials of demcizumab. The first trial is in combination with standard-of-care gemcitabine plus Abraxane<sup>®</sup> (paclitaxel protein-bound particles for injectable suspension) (albumin bound) in first-line advanced pancreatic cancer patients and the second trial is in combination with standard-of-care carboplatin and pemetrexed (Alimta®) in first-line advanced non-small-cell lung cancer, or NSCLC, patients. In both Phase Ib trials, we have employed a risk mitigation strategy in an effort to minimize toxicity while maintaining efficacy. Initial demcizumab Phase Ib data from these ongoing trials suggest encouraging anti-tumor activity, and manageable hypertension as a common treatment-related adverse event. Three cases of pulmonary hypertension and heart failure have occurred in patients who have been dosed in earlier cohorts for longer than 125 days. As a result, additional cohorts exploring a shorter duration of treatment (truncated dosing) were evaluated. Data from the Phase Ib NSCLC trial were most recently presented at the European Society for Medical Oncology (ESMO) 2014 Congress in Madrid, Spain in September 2014. The

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Phase Ib trial in pancreatic cancer, which originally used demcizumab plus standard-of-care gemcitabine, was updated in 2013 to explore the combination of demcizumab with gemcitabine and Abraxane<sup>®</sup> chemotherapy. Data from the Phase Ib pancreatic cancer trial were most recently presented at the 26<sup>th</sup> AACR-NCI-EORTC International Conference on Molecular Targets and Cancer

Therapeutics in Barcelona, Spain in November 2014. To date we have enrolled 64 patients at or above our identified Phase II dose of demcizumab in the Phase Ib trials with no moderate to severe cardiopulmonary events. In addition to the two Phase Ib trials of demcizumab nearing completion, a Phase Ib/II trial in recurrent ovarian cancer combining demcizumab with paclitaxel was initiated in 2013 and is currently enrolling patients in the Phase Ib portion of that trial. Initial signs of activity were seen in both Phase 1b trials. We also initiated and began enrolling patients in a Phase II randomized trial of demcizumab in combination with standard-of-care carboplatin and pemetrexed in NSCLC in February 2015 and have initiated and intend to enroll patients in a Phase II randomized trial of demcizumab is part of our strategic collaboration with Celgene Corporation, or Celgene, which is discussed below under Collaboration and License Agreements Strategic Alliance with Celgene. Celgene retains an option through the end of certain Phase II clinical trials to obtain an exclusive license to demcizumab.

Anti-DLL4/VEGF Bispecific (OMP-305B83). OMP-305B83 is a novel monoclonal antibody that targets and inhibits both DLL4 and vascular endothelial growth factor, or VEGF. Preclinical testing suggests that the efficacy of OMP-305B83 could potentially exceed the efficacy of either anti-DLL4 therapy or anti-VEGF therapy alone. We filed an IND for this product candidate in 2014, and are currently enrolling patients with advanced solid tumors in a single-agent Phase Ia trial. This program is part of our strategic collaboration with Celgene. Celgene retains an option through the end of certain Phase I clinical trials to obtain an exclusive license to our anti-DLL4/VEGF bispecific program, including OMP-305B83.

Tarextumab (Anti-Notch2/3, OMP-59R5). Tarextumab is a fully human monoclonal antibody that targets the Notch2 and Notch3 receptors. Initially discovered by screening a phage display library against the Notch2 receptor, the antibody binds to a conserved epitope on Notch2 and Notch3. The program is in two randomized Phase II clinical trials: one in combination with gemcitabine and Abraxane® in pancreatic cancer patients (the ALPINE trial) and one in combination with platinum chemotherapy and etoposide in small cell lung cancer patients (the PINNACLE trial). Both trials test potential predictive biomarkers to identify patients that may derive the greatest benefit from tarextumab. A single-agent Phase I trial in advanced solid tumor patients has been completed. Data for the Phase I trial were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2012, and additional Phase I clinical data were presented in a plenary session at the EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in November 2012. Data from the Phase Ib portion of the ALPINE trial in pancreatic cancer were most recently presented at the 2015 Gastrointestinal Cancers Symposium (ASCO GI) conference in San Francisco in January 2015. Data from the Phase Ib portion of the PINNACLE trial were most recently presented at the ESMO 2014 Congress in Madrid, Spain in September 2014. Tarextumab was well tolerated in combination with chemotherapy, and early signs of potential efficacy were noted on both Phase Ib trials. As presented at the 2015 ASCO GI conference, in pancreatic cancer, median progression-free survival and overall survival values for the three drug combination of tarextumab-gemcitabine-Abraxane® were 5.6 months and 11.6 months, respectively, for all patients treated with the three-drug combination, with a median progression free survival and overall survival benefit of 6.6 and 14.6 months seen in patients with high Notch3 expression (using a 50% cut-off) treated with the triplet of tarextumab-gemcitabine-Abraxane<sup>®</sup>. Given the small sample size and potential imbalances in patient characteristics, these encouraging preliminary efficacy and predictive biomarker observations are being further assessed in the ongoing, randomized placebo controlled Phase II ALPINE trial. Additionally, based on these observations, and the input of the ALPINE clinical investigators, the OncoMed/GlaxoSmithKline Joint Steering Committee (JSC) recently approved submitting a protocol amendment to the Phase II ALPINE trial to define the primary

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endpoint of the trial to be median overall survival, with progression free survival being the secondary endpoint, and increasing the sample size of the trial to 160 patients from the previously defined 124 patients. We recently received orphan drug designation from the U.S. Food and Drug Administration, or FDA, for tarextumab for both pancreatic and small cell lung cancer indications. Tarextumab is part of our collaboration with GlaxoSmithKline LLC (formerly SmithKline

Beecham Corporation), or GSK, which is discussed below under Collaboration and License Agreements Strategic Alliance with GSK. GSK retains an option through the end of certain Phase II trials to obtain an exclusive license to tarextumab.

*Brontictuzumab (Anti-Notch1, OMP-52M51).* Brontictuzumab is a humanized monoclonal antibody targeting the Notch1 receptor. We are currently enrolling two Phase Ia clinical trials to evaluate brontictuzumab in patients with certain hematologic or solid tumor malignancies. This clinical program has strong predictive biomarker hypotheses in both hematological and solid tumor malignancies to identify patients that may derive the greatest benefit from brontictuzumab. Data from the Phase I solid tumor trial were most recently presented in a plenary session at the 26<sup>th</sup> AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in Barcelona, Spain in November 2014. Brontictuzumab was well tolerated with diarrhea being the most common adverse event. Early signs of potential activity were also noted, particularly in biomarker positive patients. Brontictuzumab is part of our GSK collaboration. We have now initiated dosing of patients in the biomarker-directed expansion cohort of the solid tumor trial. GSK retains an early option through the end of certain Phase I trials to obtain an exclusive license to brontictuzumab or a standard option through the end of certain Phase II trials.

*Vantictumab (Anti-Fzd7, OMP-18R5).* Vantictumab is a fully human monoclonal antibody, identified by screening against the Frizzled7 receptor, or Fzd7, that binds a conserved epitope on five Frizzled receptors and inhibits Wnt signaling. We believe vantictumab is the first monoclonal antibody designed to inhibit Wnt signaling to enter clinical testing. Vantictumab has completed a Phase I single-agent trial in advanced solid tumor patients, and we most recently reported data for this trial at the 2013 European Cancer Congress in September 2013. In this first-in-human trial, vantictumab has been tolerable, has modulated the Wnt pathway in patient samples and has had single-agent activity in patients with neuroendocrine tumors, or NETs. We initiated three Phase Ib clinical trials in 2013 of vantictumab in combination with standard-of-care therapies in distinct solid tumor indications, including breast cancer, lung cancer, and pancreatic cancer. These trials are currently enrolling patients. Vantictumab is part of our Wnt pathway collaboration with Bayer Pharma AG (formerly Bayer Schering Pharma AG), or Bayer, which is discussed below under Collaboration and License Agreements Strategic Alliance with Bayer. Bayer retains an option to exclusively license vantictumab at any point through completion of certain Phase I trials.

*Ipafricept (Fzd8-Fc, OMP-54F28).* Ipafricept, our second product candidate targeting the Wnt pathway, is a proprietary fusion protein based on a truncated form of the Frizzled8 receptor, or Fzd8. Ipafricept is in a Phase I single-agent trial in patients with advanced solid tumors and we most recently reported results from this trial at the 2014 ASCO conference. Ipafricept was well tolerated, has modulated the Wnt pathway in patient samples and demonstrated early signs of efficacy in various refractory solid tumor patients. We are currently enrolling three Phase Ib trials, one in each of pancreatic cancer, ovarian cancer, and hepatocellular carcinoma, of ipafricept in combination with standard-of-care therapies. Ipafricept is part of our Bayer collaboration. Bayer retains an option to exclusively license ipafricept at any point through completion of certain Phase I trials.

*Wnt biologic #3*. As part of our Bayer collaboration, we have advanced an additional bispecific biologic product candidate to preclinical studies.

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*Wnt small molecule inhibitors*. We have an active collaboration with Bayer to discover and develop several small molecule inhibitors of the Wnt pathway. The first potential small molecule product candidate from this effort was advanced to preclinical testing in 2014.

*RSPO-LGR*. We identified that the R-spondin, or RSPO, ligands signal through the LGR receptor family, which is emerging as an important CSC pathway. Studies have demonstrated that certain LGR receptors are distributed specifically on adult stem cells in mammalian tissues, and these LGR-expressing cells have been linked to the development of cancer. We are conducting preclinical studies of antibodies that modulate the RSPO-LGR pathway and we plan to file an IND for our first product

candidate targeting the RSPO-LGR pathway, anti-RSPO3 (OMP-131R10), during the first half of 2015. Programs in the RSPO-LGR pathway are part of our strategic collaboration with Celgene. Celgene may designate up to four programs across both of the RSPO-LGR signaling pathway and a specified undisclosed pathway for which it wishes to retain its option to develop biologic therapeutics targeting such pathways. Celgene designated anti-RSPO3 as the first of four potential programs in November 2014. Celgene s right to designate programs within the RSPO-LGR pathway will expire on the fourth anniversary of the date of the agreement, or, if Celgene makes a specified extension payment, upon the sixth anniversary of the date of the agreement. If Celgene designates targets within the RSPO-LGR pathway, including anti-RSPO3, Celgene retains the right to exercise its option during certain time periods through the end of certain Phase I clinical trials to obtain an exclusive license to develop further and commercialize such designated biologic therapeutics.

*Undisclosed pathways.* We are also working on multiple additional discovery programs in undisclosed cancer stem cell pathways, as well as multiple immuno-oncology discovery programs. Portions of this research activity are part of our strategic collaboration with Celgene.

#### Strategy

We believe that a key reason for the limitations of many current cancer treatments is that they fail to impede the growth of CSCs, which we believe are responsible for the initiation, metastasis and recurrence of many cancers. Our goal is to build a leading biopharmaceutical company to discover, develop and commercialize novel anti-cancer stem cell and immuno-oncology therapies in a capital-efficient manner. Key elements of our strategy to achieve this goal are:

*Continue to discover and advance novel cancer therapeutics based on our proprietary discovery and drug development platform.* Our proprietary CSC and antibody platforms are generating novel product programs, and we plan to continue discovery activities to identify new potential CSC pathways and anti-cancer stem cell product candidates. These efforts have led to the discovery of multiple proprietary anti-CSC product candidates, six of which are in clinical development, with additional IND filings anticipated in 2015 and in future years. In addition, we have several active discovery efforts underway in immuno-oncology research.

Advance demcizumab, tarextumab, and our other programs to determine their utility as treatments for cancer. We are conducting randomized Phase II trials of demcizumab in first-line pancreatic and non-small-cell lung cancer in combination with standard-of-care chemotherapy. Enrollment is underway in the NSCLC trial and has not yet commenced for the pancreatic trial. We also initiated a Phase Ib/II trial of demcizumab in recurrent ovarian cancer at MDACC in 2013. We also have extensive preclinical data in multiple other indications. We are actively considering opportunities to broaden development of demcizumab and tarextumab over time. We also have Phase II trials underway with tarextumab in pancreatic cancer and small cell lung cancer. Across our pipeline, we currently have 16 clinical trials underway.

*Collaborate with our partners, GSK, Bayer, and Celgene to advance specific CSC pathway programs forward in clinical development.* We have multiple product candidates under our GSK, Bayer and Celgene collaborations and are working closely with our partners to advance programs in development. Under our GSK collaboration focused on the Notch pathway, we are currently developing tarextumab in a randomized

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Phase II trial in pancreatic cancer patients and a randomized Phase II trial in small cell lung cancer patients and brontictuzumab in a Phase I trial in patients with hematologic tumors and a Phase I trial in patients with solid tumors. Under our Bayer collaboration focused on the Wnt pathway, we are developing vantictumab and ipafricept, each of which is currently in three Phase Ib trials. We also collaborate with Bayer on Wnt pathway small molecule discovery and development. Our Celgene collaboration includes demcizumab, the anti-DLL4/VEGF bispecific program, programs in the RSPO-LGR pathway, and programs in an undisclosed pathway. Under our collaborations, GSK, Bayer and Celgene have certain options during certain time periods through the end of specified Phase I or

Phase II trials to obtain exclusive licenses to antibody or protein-based product candidates. In the event that these options are not exercised at the end of the relevant option periods, we will have worldwide rights to these programs.

*Utilize biomarker approaches to identify subsets of cancer patients most likely to benefit from our therapies.* In some of our programs, such as our tarextumab, brontictuzumab and vantictumab programs, we identified predictive biomarkers that have the potential to assist in patient selection. In other programs, such as our demcizumab, ipafricept, and anti-RSPO3 programs, we have extensive biomarker identification/validation research ongoing. We are working on developing these biomarkers through the course of our current clinical trials for all of our programs, with the plan to potentially utilize those biomarkers in Phase II and subsequent trials to identify patients most likely to benefit from treatment and improve patient outcomes. Where biomarker approaches are successfully utilized in clinical testing, we may elect to develop companion diagnostics in conjunction with suitable third-party development and commercialization partners. Our current efforts on our demcizumab, tarextumab, brontictuzumab, vantictumab and ipafricept product candidates, as well as our other programs, could potentially lead to development of future companion diagnostics.

*Use pharmaceutical collaborations as appropriate to provide funding, create value and leverage partners expertise to bring medicines to patients.* We believe that our GSK, Bayer and Celgene collaborations provide validation of our scientific approach, significant funding to advance our pipeline and access to development and commercial expertise for our partnered assets. To facilitate the capital-efficient development and commercialization of our independent programs, we routinely engage in partnering discussions with a range of pharmaceutical and biotechnology companies.

We have assembled a strong team of scientific, clinical and business leadership. Paul J. Hastings, our Chairman and Chief Executive Officer, has over 25 years of biopharmaceutical experience, including roles as Chief Executive Officer at multiple public companies. John Lewicki, Ph.D., our Executive Vice President and Chief Scientific Officer, has over 25 years of research experience in biotechnology. Jakob Dupont, M.D., our Senior Vice President and Chief Medical Officer, has over 15 years of drug development experience in academia and industry and has played a key role in the clinical development of a number of anti-cancer agents, including recent clinical leadership on Avastin<sup>®</sup> development at Genentech (Roche).

Since our founding in August 2004, we have raised \$626.4 million, consisting of \$303.2 million in the form of equity financings, \$322.0 million in the form of collaboration funding from our pharmaceutical partnerships, and \$1.2 million in grants. As of December 31, 2014, we had \$232.0 million of cash, cash equivalents and short-term investments.

We believe that our broad, novel pipeline of antibody and protein-based therapeutics, our leadership in the fields of CSCs and cancer biology and our experienced scientific, clinical and business management team provide us with distinct advantages that enable us to continue to discover and advance novel anti-cancer stem cell and immuno-oncology programs.

#### **Understanding Cancer**

Cancer is a leading cause of death worldwide, with approximately 14.1 million new cases reported and 8.2 million deaths associated with the disease in 2012 according to the International Agency for Research on Cancer, or IARC. The IARC has projected that by 2030 there will be over 23 million people annually diagnosed with cancer and over

13 million deaths worldwide. The medical costs associated with cancer in the United States alone in 2010 have been estimated by the National Cancer Institute at the National Institutes of Health to be over \$120 billion and according to IMS Health the amount spent in the United States on drugs to treat cancer exceeded \$37 billion in 2013.

Cancer is a broad group of diseases in which cells divide and grow in an uncontrolled fashion, forming malignancies that can invade other parts of the body. In normal tissues, the rates of new cell growth and cell

death are tightly regulated and kept in balance. In cancerous tissues, this balance is disrupted as a result of mutations, causing unregulated cell growth that leads to tumor formation and growth. While tumors can grow slowly or rapidly, the dividing cells will nevertheless accumulate and the normal organization of the tissue will become disrupted. Cancers can subsequently spread throughout the body by processes known as invasion and metastasis. Once cancer spreads to sites beyond the primary tumor, it is generally incurable. Cancer can arise in virtually any part of the body, with the most common types arising in the prostate gland, breast, lung, colon and skin. Dysregulated cell growth in vital organs such as the liver, lung or brain can impair their normal function with consequences that may ultimately lead to death.

Chemotherapy, radiation and surgical resection of tumors are the most common approaches for treating cancer. While heightened vigilance, new diagnostic tests, combination therapies, improved treatment regimens and targeted therapies (including monoclonal antibodies such as Herceptin<sup>®</sup> and Avastin<sup>®</sup> as well as small molecules such as Nexavar<sup>®</sup> and Tarceva<sup>®</sup> have resulted in improvements in overall survival for many cancer patients, we believe that there is still room for significant improvement in the treatment of cancer. Therapeutic effects of chemotherapy and many targeted therapies are often relatively transient, and acquired resistance to therapies remains a significant clinical problem with patients frequently relapsing and the disease metastasizing to distant organs.

# **Understanding Cancer Stem Cells**

The discovery of solid tumor CSCs in 2000 by our scientific founders provides a new framework for understanding cancer and, more importantly, a promising new therapeutic strategy for attacking cancer. CSCs are a subpopulation of tumor cells that share certain properties with normal stem cells (e.g., the ability to proliferate indefinitely and to differentiate into multiple cell types), but, unlike normal stem cells, their growth control has lost normal restraints as a result of cancer-causing mutations. CSCs are relatively resistant to many common cancer therapies. CSCs are believed to be responsible for tumor growth, recurrence after treatment with conventional therapies and metastatic spread of the disease. The inability of current therapies to efficiently eradicate CSCs may be a key reason for the failure of current treatments to achieve durable clinical responses.

The CSC paradigm is based on the observation that most tumors are highly heterogeneous and comprised of many different cell types. Experimental observations indicate that tumor cells vary greatly in their ability to seed new tumor growth. Subpopulations of tumorigenic cancer cells are capable of continuous proliferation to sustain the growth of a tumor, a process analogous to self-renewal of normal stem cells. In contrast, more differentiated tumor cells are incapable of dividing indefinitely and are therefore less tumorigenic, or non-tumorigenic. Tumorigenic CSCs are a resilient subset of cells found in tumors that share certain features with normal stem cells, but have lost normal constraints on growth control because of cancer-causing mutations, leading to tumor initiation, recurrence and metastasis. Also referred to as tumor-initiating cells, CSCs were initially discovered in leukemia, and were subsequently discovered by our scientific founders in solid tumors derived from patients with breast cancer. In studies that defined the existence of breast cancer stem cells, human tumor biopsies were obtained and tumor cells were fractionated into distinct subpopulations based on their expression of two surface markers, CD44+ and CD24-. It was subsequently demonstrated that only the minor subpopulation of cells with the CD44+/CD24- phenotype markers was capable of initiating tumor growth when implanted into appropriate host mice, whereas the bulk tumor cells were non-tumorigenic. Importantly, the tumors harvested from animals injected with tumor-initiating cells recapitulated the cellular heterogeneity of the original tumor biopsy, demonstrating two important properties of CSCs their ability to self-renew and their ability to generate differentiated, non-tumorigenic progeny. Using similar approaches, CSCs have subsequently been identified in many other solid tumor types, including cancers of the colon, lung, pancreas, brain and skin. CSCs may arise from normal tissue stem cells that have lost the ability to regulate growth, or may arise from differentiated tumor cells that have reacquired the capacity to self-renew. Irrespective of their cell of origin, CSCs possess a number of fundamental properties that enable the growth, proliferation and metastasis of solid tumors.

CSCs have been shown by us and others to be selectively resistant to cytotoxic chemotherapy, radiotherapy and some targeted therapies. Because of the inherent resistance of CSCs to traditional therapies, many agents currently utilized for cancer treatment are not effective in targeting and eliminating CSCs. Thus, therapies that effectively produce early clinical responses, as noted by reductions in tumor volume, may nevertheless have limited effectiveness if they spare CSCs, as these cells will ultimately promote disease recurrence and spread. Conversely, therapeutic strategies aimed at eliminating CSCs within solid tumors, either specifically or in addition to bulk tumor cells, offer the potential of reducing disease progression and providing durable responses.

We have built a number of proprietary technologies that enable us to characterize CSCs, to identify novel drug targets and to evaluate the effects of our therapeutic product candidates on CSCs. Our expertise in identifying, isolating and monitoring CSCs using specific surface markers and flow cytometry enables our scientists to evaluate the importance of specific targets associated with key biologic pathways implicated in both stem cell biology and cancer. We develop antibodies against these targets using advanced protein engineering technologies, including antibody humanization, phage display, proprietary mammalian display and bispecific antibody platforms. We test our antibodies in proprietary xenograft models derived from freshly resected human tumors subsequently propagated in mice. We believe these patient-derived models are more representative of the clinical features of human tumors than the cell line-based models used in traditional cancer research. Our models also offer the ability to test the effects of therapeutic candidates on human tumors with varied genetic backgrounds.

#### Our Approach: Targeting Key Pathways of Cancer Stems Cells

Our goal is to significantly improve cancer treatment by specifically targeting the key biologic pathways required for the maintenance, proliferation and survival of CSCs. Among these important regulatory signals, we are initially targeting the Notch, Wnt and RSPO-LGR pathways. Additionally, we are actively researching new pathways that appear to be important in the regulation of CSCs. Our basic approach has been to develop antibodies and other protein-based therapeutics that target the extracellular and cell surface proteins that are critical to the activation of these pathways.

The Notch and Wnt pathways play key roles in embryonic development by regulating the fate of cells and tissues in normal organ development. These pathways have been known to be critical for the maintenance of stem cells and have been linked centrally to cancer. The Notch pathway has also been linked to other biological processes that are being targeted in cancer. For instance, the pathway plays an important role in neovascularization and has been linked to modulation of the immune system, including the regulation of T cell activation. Notch proteins are known to be activated by mutations in hematologic malignancies. The Wnt pathway is frequently activated by mutations in colon cancer. Our approach has been to (1) develop specific antibodies against key extracellular proteins that regulate the Notch and Wnt pathways, (2) characterize these antibodies in detail to assess their binding affinities and ability to inhibit the target protein and (3) optimize their biophysical properties to ensure their high quality of production for ultimate development and commercial manufacturing. To support these efforts, we have developed an advanced understanding of Notch- and Wnt-pathway biology and have developed proprietary tools and reagents to aid in the evaluation of candidate antibodies and enhance our understanding of mechanisms underlying pathway inhibition. Through this approach, we have successfully generated specific antibodies that block the Notch and Wnt pathways, and we believe that we were among the first companies to initiate clinical trials with antibodies targeting these pathways.

The RSPO-LGR pathway is comprised of a family of four cell signaling ligands known as R-spondins 1-4 and three related receptor proteins, LGR4-6. This pathway has been highlighted as a key pathway in adult tissue stem cells and has been linked to the development of cancer. We have identified multiple antibodies targeting

this pathway and are currently progressing anti-RSPO3 (OMP-131R10) in preclinical development. Inhibition of CSC pathways has been shown to result in synergistic inhibition of tumor growth when combined with chemotherapeutic agents. Furthermore, we have shown that inhibition of these stem cell pathways drives differentiation of CSCs toward a non-tumorigenic state. Thus, CSC-directed agents hold the potential promise of dramatically improving cancer treatment. As a result of our efforts to discover novel antibody and protein-based treatments targeting CSCs, six of our product candidates are in clinical development, and we will file an IND for a seventh product candidate, anti-RSPO3 (OMP-131R10) in the first half of 2015.

#### **Our Product Candidates and Preclinical Programs**

The following table summarizes the status of, and certain of our plans for, our product candidates and preclinical programs, each of which will be described and discussed in further detail below.

GSK, Bayer, and Celgene have certain opt-in rights to the OncoMed proprietary programs identified in the chart with their respective company logos.

We anticipate potential data readouts for multiple Phase II clinical trials for our product candidates through 2017. We also anticipate multiple potential milestones from our strategic alliance partners in the coming years based on successful advancement and trial results for our product candidates. The timing of these programs and receipt of these milestones is subject to the risks and uncertainties set forth under the caption Risk Factors.

#### Demcizumab (Anti-DLL4, OMP-21M18)

Demcizumab (anti-DLL4, OMP-21M18) is a humanized monoclonal antibody that inhibits Delta Like Ligand 4, or DLL4, in the Notch signaling pathway. We completed a single-agent Phase Ia trial in advanced solid tumor patients in 2011, which showed promising evidence of single-agent activity in heavily pretreated patients,

with a partial response in one patient with recurrent pancreatic adenocarcinoma and 17 of 55 (31%) patients with stable disease for at least three months. Adverse events, including hypertension, bleeding and a few cardiopulmonary events were observed. Enrollment has recently been completed in two ongoing Phase Ib combination trials of demcizumab. The first trial is in combination with standard-of-care gemcitabine and Abraxane<sup>®</sup> (paclitaxel protein-bound particles for injectable suspension) (albumin bound) in first-line advanced pancreatic cancer patients and the second trial is in combination with standard-of-care carboplatin and pemetrexed (Alimta®) in first-line advanced NSCLC patients. The initial safety and efficacy data from these demcizumab Phase Ib trials were encouraging, although a few cases of reversible pulmonary hypertension and heart failure occurred in patients who were treated for a prolonged period of time. As a result, we added new cohorts to these trials to enable the evaluation of a more limited duration of treatment (truncated dosing). We initiated a Phase Ib/II trial of demcizumab with paclitaxel in ovarian cancer in the second half of 2013. We also initiated a Phase II trial for demcizumab in combination with standard-of-care carboplatin and pemetrexed (Alimta®) in non-small cell lung cancer in February 2015 and are currently working to begin enrolling patients in a Phase II trial for demcizumab in combination with standard-of-care gemcitabine and Abraxane<sup>®</sup> in pancreatic cancer. Demcizumab was granted orphan drug designation for the treatment of pancreatic cancer by the FDA in 2014. Demcizumab is part of our strategic collaboration with Celgene. Celgene retains an option during certain time periods through the end of certain Phase II clinical trials to obtain an exclusive license to demcizumab, provided such clinical trials are conducted within a specified time period after the date of our agreement with Celgene.

We initiated a single-agent Phase Ia trial of demcizumab in patients with advanced solid tumors in 2008 and completed the trial in November 2011. A total of 55 patients were treated in the trial. Interim results from this first-in-human trial were presented at the 22nd EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in Berlin in 2010. In 2010, we initiated three Phase Ib clinical trials of demcizumab in combination with chemotherapy based on the single-agent data from our Phase Ia trial and our preclinical datasets. One trial enrolled first-line advanced pancreatic cancer patients, assessing safety and efficacy of demcizumab in combination with standard-of-care gemcitabine and Abraxane<sup>®</sup>, a second trial enrolled first-line advanced NSCLC patients, assessing safety and efficacy of demcizumab in combination with standard-of-care carboplatin and pemetrexed (Alimta<sup>®</sup>), and a third trial (which was closed due to resource prioritization) enrolled first or second-line colorectal cancer, assessing safety and efficacy of demcizumab in combination with standard-of-care FOLFIRI chemotherapy.

We most recently presented data from the NSCLC Phase Ib trial at the 2014 European Society for Medical Oncology (ESMO) 2014 Congress in Madrid, Spain in September 2014. As reported at such conference, in the ongoing Phase Ib clinical trial, 39 patients who had not received prior chemotherapy for their Stage IIIb or IV NSCLC were treated with demcizumab, pemetrexed and carboplatin. The combination therapy was generally well tolerated with nausea, fatigue and hypertension being the most common related toxicities. Truncated dosing (in which we limit the duration of therapy to 63 days), monitoring with BNP and the administration of cardioprotective agents, if indicated, are being utilized in the current dose cohorts to maximize the therapeutic index and minimize potential cardiopulmonary toxicity.

Other demcizumab NSCLC Phase Ib results presented at the ESMO 2014 Congress include:

Of 33 patients evaluable for efficacy, one (3%) had a complete response, 15 (45%) had a partial response, and 13 (39%) had stable disease as measured by the Response Evaluation Criteria in Solid Tumors, or RECIST, criteria. The overall clinical benefit rate was 88%.

Median progression-free survival was not reached as of July 25, 2014 (the ESMO 2014 Congress data cutoff date) for patients treated with the Phase II regimen of 5mg/kg once every three weeks.

Eight patients treated with demcizumab once every three weeks at doses of 5mg/kg or 7.5mg/kg plus pemetrexed and carboplatin on-study and in some cases continued administration of protocol defined chemotherapy off-study remained progression free for greater than 300 days.

The truncated dosing schedule did not appear to negatively impact drug efficacy by RECIST: among the 14 evaluable patients who received demcizumab on a truncated dosing schedule, one (7%) had a complete response, seven (50%) had a partial response, five (36%) achieved stable disease, and one (7%) had progressive disease, resulting in an overall clinical benefit rate in this subset of patients of 93%. A RECIST partial response means that there has been at least a 30% decrease in the sum of the diameters of measured tumor lesions, taking as reference the baseline sum diameters, and that there has been no growth of new or non-measurable tumor lesions. RECIST stable disease means that there has been less than a 30% decrease and no more than a 20% increase in the sum of the diameters of measured tumor lesions, taking as reference the smallest sum of measured tumor lesions since treatment started, and that there has been no growth of new target or non-measurable tumors.

Data from the ongoing pancreatic cancer Phase Ib trial were most recently presented at the ESMO 2014 Congress in September 2014 in Madrid, Spain, and the 26th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in November 2014 in Barcelona, Spain. As presented at the ESMO 2014 Congress, in 47 pancreatic cancer patients evaluable for safety, the combination of demcizumab and gemcitabine, with or without Abraxane<sup>®</sup>, was generally well tolerated in patients. Fatigue, nausea and vomiting were the most common drug related toxicities. Among 22 evaluable patients who received the demcizumab + gemcitabine + Abraxane<sup>®</sup> combination, nine (41%) achieved partial responses and 10 (45%) had stable disease as measured by RECIST criteria, resulting in an overall clinical benefit rate of 86 percent. Median progression-free survival for the demcizumab + gemcitabine + Abraxane<sup>®</sup> combination was not reached at the Phase II dose at the time of data cut off. Six patients were still undergoing treatment at the final dose tested of 3.5mg/kg as of July 15, 2014.

We implemented a truncated dosing schedule for demcizumab in both Phase Ib trials following an observation of reversible cardiopulmonary toxicities in earlier studies. Additionally, all patients are being followed with cardiac monitoring using B-type natriuretic peptide (BNP) (an early indicator of cardiotoxicity) and echocardiography. Cardioprotective medications, such as angiotensin-converting enzyme inhibitors, were administered to patients with rising BNPs. The truncated dosing and cardiac monitoring strategies appear to have mitigated the risks of cardiopulmonary toxicity. None of the 26 pancreatic cancer patients treated in this manner have developed moderate-to-severe heart failure or pulmonary hypertension at the time of analysis. The truncated dosing and cardiac monitoring strategies will be further evaluated in the randomized Phase II trials for demcizumab.

In our two ongoing Phase Ib trials, we have seen multiple early, objective responses and stable disease in the NSCLC and pancreatic cancer trials. We have included Data Safety Monitoring Boards, or DSMB, to oversee the trials, to assess efficacy and safety and to determine potential dose escalation of demcizumab on a cohort-by-cohort basis and have determined dosing and treatment schedules for randomized Phase II trials in both NSCLC and pancreatic cancer patient populations. We initiated a randomized Phase II trial of demcizumab in combination with standard-of-care carboplatin and pemetrexed (Alimta<sup>®</sup>) in NSCLC in February 2015, and plan to enroll patients in a randomized Phase II trial of demcizumab in combination with standard-of-care genetiabine and Abraxane<sup>®</sup> in pancreatic cancer in 2015.

We initiated a Phase Ib/II trial of demcizumab in combination with paclitaxel in platinum-resistant ovarian cancer at MDACC in the second half of 2013. This trial is a part of MDACC s NCI-Ovarian Cancer SPORE grant. We are providing resources for data monitoring, including an industry standard database for the trial. In addition, we are actively evaluating other potential Phase II trial designs in other solid tumor settings and may initiate additional trials beyond pancreatic cancer, NSCLC, and ovarian cancer trials.

We believe demcizumab was the first Notch pathway antibody to enter clinical testing. We have completed and published or presented multiple preclinical studies demonstrating robust anti-tumor and anti-CSC activity in multiple solid tumor types, including pancreatic, lung, breast, colon, melanoma and ovarian cancers.

# Anti-DLL4/VEGF Bispecific (OMP-305B83)

We utilized our proprietary bispecific antibody technology to discover a monoclonal antibody (OMP-305B83) that targets both DLL4 and VEGF. VEGF is the target for bevacizumab, which is currently approved and used to treat a number of solid tumors including colorectal, NSCLC, breast, renal cell, brain cervical, and ovarian cancers and had worldwide revenues of \$6.7 billion in 2013. We filed an IND for OMP-305B83 in 2014 and are currently enrolling advanced solid tumor patients in a single-agent Phase Ia trial. We believe our bispecific approach offers unique opportunity given the related biology of these two factors in regulating new blood vessel formation. We have generated data which suggest that simultaneous targeting of both DLL4 and VEGF can result in substantially improved anti-tumor activity compared to either anti-DLL4 or anti-VEGF alone. This program is part of our strategic collaboration with Celgene. Celgene retains an option during certain time periods through the end of certain Phase I clinical trials to obtain an exclusive license to our anti-DLL4/VEGF bispecific program, including OMP-305B83.

# Tarextumab (Anti-Notch2/3, OMP-59R5)

We identified an antibody, tarextumab (anti-Notch2/3, OMP-59R5), that binds to both the Notch2 and Notch3 receptors. Originally identified from a screen against Notch2, the antibody cross-reacts with Notch3. Our tarextumab antibody is a fully human antibody derived from phage display technology licensed from MorphoSys AG, or MorphoSys. Based on preclinical experiments, we believe tarextumab exhibits two mechanisms of action: (1) by downregulating Notch pathway signaling, tarextumab appears to have anti-CSC effects, and (2) tarextumab affects pericytes, impacting stromal and tumor microenvironment. We initiated a Phase Ib/II trial in 2012 in pancreatic cancer patients, and advanced to the Phase II portion of this trial in 2014. In this Phase II clinical trial, called ALPINE (Antibody therapy in first-Line Pancreatic cancer Investigating anti-Notch Efficacy and safety), tarextumab is being tested in combination with gemcitabine and Abraxane<sup>®</sup> in first-line advanced pancreatic cancer patients.

We initiated a Phase Ia dose-escalation trial of tarextumab in 2010 and have completed enrollment of advanced refractory solid tumor patients in the trial. We presented interim results of this trial in a poster discussion session at the ASCO Annual Meeting in June 2012. Additional Phase I clinical data were presented in a plenary session at the EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in November 2012. In the Phase I trial, tarextumab was generally well tolerated. We established three maximum tolerated doses (MTDs) of 2.5mg/kg weekly, 7.5mg/kg every other week and 7.5mg/kg administered every three weeks for the product candidate. The dose limiting toxicity was diarrhea. Diarrhea appeared less pronounced with every other and every three week dosing schedules. The other most common treatment-related adverse events that occurred in the Phase Ia trial included fatigue, nausea, anemia, decreased appetite, hypokalemia, and vomiting. The pharmacokinetics of tarextumab in patients are characterized by fast and dose-dependent clearance. However, pharmacodynamic analyses on surrogate and tumor tissue suggest that Notch pathway modulation is sustained for a week or more after dosing. There was also clear downregulation of the Notch3 target in serial tumor biopsies after treatment with tarextumab. Several patients (Kaposi s Sarcoma, adenoid cystic carcinoma, liposarcoma, triple negative breast cancer, and rectal cancer) had prolonged stable disease for 56 or more days.

Final data from the Phase Ib portion of the ALPINE trial were most recently presented at the 2015 ASCO GI conference in San Francisco in January 2015. As presented at the 2015 ASCO GI conference, tarextumab was generally well tolerated when administered with gemcitabine and Abraxane<sup>®</sup> with manageable, on-target drug-related toxicities. The Phase II dose of tarextumab was determined to be 15 mg/kg every two weeks in combination with the standard-of-care. Among the 29 patients evaluable for response using RECIST criteria, 11 (38%) achieved partial responses, with an additional 10 (35%) achieving stable disease for an overall clinical benefit rate of 73%. Median progression-free survival, or PFS, and overall survival, or OS, values for the three drug combination of tarextumab-gemcitabine-Abraxane<sup>®</sup> were 5.6 months and 11.6 months, respectively, for all patients treated with the

three-drug combination.

Additionally, the data presented included biomarker analyses that showed that among patients whose tumor samples had elevated levels of Notch3 gene expression, trends toward higher response rates and longer survival were noted, as compared to patients with low Notch3 expression. Median progression-free survival and overall survival for patients with high Notch 3 expression (using a 50% cut-off) were 6.6 months and 14.6 months, respectively. Given the small sample size and potential imbalances in patient characteristics, these encouraging preliminary efficacy and predictive biomarker observations are being assessed in the ongoing randomized, placebo-controlled, Phase II ALPINE trial, comparing the efficacy of standard-of-care gemcitabine and Abraxane<sup>®</sup> either with tarextumab or with placebo. Finally, based on these encouraging observations, and the input of the ALPINE clinical investigators, the OncoMed/GSK JSC recently approved submitting a protocol amendment to the Phase II ALPINE trial to define the primary endpoint as median overall survival, with median progression free survival as the secondary endpoint, and to increase the sample size to 160 patients from the previously defined 124 patients.

We initiated a second Phase Ib/II trial called PINNACLE (Phase Ib/II Investigation of anti-Notch Antibody therapy with platinum chemotherapy and etoposide in small cell Lung carcinoma Efficacy and safety) in small cell lung cancer in the first half of 2013. Data from the Phase Ib portion of the PINNACLE trial were most recently presented at the ESMO 2014 Congress in Madrid, Spain in September 2014. As presented at ESMO 2014, OncoMed s Phase Ib PINNACLE trial of tarextumab enrolled 20 small cell lung cancer patients. Tarextumab was administered up to a dose of 15mg/kg every two weeks in combination with etoposide and cisplatin. Following that cohort, patients were treated with 15 mg/kg of tarextumab in combination with etoposide and carboplatin to confirm safety and tolerability of the highest tolerated dose. Tarextumab was well tolerated; diarrhea, fatigue, decreased appetite and nausea were the most common treatment-related toxicities, and these events were mostly Grade 1 or 2 and easily managed with supportive care. Of 16 patients evaluable for efficacy, 13 (81%) achieved partial responses and the remaining three patients achieved stable disease. As of the data cut off of August 29, 2014, seven patients remained on treatment.

The Phase II portion of the PINNACLE trial commenced in December 2014. In the PINNACLE trial, tarextumab is being tested in combination with platinum chemotherapy and etoposide in first-line extensive-stage small cell lung cancer patients, compared to standard-of-care platinum chemotherapy and etoposide with placebo.

Both of our Phase II trials include analyses of a potential predictive biomarker of Notch3 tumor overexpression to identify patients that might derive the greatest benefit from tarextumab. Tarextumab is part of our collaboration with GSK. GSK has the option through the completion of certain Phase II trials to obtain an exclusive license to tarextumab.

In January 2015, we received orphan drug status designation from the FDA for tarextumab for both pancreatic and small cell lung cancer indications.

# Brontictuzumab (Anti-Notch1, OMP-52M51)

Our anti-Notch1 antibody, brontictuzumab, is a humanized monoclonal antibody, and has shown substantial activity in Notch-dependent tumors in preclinical studies. Two single-agent Phase Ia trials are underway for brontictuzumab, one in hematologic malignancies and one in solid tumors.

Data from the solid tumor Phase Ia trial were most recently presented in an oral plenary session at the 26th EORTC-NCI-AACR Symposium in Barcelona, Spain in November 2014. As presented at the conference, the purpose of the brontictuzumab Phase Ia clinical trial is to determine a maximum tolerated dose and to assess safety, pharmacokinetics, immunogenicity and preliminary efficacy in patients, including patients with tumors overexpressing the Notch1 intracellular domain (ICD) as measured by a predictive diagnostic test. Among 31 patients evaluable for safety, brontictuzumab had a manageable safety profile. The most common adverse event was on-target

diarrhea, which was treated with supportive care. A Phase II single-agent dose of 1.5 mg/kg every

three weeks was established and is being used in an expansion cohort of the Phase Ia trial that will only enroll patients with tumors that overexpress Notch1 ICD as measured by our predictive biomarker assay.

Our researchers used an immunohistochemistry (IHC) test to identify Notch1 ICD overexpression which is a marker of overexpression of the activated form of the Notch1 receptor. This overexpression is identified in select tumor types where the prevalence of the biomarker is estimated to occur in at least ten percent of patients. The patients enrolled in the brontictuzumab Phase Ia clinical trial include patients with the following tumor types: HER2-negative breast cancer, esophageal cancer, colorectal cancer, gastric cancer, pancreatic cancer, small cell lung cancer, adenoid cystic carcinoma (ACC) and cholangiocarcinoma.

Brontictuzumab demonstrated early signals of single-agent anti-tumor activity in four of the 17 patients evaluable for response at the time of data cut off. Of the four patients to date that demonstrated clinical benefit, three had tumors that tested positive for overexpression of the activated form of Notch1. A partial response as measured by RECIST criteria was achieved in a 28 year-old patient with ACC whose cancer previously progressed after radiation and four lines of systemic treatment. The patient s tumor tested positive using our IHC assay for Notch1 ICD. Three other patients achieved stable disease. Of these, two patients showed high levels of Notch1 receptor activation. One of these patients with refractory colorectal cancer whose cancer had progressed through eight prior lines of systemic therapy remained progression free for 294 days.

In January 2015, we initiated the expansion cohort of the brontictuzumab Phase Ia solid tumor trial. The expansion stage of the brontictuzumab Phase Ia solid tumor trial is enrolling patients whose tumors demonstrate overexpression of the activated form of Notch1. Patients tumors are prescreened using OncoMed s proprietary CLIA-validated IHC test to determine eligibility. Patients will receive brontictuzumab at the recommended Phase II dose of 1.5 mg/kg every three weeks. The expansion stage of the solid tumor Phase Ia study is expected to enroll at least ten biomarker-selected patients.

Brontictuzumab is part of our collaboration with GSK. GSK has a standard option during certain time periods through the completion of specified Phase II trials to obtain an exclusive license to brontictuzumab or, in some cases, an early option during certain time periods through completion of certain Phase I trials to obtain an exclusive license.

Brontictuzumab is the World Health Organization (WHO) registered INN (International Nonproprietary Name) for OMP-52M51, OncoMed s investigational anti-Notch1 antibody.

# Vantictumab (anti-Fzd7, OMP-18R5)

Our vantictumab product candidate is a fully human monoclonal antibody that modulates Wnt pathway signaling by binding to Frizzled receptors 1, 2, 5, 7 and 8. The antibody was identified from a phage display library licensed from MorphoSys by screening against Fzd7. We initiated Phase I clinical testing of vantictumab in 2011. Preclinically, we have observed strong anti-tumor activity in combination with multiple types of approved therapies in solid tumor models, including pancreatic, breast, lung, melanoma, hepatocellular, ovarian, colorectal and other cancers. In addition to synergy in reducing tumor volume with approved therapies, vantictumab reduces CSC frequency in our preclinical models. It also induces differentiation of tumorigenic cells to cell types that are less tumorigenic and more susceptible to conventional chemotherapy. Vantictumab is in a solid tumor, single-agent dose escalation Phase I trial, and data were presented at the 2013 ASCO meeting and updated at the 2013 European Cancer Congress (ECC) in Amsterdam in September 2013. As reported at the ECC, in the Phase Ia clinical trial, 29 patients with advanced and refractory solid tumors were treated with single-agent vantictumab. Vantictumab has been well tolerated up to the dose of 15 mg/kg every three weeks. This dose of vantictumab is above the target efficacious dose based on minimally passaged human tumor xenograft models. Vantictumab shows pharmacodynamic (PD) effects on the Wnt pathway in

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patient samples in the Phase I clinical trial. Evidence of single-agent activity of vantictumab was noted in several patients with neuroendocrine tumors (NETs). There were certain bone effects, including mild to moderate grade bone adverse

events in some patients that were appropriately managed in the trial with a bone risk mitigation plan that involved monitoring, prophylactic supplements and administration of zoledronic acid, if indicated. As reported at the ECC, the most common treatment-related adverse events in the Phase Ia trial for vantictumab have included fatigue and nausea. The Phase Ia trial has now been completed.

We initiated three Phase Ib clinical trials in 2014 in distinct solid tumor indications in combination with standard-of-care therapies, one trial in each of breast cancer, pancreatic cancer, and NSCLC. In 2014, in light of adverse bone events seen in the clinical trials, we voluntarily paused enrollment and dosing in these trials. The FDA placed the vantictumab program on partial clinical hold. We worked with bone experts, investigators, and the FDA, and the partial clinical hold was removed in approximately 90 days. The clinical trials have resumed enrollment. We may present initial data from these trials in 2015. Vantictumab is part of our collaboration with Bayer. Bayer has an option to license vantictumab at any point through completion of certain Phase Ib trials.

# Ipafricept (Fzd8-Fc, OMP-54F28)

Ipafricept is our second Wnt pathway modulator. We began enrolling the ongoing Phase Ia trial in July 2012 to evaluate ipafricept in patients with advanced solid tumors. Ipafricept is a fusion protein, or decoy receptor, containing part of the Fzd8 receptor fused to a human Immunoglobulin Fc domain. It has a distinct mechanism of action versus vantictumab (OMP-18R5) binding Wnt ligands rather than binding Frizzled receptors. Ipafricept has shown evidence of strong anti-tumor activity in solid tumors including pancreatic, breast, hepatocellular, ovarian, colorectal and other cancers, and reduction of CSC frequency in multiple preclinical models, either as a single agent or when combined with approved therapies.

Initial data from the Phase Ia trial was most recently presented at the 2014 American Society for Clinical Oncology (ASCO) Annual Meeting in May 2014. As presented at the conference, the Phase Ia single-agent study of ipafricept enrolled 26 patients with advanced refractory solid tumors into seven dose-escalation cohorts to determine safety, pharmacokinetics (PK), pharmacodynamics (PD) and efficacy. Ipafricept was well tolerated up to 20 mg/kg every three weeks, double the estimated target efficacious dose based on PK and preclinical efficacy data. Ipafricept-related adverse events were mild to moderate (Grades 1 and 2) and manageable, including dysgeusia (altered taste), decreased appetite, fatigue, muscle spasms, nausea and vomiting. One related Grade 3 adverse event of increased blood phosphorus was reported. PD modulation of Wnt pathway genes was observed starting at 2.5 mg/kg. Doubling of  $\beta$ -CTX, suggesting increased bone turnover, was predominantly seen at higher dose levels and was reversible with prophylactic supplements and zoledronic acid, if indicated Of 26 evaluable patients, eight experienced prolonged stable disease with tumor assessments for 112 days or longer on the study. Tumor indications with prolonged stable disease include pancreatic, renal cell, testicular, thyroid, non-small cell lung cancer, as well as desmoid tumors and basal cell carcinoma. Patient enrollment in the Phase Ia trial has now been completed.

We initiated three Phase Ib clinical trials in 2014 in pancreatic cancer in combination with gemcitabine plus Abraxane<sup>®</sup>, in ovarian cancer in combination with taxane and platinum chemotherapy, and in hepatocellular carcinoma in combination with sorafenib. In 2014, in light of adverse bone events seen in the clinical trials, we voluntarily paused enrollment and dosing in these trials. The FDA placed the ipafricept program on partial clinical hold. We worked with bone experts, investigators, and the FDA, and the partial clinical hold was removed in approximately 90 days. The clinical trials have resumed enrollment. Ipafricept is part of our collaboration with Bayer. Bayer retains an option to license ipafricept at any point through the completion of certain Phase Ib clinical trials. In addition, we entered into a manufacturing services agreement with Bayer HealthCare LLC whereby Bayer HealthCare LLC manufactures bulk drug substance for this program.

# Wnt biologic #3

As part of our Bayer collaboration, we have advanced an additional bispecific biologic product candidate to preclinical studies.

#### Wnt Pathway Small Molecule Inhibitors

As part of our Bayer collaboration, we and Bayer have jointly initiated discovery campaigns to identify small molecule inhibitors of the Wnt pathway. We have developed assay technologies and transferred those to Bayer. Bayer is utilizing its extensive medicinal chemistry assets and capabilities to discover small molecule drug candidates that modulate Wnt signaling, and we are employing our Wnt technology to evaluate candidate compounds as a basis for advancing them into development. The programs were initiated in 2010. In 2014, the first potential product candidate from this effort advanced to preclinical testing.

## **RSPO-LGR** Pathway

In 2007, we identified that the R-spondin, or RSPO, ligands signal through the LGR receptor family and filed patents applications on therapeutic techniques based on this discovery. We believe we have a significant intellectual property position on antibodies that disrupt RSPO-LGR pathway signaling. We have identified antibodies to proteins in this family that modulate RSPO-LGR signaling and have generated preclinical data demonstrating activity. We plan to file our first IND on an antibody targeting this pathway, anti-RSPO3 (OMP-131R10), during the first half of 2015. Programs in the RSPO-LGR pathway are part of our strategic collaboration with Celgene. Celgene may designate up to four programs across both of the RSPO-LGR signaling pathway and a specified undisclosed pathway for which it wishes to retain its option to develop biologic therapeutics targeting such pathways. The anti-RSPO3 program was designated by Celgene in late 2014. Celgene s right to designate programs within the RSPO-LGR pathway will expire in December 2017, or, if Celgene makes a specified extension payment, in December 2019. For programs that Celgene designates within the RSPO-LGR pathway, including anti-RSPO3, Celgene retains the right to exercise its option during certain time periods through the end of certain Phase I clinical trials to obtain an exclusive license to further develop and commercialize such designated biologic therapeutics.

#### **Other Pathways/Discovery Programs**

We continue to pursue drug discovery activities based on our scientific expertise and proprietary suite of drug discovery technologies. We have multiple other potential target opportunities that we are elucidating from a biological standpoint, and over time we anticipate future potential product candidates to emerge. Our discovery activities also include efforts directed at fundamental biologic pathways in immuno-oncology. We have also developed multiple preclinical immunotherapeutic product candidates that are demonstrating activity and are being advanced towards clinical development. Portions of this research activity are part of our strategic collaboration with Celgene.

#### **Our Proprietary Drug Discovery Platform**

Since our founding, we have developed a suite of proprietary technologies which enables us to identify, isolate and evaluate CSCs, identify and/or validate multiple potential targets critical to CSC self-renewal and differentiation, discover targeted antibody and other protein-based therapeutics that modulate these targets and prevent the growth of CSCs, robustly test for in vivo efficacy and identify potential biomarkers. We believe that the use of these unique technologies described below provides us with a competitive advantage in cancer drug discovery and development.

#### **Cancer Stem Cell Technologies**

We have developed advanced technologies for identifying, isolating and evaluating CSCs. These technologies include proprietary markers and gene signatures for analyzing the subpopulation of CSCs in patient-derived tumor samples.

Our expertise in isolating and monitoring CSCs using specific surface markers enables our scientists to evaluate the importance of specific targets associated with key biologic pathways implicated in both stem cell biology and cancer. To aid new target discovery, we created a novel single-cell gene expression analysis platform to identify genes that are critical to CSC self-renewal and differentiation. This platform originated from our work with Fluidigm Corporation to access their microfluidics technologies. We use our proprietary gene signatures to identify differences between stem cell and progenitor cell populations in normal and cancerous tissues, which can lead to the identification of new anti-CSC targets.

In addition, we have developed proprietary methodologies to functionally define the effect of therapeutics on CSC populations. These methodologies include proprietary assays that can quantitatively measure CSC frequency before and after treatment.

## Antibody Technologies

We utilize several robust technologies for the discovery and optimization of our antibody and protein-based therapeutics, including multiple proprietary technologies. We also have significant experience in biologics cell line and process development.

# Mammalian Display Technology

We have developed a proprietary mammalian display antibody technology (MAbTrap<sup>TM</sup>) that enhances our ability to find rare and unique antibody product candidates. This technology utilizes flow cytometry to isolate mammalian cells expressing antibodies on the cell surface with desired characteristics from large libraries of candidate antibodies. We can also utilize this technology to fine-tune the characteristics of newly discovered antibodies.

# Bispecific Antibody Technology

We have also developed a proprietary bispecific antibody technology (BiMab<sup>TM</sup>), which has been used to generate our anti-DLL4/VEGF antibody (OMP-305B83) and is being used by our research group to generate other novel product candidates. This technology increases the potential for additional innovative antibodies that leverage the potential synergistic activity that we have observed with certain combinations of therapeutic targets.

# Hybridoma Technology

We have substantial expertise in hybridoma technologies for isolating antibodies from mice, including proprietary multiplex single-cell screening techniques. This capability includes the ability to often identify antibodies that cross-react with similar affinity to targets in human, cynomolgus monkey, rat, mouse and other species useful to facilitate drug development and toxicology testing. Humanized antibody product candidates derived from this effort include demcizumab (anti-DLL4, OMP-21M18) and brontictuzumab (anti-Notch1, OMP-52M51).

#### Antibody Production and Manufacturing

We also have assembled significant expertise in biologics production. We conduct cell line development and process development in-house, and utilize contract manufacturing organizations for actual production of drug product and drug substance materials. We believe this approach allows us to generate quality antibody and biologic materials in a capital-efficient manner.

# Human Tumor Bank and Xenograft Models

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We have developed a proprietary human tumor xenograft bank. This tumor bank consists of approximately 200 established tumors sourced from patients with various types of cancer, including pancreatic, breast, colon,

lung, ovarian, melanoma and other cancers. We implant these tumors in mice and utilize these models to identify and validate genes that drive tumor growth, to screen for anti-tumor activity of our product candidates, to evaluate the effects of product candidates on CSCs and to identify biomarkers that can be used to identify patients most likely to respond to our therapeutic candidates. Additionally, we use our patient-derived tumor xenograft models to identify possible indications and assess various dosing regimens that can be evaluated in our clinical trials. We believe these patient-derived models are more representative of the clinical features of human tumors than the cell line-based models used in traditional cancer research, and our models also offer the ability to test the effects of therapeutic candidates on human tumors with varied genetic backgrounds.

We have characterized these tumor xenografts in detail, including sequencing of key genes that are known to drive cancer, histology analysis, single nucleotide polymorphism (SNP) assessment, characterization of gene amplifications and deletions, and gene expression profiling. This characterization is useful for us to correlate response of our agents in relation to the genetic background and biochemical characteristics of the tumor and in the development of predictive patient selection strategies. For example, we have identified key biomarkers in a subset of our tumor xenografts that appear to strongly correlate with robust single-agent response to our brontictuzumab product candidate. Additionally, our established tumor xenograft models encompass many of the clinically relevant patient subgroups (e.g., triple-negative breast cancer, B-Raf mutated melanoma and K-Ras wild-type colorectal cancer) that we can analyze to help inform our clinical development strategies. Our data, as well as other published reports, indicate that these models may be predictive of clinical responses to an antibody.

# Cancer Stem Cells and Immuno-Oncology Research

We believe our anti-cancer stem cell candidates may be well suited to combinations with immunotherapeutic antibodies. Unlike traditional chemotherapies, which can suppress the immune system, our anti-cancer stem cell antibodies leave immune system function intact and may enhance immune function. We believe that by pushing cancer stem cells into a more differentiated state, our anti-cancer stem cell product candidates may make the cancer stem cells more susceptible to immune system activity. Our antibody expertise, including bispecific antibody capabilities, provides a platform for the development of next-generation immunotherapeutic agents.

In recent years, we have also been conducting discovery research efforts concentrated on exploring novel immunotherapeutic strategies. These efforts leverage our expertise in receptor-ligand biology, and have resulted in the potential identification of certain novel undisclosed targets that are intended to restore immune system function against tumors. To date, we have developed multiple preclinical immuno-oncology product candidates that are demonstrating efficacy and are being advanced towards clinical development.

# **Biomarker Discovery**

We have established capabilities for analyzing both predictive and pharmacodynamic biomarkers extensively in our preclinical studies and also in our clinical trials.

Predictive biomarkers are useful in identifying subsets of cancer patients with an increased probability of responding favorably to a particular treatment. We have utilized our collection of patient-derived xenograft models and discovered predictive biomarkers that correlate with response in preclinical studies for several of our lead molecules.

Pharmacodynamic biomarkers are useful for determining whether a therapeutic is effectively modulating its intended target information that is critical for optimizing the dose and schedule for delivery of therapeutics. We conduct multiple pharmacodynamic analyses to look at gene, RNA expression and protein changes in response to our agents in tumor biopsies, circulating tumor cells and surrogate tissues. Using state-of-the-art methods, including single-cell

gene expression technology, we have demonstrated on-target pharmacodynamic effects for multiple product candidates in our pipeline, including demcizumab, tarextumab, vantictumab, ipafricept and additional product candidates.

## **Collaboration and License Agreements**

## Strategic Alliance with GSK

In December 2007, we entered into a strategic alliance with GSK to develop anti-CSC antibody therapeutics targeting the Notch signaling pathway. Under this collaboration, GSK has an option to obtain an exclusive license to develop and commercialize such antibody therapeutics, which may be exercised during defined time periods through completion of Phase II proof-of-concept trials. We lead research and development efforts for Notch pathway programs prior to GSK s exercise of its option.

Upon execution of the original collaboration agreement with GSK, we received \$35.0 million in cash, comprised of \$17.5 million in an upfront payment and \$17.5 million in the form of an equity investment. We were originally eligible to receive from GSK payments totaling up to approximately \$1.4 billion for up to four product candidates, including the upfront amount and milestone payments in connection with research and development activities, and contingent consideration in connection with further development, regulatory approval and commercialization activities.

In July 2011, we amended the collaboration agreement with GSK. The parties agreed to focus the collaboration on the development of two product candidates, tarextumab and brontictuzumab. GSK also agreed to terminate its options to obtain an exclusive license to develop and commercialize demcizumab and bispecific antibodies targeting DLL4 and VEGF. Under certain circumstances we may owe GSK single-digit percentage royalties on net product sales of demcizumab. In the amendment, we and GSK also agreed to cease all further discovery and research activities under the collaboration on programs other than tarextumab and brontictuzumab. Further, the amendment provided additional funding from GSK to support certain of our development activities conducted in relation to one of these product candidates, up to a maximum of \$2.0 million. GSK retains its option to exclusively license tarextumab, which may be exercised during certain time periods through the end of proof-of-concept Phase II trials. GSK also has an option to exclusively license brontictuzumab, which may be exercises its option with respect to tarextumab or brontictuzumab, GSK will receive an exclusive license to develop and commercialize such product candidate in all indications.

We are eligible to receive from GSK, (1) with respect to tarextumab, aggregate payments of up to \$344.5 million of milestones and contingent consideration, including an option exercise fee and development, regulatory and commercialization payments, of which \$25.0 million had been earned through December 31, 2014, in addition to percentage royalties in the low double digits to high teens on net product sales, and (2) with respect to brontictuzumab, aggregate payments of up to \$349.5 million of milestones and contingent consideration, including an option exercise fee and development, regulatory and commercialization payments, of which \$14.0 million had been earned through December 31, 2014, in addition to percentage royalties in the low double digits to high teens on net product sales. In addition, we are eligible to receive bonus payments of up to \$15.0 million based on clinical success, for a total of \$670.0 million of potential future payments as of December 31, 2014. If GSK elects not to exercise its options for tarextumab and/or brontictuzumab during the relevant option periods, or if GSK terminates those programs, we will have worldwide rights to such program(s), subject to, under certain circumstances, GSK s right of first negotiation to obtain an exclusive license to develop and commercialize brontictuzumab.

In July 2012, we further amended our agreement to revise the structure of the milestone payments to reflect the decision to initiate a Phase Ib/II trial for tarextumab. We initiated the second of two Phase Ib/II trials for tarextumab in 2013, triggering a cash payment of \$8.0 million from GSK, which was recorded as deferred revenue. This deferred revenue was recognized in 2014 with the initiation of the Phase II portion of the ALPINE pancreatic cancer trial.

Under our amended agreement with GSK, there are several committees, including a Joint Steering Committee, and Joint Clinical Subteam, among others, that meet regularly to discuss our activities in the

collaboration. In general, decisions regarding development of a product candidate are made jointly through these committees prior to the exercise of GSK s option with respect to the product candidate, except for in certain circumstances. For example, GSK has final decision-making authority with respect to the design of brontictuzumab clinical trials, subject to certain pre-specified guidelines. Also for example, we have sole decision-making authority with respect to manufacture and supply matters for product candidates prior to option exercise. Following the exercise by GSK of its option for a product candidate, GSK generally assumes responsibility for all costs associated with further development of the product candidate and the Joint Steering Committee has no control over decisions relating to development of the product candidate for which the option was exercised.

We are obligated to utilize commercially reasonable efforts to progress both tarextumab and brontictuzumab into clinical development prior to GSK s exercise of its option for such product candidates. We are responsible for funding all research activities we conduct under the collaboration prior to GSK s exercise of its option for such product candidates. We intend to utilize our potential milestone payments from this collaboration towards advancement of our tarextumab and brontictuzumab programs. In general, while the Joint Steering Committee and other subteams may discuss resource allocation, they have no specific ability to control resource allocation with respect to product candidates being developed under our agreement with GSK and there are no explicit expenditure or investment requirements in our agreement with GSK.

Our agreement with GSK will expire upon expiration of GSK s payment obligations or at any time at which no product candidate that is subject to the collaboration agreement is being researched, developed or commercialized. Either party may terminate the agreement for any material breach by the other party that the breaching party fails to cure. GSK may terminate the agreement for any reason or no reason upon prior notice to us, either in its entirety or on a program by program basis. Either party may terminate the agreement if GSK challenges the licensed patents.

# Strategic Alliance with Bayer

In June 2010, we entered into a strategic alliance with Bayer to discover, develop and commercialize novel anti-CSC biologic and small molecule therapeutics targeting the Wnt signaling pathway. Under this collaboration, Bayer may exercise its option to obtain an exclusive license to develop and commercialize biologic therapeutics in one or more defined biologic therapeutic classes. Bayer may exercise its option for such biologic therapeutics at any point up to the completion of Phase I trials. If Bayer exercises its option with respect to a class of biologic therapeutics, Bayer will receive an exclusive license to develop and commercialize all therapeutics in such class in all indications. Under this collaboration, we and Bayer also agreed to jointly conduct research to discover potential new small molecule therapeutics targeting the Wnt pathway, and we granted Bayer a non-exclusive license to our Wnt pathway assay technology for the research and development of such small molecule therapeutics. Bayer may, within a specified time period, elect to advance such small molecule therapeutics into development, and obtain an exclusive license to commercialize such therapeutics. Under our collaboration, we lead the discovery and development of biologic therapeutic products prior to Bayer s exercise of its option, and Bayer leads discovery, development and commercialization of small molecule therapeutics. In addition to an upfront cash payment of \$40.0 million, we are eligible to receive option fees and research, development, regulatory and commercial milestone or post-option contingent consideration payments of up to \$387.5 million per program for each biologic therapeutic product successfully developed, in addition to royalties on net product sales. Percentage royalties for certain biologic product candidates are in the low double digits to high teens. For certain other biologic product candidates, percentage royalties are in the mid-single digits to low double digits. Bayer is obligated to make payments to us upon achievement of research, development, regulatory and commercial milestones, plus advancement fees, for small molecule therapeutics that could total up to \$112.0 million per program, in addition to single-digit percentage royalties on net product sales. To date, we have received \$30.0 million in payments specific to vantictumab and \$20.0 million

in payments specific to ipafricept. While the total number of potential programs is uncapped, the parties currently intend to advance up to three

biologic and two small molecule candidates. We may co-develop biologic therapeutic products to which Bayer obtains an exclusive license under specified circumstances. If Bayer elects not to exercise its options for any class of biologic therapeutic products under the collaboration during the relevant option periods, we will have worldwide rights to such program(s). In addition, under certain termination circumstances, we would also have worldwide rights to the terminated program(s).

In August 2012, we amended our agreement with Bayer to reallocate certain amounts between two payments applicable to our biologic product candidates and to redefine when payments applicable to certain biologic product candidates are due. In August 2013, we amended the agreement to confirm the achievement of a development milestone of \$10.0 million for dose escalation of vantictumab in Phase Ia as well as agreement on the Phase Ib trial design.

Under our agreement with Bayer, there are several committees, including a Joint Steering Committee and a Joint Development Sub-Committee, among others, that meet regularly to discuss our activities in the collaboration. Decisions are generally made jointly through these committees through the Phase I stage of development. However, we generally have final decision-making authority with respect to the development of biologic product candidates during research, preclinical, and Phase I stages of development; and Bayer generally has final decision-making authority with respect to development of small molecule projects and also with respect to biologic product candidates in later-stages of development, following Bayer s exercise of its option with respect to such biologic product candidates.

We are obligated to utilize commercially reasonable efforts to advance a certain number of biologic product candidates into clinical development prior to Bayer s exercise of its option for such product candidates. We are responsible for funding all research and development activities for a given class of biologic therapeutics under the collaboration prior to completion of certain Phase I trials for that therapeutic class. We intend to utilize our potential milestone payments from this collaboration to advance our Wnt pathway programs. In general, while the Joint Steering Committee and other committees may discuss resource allocation in the course of reviewing development plans, they have no specific ability to control resource allocation with respect to product candidates covered by the collaboration agreement and there are no minimum expenditure or investment requirements with respect to the product candidates covered by our agreement with Bayer.

Our agreement with Bayer and their payment obligations thereunder will expire on a product by product and country by country basis on the last to occur of (i) the expiry of certain patent rights covering the product in such country, (ii) the expiration of any regulatory exclusivity period in such country, (iii) ten years from first commercial sale of such product in such country, or (iv) the expiry of our payment obligations with respect to products licensed to Bayer under our agreements with certain third party licensors. Our agreement will also expire if Bayer fails to exercise all of its options within the required time periods. Either party may terminate the agreement for any material breach by the other party that the breaching party fails to cure. Bayer may terminate the agreement for any reason or no reason upon prior notice to us, either in its entirety or with respect to certain classes of compounds subject to the collaboration. Either party may terminate the agreement upon bankruptcy or insolvency of the other party, and we may terminate the agreement if Bayer challenges the licensed patents.

In April 2011, we entered into a clinical manufacturing agreement which expanded our alliance with Bayer. Pursuant to this agreement, Bayer HealthCare LLC agreed to manufacture ipafricept at its Berkeley, California site to support our clinical development activities.

# Strategic Alliance with Celgene

In December 2013, we entered into a collaboration agreement with Celgene pursuant to which we and Celgene will collaborate on research and development programs directed to the discovery and development of novel anti-CSC biologic therapeutics, and, if Celgene exercises an option to do so, the discovery, development and commercialization of novel anti-CSC small molecule therapeutics. Pursuant to the biologic therapeutic

programs, we will conduct further development of demcizumab, anti-DLL4/VEGF bispecific antibodies, biologic therapeutics directed to targets in the RSPO-LGR signaling pathway, and biologic therapeutics directed to targets in an undisclosed pathway. Celgene has options to obtain an exclusive license to develop further and commercialize biologic therapeutics in specified programs, which may be exercised during time periods specified in the collaboration agreement through completion of certain clinical trials, provided that such completion occurs within a 12 year time period, which we refer to as the Option Period. Celgene s options may be exercised on a program-by-program basis for up to six biologic programs, including the demcizumab program, the anti-DLL4/VEGF bispecific program, and up to four programs targeting the RSPO-LGR signaling pathway and/or targets in the undisclosed pathway. Celgene also has a seventh option, which, if exercised at any time until the fourth anniversary of the date of the collaboration agreement, would permit Celgene to discover, develop and commercialize small molecule therapeutics directed to targets in an undisclosed pathway under the collaboration.

Pursuant to the Agreement, we lead the discovery and development of biologic therapeutic products prior to Celgene s exercise of its option, which Celgene may elect to do on a program-by-program basis. With respect to biologic therapeutics targeting the RSPO-LGR signaling pathway and the undisclosed pathway, prior to Celgene s exercise of its option for a given program, Celgene is required to designate each program for which it wishes to retain the right to exercise its option, based on data generated by us, for up to a maximum of four programs across both the RSPO-LGR signaling pathway. Celgene s right to designate programs to identify biologic therapeutics that target the RSPO-LGR signaling pathway or the undisclosed pathway will expire on the fourth anniversary of the date of the collaboration agreement or, if Celgene makes a specified extension payment to us prior to expiration of such right for each of the RSPO-LGR signaling pathway and the undisclosed pathway development programs, upon the sixth anniversary of the date of the collaboration agreement. Following such designation(s), Celgene will have the right to exercise its option for each such program (up to four in total) within the Option Period.

Following Celgene s exercise of its option for a biologic therapeutic program, we are required to enter into an agreed form of co-development and co-commercialization agreement with Celgene for such program, pursuant to which we will have the right to co-develop and to co-commercialize products arising out of such program in the United States, and Celgene will have the exclusive right to develop and commercialize products arising out of such program outside of the United States. Our involvement in co-commercialization will include participation in specified promotion activities by means of an OncoMed dedicated sales force of up to half of the overall sales force for the applicable program products, as well as marketing and other commercial activities, with Celgene booking sales of products. We will be responsible for a one-third share of the global development costs of product candidates for programs that we are co-developing with Celgene, with Celgene bearing the remaining two thirds of such costs. However, for one program targeting either the RSPO-LGR signaling pathway or the undisclosed pathway, and any program for which we elect not to co-develop and co-commercialize products arising from such program, we and Celgene will instead enter into an agreed form of a license agreement, pursuant to which Celgene retains all rights to develop further and commercialize biologic therapeutic products on a worldwide basis, with certain support for development from us. We may elect not to co-develop and co-commercialize any products arising under such programs at any time, either prior to, or following Celgene s option exercise, with the exception of a defined period of time near commercial launch of a product under a program. If we opt out of our co-development and co-commercialization rights with respect to a program, Celgene will have the exclusive right to develop and commercialize products arising out of such program. With respect to small molecule therapeutics targeting an undisclosed pathway, following Celgene s exercise of its option, we will collaborate with Celgene on the discovery of and research on small molecule therapeutics, but Celgene will be solely responsible for development and commercialization of such therapeutics.

In addition to an upfront cash payment of \$177.3 million, including an equity investment of \$22.3 million, we are eligible to receive option fees upon Celgene s exercise of the option for each biologic therapeutic program (for up to six biologic therapeutic programs). The collaboration also includes milestone payments for achievement of specified

development, regulatory and commercial milestones, paid on a per-product and per-program basis. The option exercise payments and payments for achievement of development, regulatory and

commercial milestones may total up to (1) approximately \$791.0 million for products in the demcizumab program, including a \$70.0 million payment upon the achievement of certain pre-determined safety criteria in Phase II clinical trials with respect to demcizumab, (2) \$505.0 million for products in the anti-DLL4/VEGF bispecific program, and (3) approximately \$440.0 million for products achieving regulatory approval that are directed to targets in each of the RSPO-LGR signaling pathway and the undisclosed pathway programs for which Celgene exercises its option.

For programs in which we are co-developing and co-commercializing biologic therapeutic products in the United States, we are also entitled to share 50% of all product profits and losses in the United States. For such programs outside the United States, we are eligible to receive tiered royalties equal to a percentage of net product sales outside of the United States for each biologic program as follows: tiered royalties in the double-digits for demcizumab and royalties in the mid-single digits to the mid-teens for other biologics programs. If we elect not to co-develop or co-commercialize biologic therapeutic products or do not have the right to do so for a given program, Celgene is required to pay us tiered royalties in the high-single digits to the high-second the program, Celgene is required to pay us tiered royalties in the high-single digits to the high-teens for other biologics programs), with such royalties being increased where we had the right to co-develop and co-commercialize such biologic therapeutic products under such program but elected not to do so. We are responsible for funding all research and development activities for biologic therapeutics under the collaboration prior to Celgene s exercise of the option for such program.

We are also entitled to receive payments from Celgene upon exercise of its option for the small molecule program, as well as certain development and regulatory milestone payments through regulatory approval totaling over \$100.0 million. We will receive royalties equal to a percentage of worldwide net sales of small molecule products in the low-to mid-single digits.

The Celgene collaboration agreement will terminate upon the expiration of all of Celgene s payment obligations under all license or co-development and co-commercialization agreements entered into with respect to programs following Celgene s exercise of an option for a given program, or if Celgene fails to exercise its options within the Option Period. The collaboration agreement may be terminated by either party for the insolvency of, or an uncured material breach of the collaboration agreement by, the other party. In addition, Celgene may terminate the collaboration agreement in its entirety or with respect to one or more programs subject to the collaboration, for any reason, upon 120 days prior written notice to us and upon 60 days prior written notice in the event that Celgene reasonably believes that such termination is necessary in order to comply with any antitrust laws. We may also terminate the collaboration agreement with respect to one or more programs in the event that Celgene challenges the licensed patents with respect to such program.

If Celgene does not exercise its option with respect to a biologic therapeutic program within the Option Period, we retain worldwide rights to such program(s), except that if Celgene exercises its option to obtain a license for either the demcizumab program or the anti-DLL4/VEGF bispecific program, then for so long as such license is in effect, we cannot develop or commercialize products under the other of such two programs. In addition, under certain termination circumstances, we would also have worldwide rights to the terminated biologic therapeutic programs.

In December 2013, we sold 1,470,588 shares of our common stock to Celgene at a price of \$15.13 per share, which resulted in gross proceeds to us of \$22.3 million. We agreed with Celgene that, after we have qualified for the use of Form S-3 and upon the written request of Celgene, we would prepare and file with the Securities and Exchange Commission a registration statement on Form S-3 for purposes of registering the resale of the shares specified in Celgene s written request. We also agreed, among other things, to indemnify Celgene under the registration statement from certain liabilities and to pay all fees and expenses (excluding any legal fees of the selling holder(s) above \$10,000 per registration statement and any underwriting discounts and selling commissions) incident to our

obligations to register the resale of Celgene s shares of our common stock.

In the fourth quarter of 2014, the lead candidate in our anti-RSPO3 program, OMP-131R10, was designated as a clinical candidate in the collaboration, triggering a \$2.5 million payment from Celgene. We anticipate filing an IND for OMP-131R10 in the first half of 2015.

## Summary of Potential Future Milestones from GSK, Bayer, and Celgene Programs:

Overall, under our collaboration agreements with Celgene, Bayer, and GSK, we are eligible for over \$4 billion in total potential milestone and option payments from our partners in future years beginning January 1, 2015, including up to the following amounts for individual programs:

Demcizumab: ~\$790 million

Tarextumab: \$319.5 million

Vantictumab: \$357.5 million

Ipafricept: \$347.5 million

Brontictuzumab: \$335.5 million

Anti-DLL4/VEGF bispecific: ~\$505 million

Anti-RSPO3: ~\$440 million

Additional RSPO and undisclosed pathway biologics: ~\$440 million each, up to 3 programs

Bayer small molecule programs: \$110 million

Celgene small molecule programs: over \$100 million As of December 31, 2014, we have received over \$373 million in total from our current partners since 2007, including upfront payments, milestones, fees, and equity investments.

# The University of Michigan

In January 2001, Cancer Stem Cell Genomics, Inc. entered into a license agreement with the Regents of the University of Michigan, or the University of Michigan. In 2004, Cancer Stem Cell Genomics, Inc. merged with and into us, and we assumed this license agreement with the University of Michigan. Under the agreement and in exchange for certain

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additional consideration, the University of Michigan has granted to us an exclusive, royalty-bearing, worldwide license under certain patent rights, and a nonexclusive, worldwide license under certain technologies, to make, have made, import, use, market, offer for sale or sell products and to practice processes for any use, including human therapeutic or diagnostic use, that are covered by the licensed patents. Technologies covered by the licensed patents include certain enriched CSC compositions, CSC markers, diagnostic methods, as well as certain therapeutic methods using certain anti-CSC antibodies. Additional details regarding the patent rights exclusively licensed to us under the agreement are described in more detail below under Intellectual Property. The University of Michigan reserved certain rights to the licensed patents for noncommercial research and education purposes.

We are required to pay to the University of Michigan an annual license maintenance fee and reimburse the University of Michigan for expenses associated with the prosecution and maintenance of the licensed patents, both of which are credited towards future royalty payments. We are also required to pay to the University of Michigan percentage royalties in the low single digits based on net sales by us or our sublicensees of products or processes covered by the licensed patents until expiry of the patents. With respect to one family of licensed patent applications that does not relate to any of our seven lead therapeutic programs, we are also required to pay a tiered, single-digit percentage of any sublicense revenues, including any upfront or milestone payments, received from any sublicensees under such family of patents. Once the University of Michigan has received \$10.0 million in royalties, we may, at our option, convert the license to a fully paid-up license provided we

transfer to the University of Michigan shares of our non-voting capital stock equal to 0.25% of the fully diluted number of shares outstanding at the time of our election. We are required to use commercially reasonable efforts to develop and commercialize products and processes within certain time periods.

If not terminated earlier, this agreement terminates upon the expiration of all patent rights licensed under this agreement. Either party may terminate the agreement for any material breach by the other party that the breaching party fails to cure. We may terminate the agreement at any time upon expiration of a defined notice period.

# **MorphoSys**

In June 2006, we entered into a subscription and license agreement with MorphoSys. Under this agreement, we obtained access to certain phage display technologies, as well as a research license under certain patents covering such technologies, to identify antibodies that bind targets of interest to us as therapeutics. Under this agreement, we have obtained two exclusive, worldwide, commercial therapeutic licenses from MorphoSys to clinically develop and commercialize antibodies identified using the licensed technologies, which relate to tarextumab and vantictumab, respectively. We also obtained from MorphoSys a worldwide, non-exclusive, royalty-free extended research license to use certain antibodies identified during the subscription term for research purposes after the subscription term. As of December 31, 2014, we have paid MorphoSys an aggregate of 3.8 million (approximately \$5.3 million) under the subscription and license agreement, including technology access fees and subscription fees. We additionally paid \$47,000 for support fees. Under our amended agreement with GSK, GSK reimburses us for 50% of the payments we make to MorphoSys for tarextumab under the MorphoSys agreement, and we have received a total of \$992,000 from GSK in such reimbursements as of December 31, 2014.

For the extended research license, which lasts through 2015 and may be renewed by us on an annual basis through 2020, we must pay MorphoSys an annual license maintenance fee of 20,000. For the commercial therapeutic licenses, we must make milestone payments upon achievement of certain events and tiered, single-digit percentage royalties on net sales of licensed products on a country-by-country basis. We may owe MorphoSys up to 5.8 million in future milestone payments for each product developed using the licensed antibodies if all milestone events are achieved, primarily in Phase III clinical trials and later development. GSK would reimburse us for 50% of such payments for tarextumab. If we do not diligently pursue the development and commercialization of at least one product with respect to each commercial therapeutic license we have obtained from MorphoSys, then MorphoSys has the right to terminate that license if the failure to use diligence is not cured within a defined notice period.

This agreement will remain in effect, unless terminated, until the earlier of the time at which the last commercial license terminates or the date all obligations to pay all royalties have ceased. Either party may terminate the agreement in the event of an uncured material breach by the other party.

# Lonza Sales AG

In August 2012, we entered into a multi-product license agreement and a collaboration agreement with Lonza Sales AG, or Lonza. These agreements cover the process development and manufacturing of our biologics portfolio with Lonza. Under the collaboration agreement, Lonza will be our preferred supplier of process development and manufacturing services for our bulk drug substances in their Slough, United Kingdom facility. The parties also agreed to establish a joint steering committee governance structure to oversee, coordinate and expedite the performance of the collaboration agreement, resolve disputes arising between the parties; monitor the progress of the relevant services; and plan and assess needs for future services. Under the multi-product license agreement, we receive licenses to utilize Lonza s glutamine synthetase gene expression system and related technologies for commercial production of our product candidates. Under this license agreement, we paid an upfront payment of \$488,000 and are obligated to pay

Lonza certain payments up to £1.4 million on

achievement of specified milestones for each licensed product, and royalties up to the very low single digits on sales of licensed products. The multi-product license agreement shall remain in force on a product by product and country by country basis until expiration of our obligation to make payments to Lonza with respect to such product in such country. The agreement can otherwise be terminated by us for any reason or no reason upon advance written notice to Lonza, or by either us or Lonza upon the other party s material breach of the agreement, or if the other party ceases to carry on business. Lonza may also terminate the licenses granted under the agreement if we challenge any of the Lonza patent rights.

The collaboration agreement shall remain in force for five years, unless either party elects to terminate the collaboration agreement by prior written notice effective on the date that is two and a half years after the effective date of the agreement, or unless the parties mutually agree in writing to extend the term of the collaboration agreement prior to the end of the five year term for an additional two years. Either we or Lonza may elect to terminate the collaboration agreement upon advance written notice for material breach by the other party, or if the other party ceases to carry on business. The collaboration agreement can also be terminated by either party by advance written notice in the event that Lonza is no longer obligated to provide manufacturing services to us.

# **Intellectual Property**

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, novel biological discoveries, antibody technologies, biomarkers, screening technologies and other know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S., international and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position.

As a normal course of business, we pursue both composition-of-matter patents and method-of-use patents for our product candidates. We also seek patent protection with respect to novel biological discoveries, including new targets and applications, as well as to biomarkers and novel antibody technologies. We are also pursuing patents covering our proprietary screening and CSC technologies.

We have a total of over 400 patents and pending patent applications in our patent portfolio. As of December 31, 2014, we were sole owners of 39 issued patents or allowed patent applications in the United States and 62 issued patents or allowed patent applications in foreign jurisdictions, as well as approximately 291 additional pending patent applications (including provisionals) in the United States, Europe and other jurisdictions. In addition to the patents and patent applications owned solely by us, our patent portfolio also includes patents and patent applications licensed from the University of Michigan. As of December 31, 2014, we had an exclusive, worldwide license from the University of Michigan to 12 issued U.S. patents and 21 issued foreign patents, as well as approximately 13 pending applications in the U.S. or selected foreign jurisdictions. A few of the patents and patent applications in the portfolio licensed from the University of Michigan are jointly owned by us.

The patent portfolios for our seven most advanced product candidates as of December 31, 2014 are summarized below.

*Demcizumab (Anti-DLL4, OMP-21M18).* A core patent family in our demcizumab portfolio is owned solely by us and covers both the composition of matter and methods of use of demcizumab. This family

includes an issued U.S. composition-of-matter patent, 12 issued foreign patents, and approximately 13 additional pending U.S. or foreign patent applications. The issued U.S. patent expires in 2028. Other patents that issue in this family will generally be expected to expire in 2027. Our portfolio also includes an issued U.S. patent exclusively licensed from the University of Michigan that broadly covers the use

of anti-DLL4 antibodies for the treatment of cancer and expires in 2022 as well as a couple of issued foreign patents exclusively licensed from the University of Michigan that expire in 2021 or 2025. We are also sole owners of two additional issued U.S. patents that relate to certain uses of demcizumab and expire in 2030 or 2032. Also included in our demcizumab portfolio are additional Patent Cooperation Treaty, or PCT, foreign, and U.S. patent applications that relate to demcizumab, certain uses of demcizumab, and/or related biomarkers, which, to the extent they issue as patents or are used to establish nonprovisional patent applications that issue as patents, will generally be expected to expire between 2021 and 2035.

*Tarextumab (Anti-Notch2/3, OMP-59R5).* A core patent family in our tarextumab portfolio is owned solely by us and covers both the composition of matter and methods of use of tarextumab. This family includes an issued U.S. composition-of-matter patent expiring in 2030, an issued U.S. method-of-use patent expiring in 2029, two allowed U.S. patent applications, ten allowed foreign patent applications or issued foreign patents and approximately 20 additional pending foreign patent applications. Patents that issue in this family are generally expected to expire in 2029. We are also sole owners of an issued U.S. patent broadly covering tarextumab that expires in 2028, an issued U.S. patent broadly covering uses of tarextumab in the treatment of cancer that expires in 2027 and a number of issued foreign patents that relate to tarextumab and/or certain of its uses and expire in 2025 or 2027. Our portfolio also includes additional pending U.S., PCT and foreign patent applications relating to tarextumab, certain of its uses, and/or related biomarkers, which, to the extent they issue or are used to establish nonprovisional patent applications that issue, will generally be expected to have expiration dates ranging from 2025 through 2035.

**Brontictuzumab** (Anti-Notch1, OMP-52M51). Our brontictuzumab portfolio includes a core patent family that is owned solely by us and covers both the composition of matter and methods of using brontictuzumab. As of December 31, 2014, this family includes one issued U.S. composition-of-matter and method-of-use patent expiring in 2029, two allowed U.S. patent applications, ten allowed foreign patent applications or issued foreign patents and approximately 20 additional pending U.S. or foreign patent applications. Patents that issue in this family are generally expected to expire in 2029. Our portfolio also includes several additional issued U.S. and foreign patents relating to certain uses of brontictuzumab that expire in 2025 or 2031. Our portfolio further includes a pending PCT application and other pending patent applications in the U.S. and certain foreign countries relating to brontictuzumab, certain of its uses and/or related biomarkers, which, to the extent they issue or are used to establish nonprovisional patent applications that issue, will generally be expected to have expiration dates ranging from 2025 through 2035.

*Vantictumab (OMP-18R5).* A core patent family in our vantictumab portfolio is owned solely by us, covers both the composition of matter and methods of use of vantictumab and includes an issued U.S. composition-of-matter patent expiring in 2029, an issued U.S. method-of-use patent expiring in 2029, an allowed U.S. patent application, three issued foreign patents and approximately 15 additional pending U.S. and foreign patent applications. To the extent that additional patents in this family issue, they are also expected to expire in 2029. Other U.S., PCT, and foreign patent applications in our portfolio relate to vantictumab, certain of its uses, and/or related biomarkers and, to the extent they issue or are used to establish nonprovisional patent applications, are expected to have expiration dates ranging from 2024 through 2035. An additional foreign patent in our portfolio exclusively licensed from the University of Michigan broadly relates to vantictumab and expires in 2024.

*Ipafricept (Fzd8-Fc, OMP-54F28).* We solely own a patent family that specifically covers both the composition of matter and methods of use of ipafricept and includes one pending U.S. patent application, two issued foreign patents, and approximately 17 pending foreign patent applications. Patents that issue in this family are expected to expire in 2031. We are also the sole owners of two broad issued U.S. patents relating to certain Fzd-Fc biologics and uses of Fzd-Fc biologics in the treatment of cancer that expire in 2026 or 2027, an issued U.S. patent to related polynucleotides that expires in 2026, and two related issued foreign patents. Additional U.S., PCT, and foreign pending

patent applications in our portfolio that are solely owned by us relate to ipafricept, certain uses of ipafricept, and/or related biomarkers and, to the extent they issue or are used to establish nonprovisional patent applications that issue, are expected to expire between 2026 and 2035.

Anti-DLL4/VEGF (OMP-305B83). A core patent family solely owned by us specifically covers both the composition of matter and methods of use of OMP-305B83 and includes an issued U.S. composition-of-matter patent expiring in 2032, a pending U.S. patent application, and approximately 29 foreign patent applications. Patents that issue in this core family are generally expected to expire in 2032. Our portfolio also includes several issued U.S. and foreign patents that that relate to OMP-305B83 and/or certain methods of its use and expire between 2021 and 2028. Additional U.S., PCT and foreign patent applications solely owned by us that relate to OMP-305B83, certain methods of its use, and/or related biomarkers are also pending and, to the extent they issue or are used to establish nonprovisional patent applications that issue, are expected to expire between 2027 and 2035.

*Anti-RSPO3 (OMP-131R10).* Our OMP-131R10 portfolio includes a core patent family that is solely owned by us and specifically covers both the composition of matter and methods of use of OMP-131R10. As of December 31, 2014, this family includes one U.S. patent application, one PCT application, and one foreign patent application. Patents that issue from the applications in this core family will be expected to expire in 2033. We are also sole owners of an issued U.S. composition-of-matter patent broadly covering human or humanized monoclonal anti-RSPO3 antibodies that disrupt binding of RSPO to LGR or disrupt RSPO activation of LGR signaling and an issued U.S. patent broadly covering uses of such anti-RSPO3 antibodies in the treatment of cancer. Both patents expire in 2028. Also included in our OMP-131R10 portfolio are additional foreign and U.S. patent applications that relate to OMP-131R10, certain uses of OMP-131R10, and/or related biomarkers, which, to the extent they issue as patents, or are used to establish nonprovisional patent applications that issue as patents, will be expected to expire between 2028 and 2035.

Our portfolio also includes patents and patent applications relating to our platform technologies, including CSC technologies, bispecific antibody engineering technologies and antibody display technologies, including our mammalian display technologies. A number of the patents and patent applications exclusively licensed from the University of Michigan are based in part on the discovery by our scientific founders of CSCs in solid epithelial tumors and relate to enriched CSC compositions, CSC markers, methods for enriching for CSCs and/or assays for screening anti-CSC agents. Two of the licensed U.S. CSC patents are jointly owned by us, cover certain assays for determining the effect of agents on CSC frequency in solid epithelial tumors and expire in 2021. In addition, we are sole owners of several pending U.S. and foreign patent applications directed to our bispecific antibody technology, which, to the extent they issue, are expected to expire in 2030. We also own an issued U.S. patent expiring in 2031, an allowed U.S. patent applications, three issued foreign patents, and several pending U.S. and foreign patents that issue from our antibody display patent applications will be expected to expire in 2031.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or the USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent that covers a drug or biological product may also be eligible for patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. Under the Biologics Price Competition and Innovation Act of 2009, or BPCIA, products approved as a biological product under a biologics license

application, or BLA, in the United States may qualify for a 12-year period of non-patent exclusivity. See Government Regulation Biologics License Applications below for additional information on such exclusivity. In the future, if and when our product candidates receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those products, depending upon the length of the clinical trials for each drug and other factors, including those involved in the filing of a BLA.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary position for our product candidates and technologies will depend on our success in obtaining effective claims and enforcing those claims once granted. However, patent applications that we may file or license from third parties may not result in the issuance of patents. We also cannot predict the breadth of claims that may be allowed or enforced in our patents. The issued patents that we own or license, or may receive in the future, may be challenged, invalidated or circumvented. For example, we cannot be certain of the priority of inventions covered by pending third-party patent applications. If third parties prepare and file patent applications in the United States that also claim technology or therapeutics to which we have rights, we may have to participate in interference proceedings in the USPTO to determine priority of invention, which could result in substantial costs to us, even if the eventual outcome is favorable to us. We may also need to participate in opposition proceedings before the European Patent Office, or EPO, regarding patents in our portfolio. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent.

Our commercial success, like the commercial success of other companies in our industry, will depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our product candidates or processes, obtain licenses or cease certain activities. We or our collaborators may not have rights under some patents that may cover the composition of matter, manufacture or use of product candidates that we seek to develop and commercialize, drug targets to which our product candidates bind, or technologies that we use in our research and development activities. As a result, our ability to develop and commercialize our product candidates may depend on our ability to obtain licenses or other rights under such patents. The third parties who own or control such patents may be unwilling to grant those licenses or other rights to us or our collaborators under terms that are commercially viable or at all. We may become involved in proceedings, such as opposition proceedings before the EPO or interference proceedings before the USPTO, challenging the validity or enforceability of such patents owned by third parties, but such proceedings may not be resolved in our favor. Third parties who own or control such patents could bring claims based on patent infringement against us or our collaborators and seek monetary damages and to enjoin further clinical testing, manufacturing and marketing of the affected product candidates or products. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. If a third party commences a patent infringement action against us, or our collaborators, it could consume significant financial and management resources, regardless of the merit of the claims or the outcome of the litigation. If we do not settle and are not successful in defending against any such patent infringement action, we could be required to pay substantial damages or we, or our collaborators, could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is claimed by the third party s patent.

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our collaborators, employees and consultants, and invention assignment agreements with our employees. We also have agreements requiring assignment of inventions with selected consultants and collaborators. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses requiring invention assignment, to grant us ownership of technologies that are developed through a relationship with a third party.

# Competition

We compete in the segments of the pharmaceutical, biotechnology and other related markets that address solid tumor cancers and hematologic cancers. We face significant competition from many pharmaceutical and biotechnology

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companies that are also researching and selling products designed to address these markets. Many of our competitors have materially greater financial, manufacturing, marketing, research and drug development

resources than we do. Large pharmaceutical companies in particular have extensive expertise in preclinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors.

It is possible that our competitors will develop and market drugs or other treatments that are less expensive and more effective than our product candidates, or that will render our product candidates obsolete. It is also possible that our competitors will commercialize competing drugs or treatments before we or our partners can launch any products developed from our product candidates. If approved for marketing by the FDA or other regulatory agencies worldwide, demcizumab or our other product candidates, would compete against existing cancer treatments such as Avastin<sup>®</sup>, Erbitux<sup>®</sup>, Yervoy , chemotherapies and potentially against other novel drug candidates or treatments that are currently in development. Additionally, there are several additional monoclonal antibodies in development for cancer, such as anti-DLL4 antibodies from Regeneron (REGN421, also known as SAR153192 and enoticumab) and MedImmune (MEDI0639), which we believe are both in Phase I development.

In the Notch pathway, several companies, including Merck, Lilly, Pfizer, Roche and others, have attempted to advance small molecule gamma-secretase inhibitors, or GSIs, in clinical development. The advancement of these agents appears to have been complicated with toxicities, particularly gastrointestinal toxicity. While our Notch pathway targeting agents will also likely show signs of toxicity, we believe our approach of selectively modulating the Notch pathway, via highly-targeted antibodies, may offer improved therapeutic index over less-selective small molecule approaches such as GSIs. With respect to the Wnt pathway, we believe that there may be some early stage small molecule programs from other companies. We have limited knowledge as to the status and target specificity of these compounds, but we are not aware of any cancer therapies currently marketed or beyond Phase I development that specifically down-regulate Wnt pathway signaling. We believe our antibodies and protein-based therapeutics targeting the Wnt pathway have the potential to be first-in-class therapies in this pathway and may offer beneficial selectivity profiles.

Established pharmaceutical and biotechnology companies that are known to be involved in oncology research and currently sell or are developing drugs in our markets of interest include Amgen, AbbVie, Astellas, AstraZeneca, Bayer, BMS, Celgene, Genentech (Roche), GSK, Johnson & Johnson, Lilly, Merck, Merck Serono, Novartis, Pfizer, Regeneron, Sanofi, and others. There are also biotechnology companies of various sizes that are developing therapies against CSCs, including Stemline Therapeutics, Inc. and Verastem, Inc., among others. These companies and others also compete with us in recruiting and retaining qualified scientific and management personnel, and in acquiring technologies complementary to, or necessary for, our programs.

# Manufacturing

Our current product candidates are manufactured using specialized biopharmaceutical process techniques. We generally conduct mammalian cell line development and process development in house, and then transfer the production cell line and process to our contract manufacturers for bulk protein production. Our contract manufacturers to date have included Lonza and Bayer. If GSK, Bayer or Celgene exercises their options for the further development of programs under their respective option and license agreements, they would assume manufacturing responsibility for the applicable product candidates. We rely on contract manufacturing organizations to produce other product candidates in accordance with the FDA s current good manufacturing practices, or cGMP, regulations for use in our clinical trials. However, we currently rely on a single source supplier for our requirements of the bulk drug substance of each of our product candidates. The manufacture of drug and biologic products is subject to extensive cGMP regulations, which impose various procedural and documentation requirements and govern all areas of recordkeeping,

production processes and controls, personnel and quality control. We expect to rely on contract manufacturers for the manufacture of clinical and commercial supplies of our compounds other than those product candidates for which GSK, Bayer and/or Celgene have exercised their option.

We purchase quantities of our product candidates from our contract manufacturers pursuant to purchase orders that we place from time to time. If we were unable to obtain sufficient quantities of product candidates or receive raw materials in a timely manner, we could be required to delay our ongoing clinical trials and seek alternative manufacturers, which would be costly and time-consuming. We may consider adding secondary sources for manufacturing in the future.

### **Government Regulation**

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements on the clinical development, manufacture, marketing and distribution of our product candidates. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, and export and import of our product candidates.

In the United States, the FDA regulates drugs, medical devices and biologic products under the Federal Food, Drug, and Cosmetic Act, or FFDCA, its implementing regulations and other laws, including, in the case of biologics, the Public Health Service Act. Our product candidates are subject to regulation by the FDA as biologics. Biologics require the submission of a Biologics License Application, or BLA, and approval by the FDA before being marketed in the United States. None of our product candidates has been approved by the FDA for marketing in the United States, and we currently have no BLAs pending. If we fail to comply with applicable FDA or other requirements at any time during the product development process, clinical testing, the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA s refusal to approve pending applications, license suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any FDA enforcement action could have a material adverse effect on us. The process required by the FDA before our biologic product candidates may be marketed in the United States generally involves the following:

completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies all performed in accordance with the FDA s current good laboratory practice, or cGLP, regulations;

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

performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug candidate for each proposed indication;

submission to the FDA of a BLA;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP regulations; and

FDA review and approval of the BLA prior to any commercial marketing, sale or shipment of the product. The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our drug candidates will be granted on a timely basis, if at all.

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical studies include laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the

clinical trial can begin. Submission of an IND may result in the FDA not allowing the clinical trials to commence or not allowing the clinical trials to commence on the terms originally specified in the IND. A separate submission to an existing IND must also be made for each successive clinical trial conducted during drug development, and the FDA must grant permission, either explicitly or implicitly by not objecting, before each clinical trial can begin.

Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be used. Each protocol must be submitted to the FDA as part of the IND. An independent institutional review board, or IRB, for each medical center proposing to conduct a clinical trial must also review and approve a plan for any clinical trial before it can begin at that center and the IRB must monitor the clinical trial until it is completed. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice, or GCP, requirements, including the requirements for informed consent.

All clinical research performed in the United States in support of a BLA must be authorized in advance by the FDA under the IND regulations and procedures described above. However, a sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA so long as the clinical trial is conducted in compliance with an international guideline for the ethical conduct of clinical research known as the Declaration of Helsinki and/or the laws and regulations of the country or countries in which the clinical trial is performed, whichever provides the greater protection to the participants in the clinical trial. We are conducting our demcizumab (OMP-21M18) Phase Ib clinical trials in Australia, New Zealand and Europe, our demcizumab Phase Ib/II trial in the United States, and our demcizumab Phase II trials in the United States, Europe, Australia and, for one Phase II trial, Canada. We may include clinical trial centers in the United States, Canada, Australia and Europe in any other Phase II clinical trials that we may initiate for demcizumab in the future. We designed our clinical trials to comply with FDA regulatory requirements for the use of foreign clinical data in support of a BLA, and we intend to utilize data from these demcizumab Phase Ib and Phase II clinical trials in support of our future U.S. and worldwide development and potential commercialization. We may pursue similar development strategies for our other product candidates. Presently, for our other clinical stage candidates, we are utilizing clinical research sites in the United States. We plan to include the United States, Europe and other territories in our later-stage clinical development program for our product candidates we develop independently prior to filing for a BLA with the FDA, or comparable applications with the European Medicines Agency, or EMA, and other relevant regulatory agencies in global markets.

# **Clinical Trials**

For purposes of BLA submission and approval, clinical trials are typically conducted in three sequential phases, which may overlap or be combined.

Phase I clinical trials are initially conducted in a limited population of subjects to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients with severe problems or life-threatening diseases to gain an early indication of its effectiveness.

Phase II clinical trials are generally conducted in a limited patient population to: evaluate preliminarily the efficacy of the product candidate for specific targeted indications in patients with the disease or condition under study; evaluate dosage tolerance and appropriate dosage; and identify possible adverse effects and safety risks.

Phase III clinical trials are commonly definitive efficacy studies of the experimental medication. Phase III trials are typically conducted when Phase II clinical trials demonstrate that a dose range of the

product candidate is effective and has an acceptable safety profile. Phase III clinical trials are generally undertaken with large numbers of patients, such as groups of several hundred to several thousand, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded patient population at multiple, geographically-dispersed clinical trial sites.

In some cases, the FDA may condition approval of a BLA on the sponsor s agreement to conduct additional clinical trials to further assess the biologic s safety and effectiveness after BLA approval. Such post-approval clinical trials are typically referred to as Phase IV clinical trials.

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

### **Biologics License Applications**

The results of preclinical studies and of the clinical trials, together with other detailed information, including extensive manufacturing information and information on the composition of the biologic, are submitted to the FDA in the form of a BLA requesting approval to market the biologic for one or more specified indications. The FDA reviews a BLA to determine, among other things, whether a biologic is safe and effective for its intended use.

Once a BLA has been accepted for filing, by law the FDA has 180 days to review the application and respond to the applicant. However, the review process is often significantly extended by FDA requests for additional information or clarification. Under the Prescription Drug User Fee Act, the FDA has a goal of responding to BLAs within ten months of the filing date, but this timeframe is often extended. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The FDA may deny approval of a BLA if the applicable statutory and regulatory criteria are not satisfied, or it may require additional clinical data or an additional Phase III clinical trial. Even if such data are submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret data. Once the FDA approves a BLA, or supplement thereto, the FDA may withdraw the approval if ongoing regulatory requirements are not met or if safety problems are identified after the biologic reaches the market. Where a withdrawal may not be appropriate, the FDA still may seize existing inventory of such biologic or require a recall of any biologic already on the market. In addition, the FDA may require testing, including Phase IV clinical trials and surveillance programs to monitor the effect of approved biologics which have been commercialized. The FDA has the authority to prevent or limit further marketing of a biologic based on the results of these post-marketing programs.

A sponsor may also seek approval of its product candidates under programs designed to accelerate FDA review and approval of BLAs. For instance, a sponsor may seek FDA designation of a product candidate as a fast track product. Fast track products are those products intended for the treatment of a serious or life-threatening disease or condition and which demonstrate the potential to address unmet medical needs for such diseases or conditions. If fast track designation is obtained, the FDA may initiate review of sections of a BLA before the application is complete. This

rolling review is available if the applicant provides and the FDA approves a schedule for the remaining information. In some cases, a fast track product may be approved on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint

that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments, under the FDA s accelerated approval program. Approvals of this kind typically include requirements for appropriate post-approval Phase IV clinical trials to validate the surrogate endpoint or otherwise confirm the effect of the clinical endpoint. In addition, the Food and Drug Administration Safety and Innovation Act, or FDASIA, which was enacted and signed into law in 2012, established a new category of drugs referred to as breakthrough therapies that may be subject to accelerated approval. A sponsor may seek FDA designation of a drug candidate as a breakthrough therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation provides all of the features of fast track designation in addition to intensive guidance on an efficient drug development program beginning as early as Phase I, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate. Product candidates may also be eligible for priority review, or review within a six month timeframe from the date a complete BLA is accepted for filing, if a sponsor shows that its product candidate provides a significant improvement compared to marketed products. When appropriate, we intend to seek fast track designation and/or accelerated approval for our biologics. We cannot predict whether any of our product candidates will obtain a fast track and/or accelerated approval designation, or the ultimate impact, if any, of the fast track or the accelerated approval process on the timing or likelihood of FDA approval of any of our proposed biologics.

Biologics may be marketed only for the FDA approved indications and in accordance with the provisions of the approved labeling. Further, if there are any modifications to the biologic, including changes in indications, labeling, or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require us to develop additional data or conduct additional preclinical studies and clinical trials.

Before approving an application, the FDA will inspect the facility or the facilities at which the biologic product is manufactured, and will not approve the product unless cGMP compliance is satisfactory. The FDA may also inspect the sites at which the clinical trials were conducted to assess their compliance, and will not approve the biologic unless compliance with GCP requirements is satisfactory.

The testing and approval processes require substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all. Even if we believe a clinical trial has demonstrated safety and efficacy of one of our product candidates for the treatment of a disease, the results may not be satisfactory to the FDA. Preclinical and clinical data may be interpreted by the FDA in different ways, which could delay, limit or prevent regulatory approval. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals which could delay or preclude us from marketing our product candidates. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the products. After approval, certain changes to the approved biologic, such as adding new indications, manufacturing changes or additional labeling claims, are subject to further FDA review and approval. Depending on the nature of the change proposed, a BLA supplement must be filed and approved before the change may be implemented. For many proposed post-approval changes to a BLA, the FDA has up to 180 days to review the application. As with new BLAs, the review process is often significantly extended by the FDA requests for additional information or clarification.

We believe that any of our products approved as a biological product under a BLA should qualify for a 12-year period of non-patent exclusivity currently permitted by the BPCIA. Specifically, the BPCIA established an abbreviated pathway for the approval of biosimilar biologics, including the possible designation of a biosimilar as interchangeable, based on their similarity to existing brand products. Under the BPCIA, an application for a

biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. There is a risk that, as proposed by President Obama, the U.S. Congress could amend the BPCIA to significantly shorten this exclusivity period or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. The BPCIA is complex and is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes that operate to limit the scope or length of exclusivity afforded by the BPCIA could have a material adverse effect on the future commercial prospects for our biological products. In addition, foreign regulatory authorities may also provide for exclusivity periods for approved biological products. For example, biological products in Europe may be eligible for a 10-year period of exclusivity.

## **Other Regulatory Requirements**

Any biologics manufactured or distributed by us or our collaborators pursuant to FDA approvals would be subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences associated with the product. Manufacturers and their subcontractors 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 ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a drug from distribution or withdraw approval of the BLA for that product.

The FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe legally available biologics for uses that are not described in the product s labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers communications regarding off-label use.

# **Regulation of Diagnostic Tests**

In the United States, the FFDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Diagnostic tests are classified as medical devices under the FFDCA. Unless an exemption or FDA exercise of enforcement discretion applies, diagnostic tests generally require marketing clearance or approval from the FDA prior to commercialization. The two primary types of FDA

marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval.

To obtain 510(k) clearance for a medical device, or for certain modifications to devices that have received 510(k)clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or to a preamendment device that was in commercial distribution before May 28, 1976, or a predicate device, for which the FDA has not yet called for the submission of a PMA. In making a determination that the device is substantially equivalent to a predicate device, the FDA compares the proposed device to the predicate device or predicate devices and assesses whether the subject device is comparable to the predicate device or predicate devices with respect to intended use, technology, design and other features which could affect safety and effectiveness. If the FDA determines that the subject device is substantially equivalent to the predicate device or predicate devices, the subject device may be cleared for marketing. The 510(k) premarket notification pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer. In response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) regulatory pathway, the FDA initiated an evaluation of the program, and in January 2011 announced several proposed actions to reform the review process governing medical device clearance. In addition, as part of FDASIA, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several Medical Device Regulatory Improvements and miscellaneous reforms which are further intended to clarify and improve medical device regulation both pre- and post-clearance and approval. We anticipate that the changes may also result in additional requirements with which manufacturers will need to comply in order to obtain or maintain 510(k) clearance for their devices. These additional requirements could increase the cost or time for manufacturers seeking marketing clearances through the 510(k) process.

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA s satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. The FDA s review of an initial PMA application is required by statute to take between six to ten months, although the process typically takes longer, and may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA is evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny the approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

On July 31, 2014, the FDA issued a final guidance document addressing the development and approval process for In Vitro Companion Diagnostic Devices. According to the guidance document, for novel therapeutic products that depend on the use of a diagnostic test and where the diagnostic device could be essential for the safe and effective use of the corresponding therapeutic product, the premarket application for the companion diagnostic device should be developed and approved or cleared contemporaneously with the therapeutic, although the FDA recognizes that there may be cases when contemporaneous development may not be possible. However, in cases where a drug cannot be used safely or effectively without the companion diagnostic, the FDA s guidance indicates it will generally not approve the drug without the approval or clearance of the diagnostic device.

# Healthcare Reform

In March 2010, the President signed one of the most significant healthcare reform measures in decades. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act,

collectively known as the Affordable Care Act, substantially changes the way healthcare will be financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The comprehensive \$940 billion dollar overhaul is expected to extend coverage to approximately 32 million previously uninsured Americans. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse, which will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. Additionally, the Affordable Care Act:

increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;

extends the rebate program to individuals enrolled in Medicaid managed care organizations;

addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

expands the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer s Medicaid rebate liability;

expands access to commercial health insurance coverage through new state-based health insurance marketplaces, or exchanges;

requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D; and

imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell branded prescription drugs to specified federal government programs.

The Affordable Care Act also establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. Beginning in 2014, IPAB is mandated to propose changes in Medicare payments if it is determined that the rate of growth of Medicare expenditures exceeds target growth rates. The IPAB has broad discretion to propose policies to reduce expenditures, which may have a negative impact on payment rates for services, including imaging services. A proposal made by the IPAB is required to be implemented by the U.S. government s Centers for Medicare & Medicaid Services unless Congress adopts a proposal with savings greater than those proposed by the IPAB. IPAB proposals may impact payments for physician and free-standing services beginning in 2015 and for hospital services beginning in 2020.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation s automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The full impact on our business of the Affordable Care Act and other new laws is uncertain. Nor is it clear whether other legislative changes will be adopted, if any, or how such changes would affect the demand for our drugs once commercialized.

#### Third-Party Payor Coverage and Reimbursement

Although none of our drug candidates has been commercialized for any indication, if they are approved for marketing, commercial success of our drug candidates will depend, in part, upon the availability of coverage and reimbursement from third-party payors at the federal, state and private levels. Government payor programs, including Medicare and Medicaid, private health care insurance companies and managed-care plans have attempted to control costs by limiting coverage and the amount of reimbursement for particular procedures or drug treatments. The U.S. Congress and state legislatures from time to time propose and adopt initiatives aimed at cost-containment. Ongoing federal and state government initiatives directed at lowering the total cost of health care will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid payment systems. Examples of how limits on drug coverage and reimbursement in the United States may cause reduced payments for drugs in the future include:

changing Medicare reimbursement methodologies;

fluctuating decisions on which drugs to include in formularies;

revising drug rebate calculations under the Medicaid program; and

#### reforming drug importation laws.

Some third-party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care providers who use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our drug candidates and operate profitably.

#### Other Healthcare Laws and Regulations

We are also subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. The laws that may affect our ability to operate include:

the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers. Further, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. In addition, the Affordable Care Act

provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Affordable Care Act, among other things, imposes new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (or up to an aggregate of \$1 million per year for knowing failures ), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers are required to submit reports to the government by the 90<sup>th</sup> day of each calendar year. Certain states also mandate implementation of commercial compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and impact our financial results.

# International 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 future drugs. Whether or not we obtain FDA approval for a drug, we must obtain approval of a drug by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the drug in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or mutual recognition procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

In addition to regulations in Europe and the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial distribution of our future drugs.

# Employees

As of December 31, 2014, we had 108 employees, 40 of whom hold Ph.D.s, M.D.s, D.V.M.s, Pharm.D.s or multiple advanced degrees. Of our total workforce, 87 employees are engaged in research and development, and 21 employees are engaged in business development, finance, legal, human resources, facilities, information technology administration and general management. We have no collective bargaining agreements with our employees, and we have not experienced any work stoppages. We believe that our relations with our employees are good.

# **Research and Development**

Our research and development costs were \$76.4 million, \$50.0 million and \$39.9 million for the years ended December 31, 2014, 2013 and 2012, respectively. See Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations for additional detail regarding our research and development activities, which are funded in part through payments received from our collaborators GSK, Bayer and Celgene.

# **Customer Concentration and Geographic Information**

All or a significant portion of our revenues for the fiscal years ended December 31, 2014, 2013 and 2012 were derived from GSK, Bayer, and Celgene. GSK and Bayer are located outside of the United States, in the United Kingdom and Germany, respectively. See Notes 2 and 10 to our audited financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

All of our revenues for the years ended December 31, 2014, 2013, and 2012 were earned in the United States. All of our long-lived assets are located in the United States.

# About OncoMed

We commenced operations in 2004 and are a Delaware corporation. Our principal offices are located at 800 Chesapeake Drive, Redwood City, California 94063, and our telephone number is (650) 995-8200. Our website address is www.oncomed.com. The information contained in, or that can be accessed through, our website is not part of this Annual Report on Form 10-K.

#### **Financial Information about Segments**

We operate only in one business segment. See Note 1 to our financial statements included in this Annual Report on Form 10-K. For financial information regarding our business, see Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes.

# **Available Information**

We file electronically with the Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. We make available on our website at www.oncomed.com, free of charge, copies of these reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The public may read or copy any materials we file with the SEC at the SEC s Public Reference Room at 100 F Street NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is www.sec.gov. The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

#### Item 1A. RISK FACTORS

The following section includes the most significant factors that may adversely affect our business and operations. You should carefully consider the risks and uncertainties described below and all information contained in this Annual Report on Form 10-K before deciding to invest in our common stock. If any of the following risks actually occur, our business, financial condition, results of operations and growth prospects may be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose all or part of your investment.

#### **Risks Related to Our Business**

# We anticipate that we will continue to incur significant losses for the foreseeable future, and if we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

We are a clinical development-stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We do not currently have any product candidates in pivotal clinical trials or approved for sale, and we continue to incur significant research and development and general and administrative expenses related to our operations. We are not profitable and have incurred losses in each year since our founding in 2004. Our net losses for the years ended December 31, 2014, 2013 and 2012 were \$50.0 million, \$26.1 million and \$22.2 million, respectively. As of December 31, 2014, we had an accumulated deficit of \$224.4 million.

We expect to continue to incur significant losses for the foreseeable future. We expect these losses and our cash utilization to increase in the near term as we continue to conduct clinical trials for demcizumab (OMP-21M18, anti-DLL4), tarextumab (OMP-59R5, anti-Notch2/3), vantictumab (OMP-18R5, anti-Fzd7), ipafricept (OMP-54F28, Fzd8-Fc), brontictuzumab (anti-Notch1, OMP-52M51) and anti-DLL4/VEGF bispecific (OMP-305B83), file additional Investigational New Drug, or IND, filings for additional product candidates such as anti-RSPO3 (OMP-131R10), and conduct research and development of our other product candidates. We are collaborating with GlaxoSmithKline LLC (formerly SmithKline Beecham Corporation), or GSK, to develop certain therapeutic antibody product candidates targeting the Notch signaling pathway, namely tarextumab and brontictuzumab. We are collaborating with Bayer Pharma AG (formerly Bayer Schering Pharma AG), or Bayer, to develop biologic and small molecule therapeutic product candidates targeting the Wnt signaling pathway, including vantictumab and ipafricept. We are also collaborating with Celgene Corporation, or Celgene, to discover, develop and commercialize certain anti-CSC biologic product candidates, including demcizumab, anti-DLL4/VEGF bispecific and anti-RSPO3, and, if Celgene exercises its option to do so, to discover and develop small molecule anti-CSC therapeutics targeting an undisclosed pathway. Under these agreements, GSK, Bayer, and Celgene have certain options to obtain exclusive licenses for the development and commercialization of the product candidates being developed in the collaboration. If either GSK or Bayer exercises its option to obtain a license to develop and commercialize such product candidates, GSK or Bayer, as applicable, will assume responsibility for funding obligations with respect to further clinical development and commercialization of such product candidates. If Celgene exercises its option to obtain a license to develop and commercialize biologic product candidates for a program under its agreement with us, then, on a program by program basis, unless we elect not to co-develop and co-commercialize the product candidates for the applicable program in the United States, or if such program is the one program targeting either the RSPO-LGR pathway or the undisclosed pathway to which we have no co-development and co-commercialization rights, we will be responsible for a one-third share of the global development costs of product candidates for such program, with Celgene bearing the remaining two-thirds of such costs, and we will be entitled to participate in the commercialization activities for product candidates for such program in the United States, and to share 50% of all profits and losses arising from U.S sales of such product candidates. If we elect not to co-develop and co-commercialize the product candidates for a program, or the program is the one program to which we do not have co-development and co-commercialization rights, then Celgene will generally assume responsibility for funding

obligations with respect to clinical development and commercialization of product candidate for such program after option exercise, with the exception of certain costs for certain continuing clinical trials for which we were responsible prior to option exercise. Also, if Celgene exercises its option to obtain a license to discover, develop and commercialize small

molecule product candidates, we will collaborate with Celgene on the discovery of and research on small molecule therapeutics, but Celgene will be solely responsible for development and commercialization of such therapeutics. However, if GSK, Bayer, or Celgene do not exercise their options, or if our collaborations with our strategic partners terminate, we will be responsible for funding further development of the relevant product candidates unless we enter into another collaboration for such product candidates.

All of our product candidates are in development, and none has been approved for sale. To date, we have derived all of our revenues from upfront payments, milestone payments and other payments we received under our collaborations with GSK, Bayer and Celgene, and have also supported our research and development efforts by utilizing certain government grants for research and development. We do not anticipate that we will generate revenue from the sale of our product candidates for the foreseeable future. If any of our product candidates receive regulatory approval, we may incur significant costs to commercialize our product candidates. Even after obtaining such regulatory approval, our products may never gain sufficient market acceptance and adequate market share. If our product candidates fail to demonstrate safety and efficacy in clinical trials, do not gain regulatory approval, or do not achieve market acceptance following regulatory approval and commercialization, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline. Because of the numerous risks and uncertainties associated with developing biopharmaceutical products, we are unable to predict the extent of any future losses or whether we will become profitable.

We are heavily dependent on the success of our most advanced product candidates which are in various stages of clinical development. All of our product candidates are still in preclinical or clinical development. If we are unable to commercialize our product candidates or if we experience significant delays in obtaining regulatory approval for, or commercializing, any or all of our product candidates, our business will be materially and adversely affected.

We have invested a significant portion of our efforts and financial resources in the development of our most advanced product candidates that are in clinical development, including demcizumab (OMP-21M18, anti-DLL4), tarextumab (OMP-59R5, anti-Notch2/3), brontictuzumab (anti-Notch1, OMP-52M51), vantictumab (OMP-18R5, anti-Fzd7), ipafricept (OMP-54F28, Fzd8-Fc), and anti-DLL4/VEGF bispecific (OMP-305B83), for the treatment of various types of cancer.

All of our product candidates are still in preclinical and clinical development. Our ability to generate product revenues will depend heavily on our ability to successfully develop and commercialize these product candidates. We do not expect that such commercialization of any of our product candidates will occur for at least the next several years, if ever. Our ability to commercialize our product candidates effectively will depend on several factors, including the following:

successful completion of preclinical studies and clinical trials, including the ability to demonstrate safety and efficacy of our product candidates;

receipt of marketing approvals from the U.S. Food and Drug Administration, or FDA, and similar regulatory authorities outside the United States;

establishing commercial manufacturing capabilities, for example, by making arrangements with third-party manufacturers;

successfully launching commercial sales of the product, whether alone or in collaboration with others;

acceptance of the product by patients, the medical community and third-party payors;

establishing market share while competing with other therapies;

a continued acceptable safety and adverse event profile of our products following regulatory approval; and

qualifying for, identifying, registering, maintaining, enforcing and defending intellectual property rights and claims covering our product candidates.

If we, or our collaborators, do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to commercialize our product candidates, which would materially and adversely affect our business, financial condition and results of operations.

## We depend on the successful development of our programs and product candidates. The development of new drugs and biologics is a highly risky undertaking, which involves a lengthy process, and the results of preclinical and early clinical trials are not necessarily predictive of future results. Our product discovery and development activities therefore may not be successful on the time schedule we have planned, or at all.

Our programs and product candidates are in the early stages of drug discovery or clinical trials and are subject to the risks of failure inherent in drug development. As of the date of this Annual Report on Form 10-K, six of our current product candidates, demcizumab (OMP-21M18, anti-DLL4), tarextumab (OMP-59R5, anti-Notch2/3), brontictuzumab (anti-Notch1, OMP-52M51), vantictumab (OMP-18R5, anti-Fzd7), ipafricept (OMP-54F28, Fzd8-Fc) and anti-DLL4/VEGF bispecific (OMP-305B83), have been tested in cancer patients. We will need to conduct significant additional preclinical studies and/or clinical trials before we can demonstrate that any of our product candidates is safe and effective to the satisfaction of the FDA and other regulatory authorities. Preclinical studies and clinical trials are expensive and uncertain processes that may take years to complete. For example, we incurred significant expenses related to the clinical development of demcizumab, one of our most advanced product candidates. Demcizumab advanced into Phase II clinical trials in early 2015 despite having entered Phase Ia in 2008. The delay of entry into Phase II trials is attributable to the occurrence of cardiopulmonary events in the Phase I trials, including hypertension, which required the administration of one or more anti-hypertensive medications. Further, in certain patients in the Phase Ia and Phase Ib trials for demcizumab, pulmonary hypertension and/or heart failure were seen, particularly in patients who were treated with demcizumab for prolonged periods of time (more than 100 days). These events were considered treatment-related, resulted in demcizumab being placed on partial clinical hold, meaning that patients on study could continue to receive treatment, but new patients could not be started on study, in our Phase Ia trial in the United States. We believe that the cardiopulmonary toxicity of demcizumab is reversible upon cessation of dosing, and we implemented a risk mitigation plan involving intermittent and truncated dosing of demcizumab, cardiac monitoring, and early intervention with cardioprotective medication, if indicated, in our Phase Ib trials to enhance the therapeutic index of demcizumab by maximizing efficacy and managing tolerability. Following our submission of a data package to the FDA including data from the Phase Ib trials, the FDA notified us in December 2012 that demcizumab was no longer on partial clinical hold in the United States, and a Phase Ib/II trial of demcizumab in combination with paclitaxel in platinum-resistant ovarian cancer patients was initiated in September 2013 at M.D. Anderson Cancer Center, or MDACC, and enrollment was completed in the Phase Ib trials in pancreatic cancer and non-small cell lung cancer. We initiated and began enrolling patients in a Phase II trial of demcizumab in combination with carboplatin and pemetrexed in non-small cell lung cancer in early 2015 and also intend to begin enrollment in a Phase II trial of demcizumab in combination with gemcitabine plus Abraxane<sup>®</sup> in pancreatic cancer in 2015.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational biologic. A number of companies in the biotechnology industry, including those with greater resources and experience than us, have suffered significant setbacks in Phase III clinical trials, despite promising results in earlier clinical trials. We do not know whether any Phase II, Phase III or other clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates. If later stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted.

Delays in the commencement or completion of clinical testing could significantly affect our product development costs. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

obtaining regulatory authorization to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;

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

manufacturing, including manufacturing sufficient quantities of a product candidate or other materials for use in clinical trials;

obtaining IRB approval or the approval of other reviewing entities to conduct a clinical trial at a prospective site;

recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including size of patient population, complexity of clinical trial protocol, the availability of approved effective treatments for the relevant disease, changed standards of care during the conduct of the trial, and competition from other clinical trial programs for similar indications;

severe or unexpected drug-related adverse effects experienced by patients in a clinical trial; and

retaining patients who have initiated a clinical trial, but may withdraw due to treatment protocol, adverse effects from the therapy, lack of efficacy from the treatment, personal issues or who are lost to further follow-up.

Clinical trials may also be delayed, suspended or terminated as a result of ambiguous or negative interim results, or results that are inconsistent with earlier results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRB or other reviewing entity overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or other regulatory authorities due to a number of factors, including:

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks; and

lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials and increased expenses associated with the services of our CROs and other third parties.

Product development costs to us and our collaborators will increase if we have delays in testing or approval of our product candidates or if we need to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur in any jurisdiction and we may need to amend clinical trial protocols to address these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, the IRB or other reviewing entities, or any of our clinical trial sites suspend or terminate any of our clinical trials, the commercial prospects for our product candidates may be harmed and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Also, if one or more clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced.

# If we are required to suspend or discontinue clinical trials due to side effects or other safety risks, or if we are required to conduct studies on the long-term effects associated with the use of our product candidates, our ability to commercialize our product candidates could be adversely affected or delayed.

Our clinical trials may be suspended, delayed, or terminated at any time for a number of safety-related reasons. For example, we may voluntarily suspend, delay, or terminate our clinical trials if at any time we believe that our product candidates present an unacceptable safety risk to the clinical trial patients. In addition, IRBs or regulatory agencies may order the temporary discontinuation or termination of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, including if they present an unacceptable safety risk to patients. Administering any product candidate to humans may produce undesirable side effects. The existence of undesirable side effects resulting from our product candidates could cause us or regulatory authorities, such as the FDA, to interrupt, delay or halt clinical trials of our product candidates for any or all targeted indications. This, in turn, could affect whether GSK, Bayer and/or Celgene exercise their development options under our strategic collaborations and could prevent us from commercializing our product candidates. Further, our programs modulate novel classes of targets. As a result, we may experience unforeseen adverse side effects with our existing and future product candidates, including demcizumab (anti-DLL4, OMP-21M18).

The pharmacokinetic, pharmacodynamic, and safety profile of preclinical studies may not be indicative of results in any clinical trial. As of the date of this Annual Report on Form 10-K, six of our current product candidates have been tested in cancer patients. We have observed adverse events in clinical trials for all our product candidates. We currently believe these adverse events are manageable. Nevertheless, such adverse events may cause challenges in development, approval and/or commercialization.

For example, following the occurrence of certain bone-related adverse events, we voluntarily halted enrollment and dosing in our ongoing Phase I clinical trials of our vantictumab (OMP-18R5, anti-Fzd7) and ipafricept (OMP-54F28, Fzd8-Fc) programs until revised protocols and risk mitigation plans could be submitted to and concurred with by the FDA and the study sites IRBs. In view of our voluntary halting of these programs, the FDA subsequently placed these programs on partial clinical hold. After review of our revised protocols and risk mitigation plans, the FDA removed its partial clinical holds on our vantictumab and ipafricept programs in August 2014 and September 2014, respectively. Failure can occur at any stage of the drug development process, and we cannot assure you that vantictumab, ipafricept or any of our product candidates will reach the point where they are able to be successfully commercialized.

The toxicity profile of demcizumab has been shown to include cardiopulmonary events, including hypertension that was generally manageable. In certain patients treated with demcizumab, reversible pulmonary hypertension and/or heart failure have been observed, resulting in the implementation of a risk mitigation strategy including limiting the intermittent and truncated dosing of demcizumab, cardiac monitoring, and early intervention with cardioprotective medication, if indicated. The most common treatment-related adverse events experienced by patients treated in our Phase Ib trials for demcizumab include fatigue, vomiting, hypertension and nausea. The most common treatment-related adverse events experienced by patients treated with tarextumab (OMP-59R5, anti-Notch2/3) include diarrhea, fatigue, decreased appetite, anemia, nausea, hypokalemia, and vomiting. The most common treatment-related adverse events experienced by patients treated with brontictuzumab (anti-Notch1, OMP-52M51) include diarrhea, nausea, fatigue and vomiting. The toxicity profile of vantictumab has been shown to include certain bone effects, including mild to moderate grade bone adverse events, resulting in the implementation of a bone risk mitigation plan involving monitoring, prophylactic supplements and administration of zoledronic acid, if indicated, in our vantictumab include fatigue and nausea. The most common treatment-related adverse events experienced by patients treated with vantictumab include fatigue and nausea. The most common treatment-related adverse events experienced by patients treated with vantictumab include fatigue and nausea. The most common treatment-related adverse events experienced by patients treated with vantictumab include fatigue and nausea. The most common treatment-related adverse events experienced by patients treated with vantictumab include fatigue and nausea. The most common treatment-related adverse events experienced by patients treated with vantictumab include fatigue and nausea. The most common treatment-

taste sensation). The toxicity profile of ipafricept has also been shown to include certain bone effects, including mild to moderate grade bone adverse events, and a bone risk mitigation plan that involves monitoring, prophylactic supplements and

administration of zoledronic acid, if indicated, has been implemented in our ipafricept trials. In addition, treatment-related adverse events have also been experienced by patients treated with anti-DLL4/VEGF bispecific (OMP-305B83) in the Phase Ia clinical trial initiated at the end of 2014.

Further treatment of patients in the ongoing trials or subsequent trials of any of our product candidates could reveal significant harmful side effects. We have not conducted complete studies on the long-term effects associated with the use of all of our product candidates. Studies of these long-term effects may be required for regulatory approval and such requirement would delay our introduction of our product candidates, including those under our collaborations with GSK, Bayer, and/or Celgene into the market. These studies could also be required at any time after regulatory approval of any of our product candidates. Absence of long-term data may also limit the approved uses of our products, if any, to short-term use. Some or all of our product candidates may prove to be unsafe for human use, which would materially harm our business.

The successful development and commercialization of our independent programs, any product candidate over which GSK, Bayer, or Celgene declines to exercise an option, for which we do not obtain anticipated research or development milestone payments prior to a decision by GSK, Bayer, or Celgene to exercise such option, or which we choose to co-develop and co-commercialize with Celgene after option exercise, will depend in large part on our ability either to raise capital to advance development of those programs or to secure collaborations with strategic partners that have the capital and expertise to bring products to market. We may be unable to secure such funds and/or secure such future collaborations.

If GSK, Bayer, or Celgene declines to exercise its options with respect to one or more product candidates covered by its collaboration agreement, or terminates its collaboration agreement with us, we will need to secure funding to advance development of those programs on our own and/or secure relationships with collaborators that have the necessary capital and expertise. In addition, if we are unable to achieve or are delayed in achieving anticipated research or development milestones, and unable to obtain or are delayed in obtaining the applicable milestone payments, for any product candidate under our collaboration agreements with GSK, Bayer, and Celgene, we are likely to need additional funding to advance such product candidate prior to our achievement of such research or development milestones or our partners decisions regarding option exercise with respect to such product candidate if development of that program is not discontinued. In addition, if Celgene exercises its option to any of the programs to which we have co-development and co-commercialization rights, and we retain our option to co-develop and co-commercialize that program, then, despite having certain mechanisms in place in our collaboration agreement with Celgene to control expenses, we may need to secure additional funding to support our obligations to pay one-third of global development costs for such program. We may also choose to advance our product candidates and programs that are not part of the GSK, Bayer, or Celgene collaborations independently without partnering such product candidates and programs, which will require substantial funds. If any of our independent product candidates receive regulatory approval and are commercialized, substantial expenditures will also be required. As of December 31, 2014, we had \$232.0 million in cash, cash equivalents and short-term investments. We believe that our available cash, cash equivalents and short-term investments will be sufficient to fund our anticipated level of operations at least through 2016, even without taking into account potential future milestone payments to us. Our future financing requirements will depend on many factors, some of which are beyond our control, including:

the rate of progress and cost of our clinical trials, preclinical studies and other discovery and research and development activities;

the timing of, and costs involved in, seeking and obtaining FDA and other regulatory approvals;

the continuation and success of our strategic alliances with GSK, Bayer and Celgene and future collaboration partners, including the exercise or non-exercise of further development options by GSK, Bayer and/or Celgene under their respective agreements;

the costs of preparing, filing, prosecuting, maintaining and enforcing any patent claims and other intellectual property rights, including litigation costs and the results of such litigation;

our ability to enter into additional collaboration, licensing, government or other arrangements and the terms and timing of such arrangements;

the potential need to acquire, by acquisition or in-licensing, other products or technologies; and

the emergence of competing technologies or other adverse market developments. Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies. We currently have no understandings, commitments or agreements relating to any of these types of transactions.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings, a credit facility, government grants and contracts and/or strategic collaborations. Additional financing may not be available to us when we need it or it may not be available to us on favorable terms, if at all. Additionally, to the extent that we seek a new strategic partner to develop any of our programs, we may not be able to secure a collaboration on favorable terms, if at all. A collaboration may not provide sufficient funding or value to bring a product to market, and further funding and/or collaborations may be required. The terms of any such collaboration may also significantly limit our share of potential future profits from the associated program, may require us to relinquish potentially valuable rights to our current product candidates, potential products or proprietary technologies, or may grant licenses on terms that are not favorable to us. If we are unable to obtain adequate financing or form favorable collaborations, when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or our commercialization efforts.

# If GSK, Bayer, and/or Celgene do not exercise their options or if they terminate any development program under their collaborations with us, whether as a result of our inability to meet milestones or otherwise, any potential revenue from those collaborations will be significantly reduced or non-existent, and our results of operations and financial condition will be materially and adversely affected.

Since our founding, we have invested a significant portion of our time and financial resources in the development of multiple product candidates that are now included in our Bayer, GSK, and Celgene collaborations. The programs included in our GSK collaboration include tarextumab (OMP-59R5, anti-Notch2/3) and brontictuzumab (anti-Notch1, OMP-52M51). The programs included in our Bayer collaboration include vantictumab (OMP-18R5, anti-Fzd7) and ipafricept (OMP-54F28, Fzd8-Fc), plus additional biologic and small molecule programs. The programs included in our Celgene collaboration include demcizumab (OMP-21M18, anti-DLL4), anti-DLL4/VEGF bispecific (OMP-305B83), and anti-RSPO3 (OMP-131R10), plus additional biologic and small molecule programs. Our ability to continue to advance these programs in development prior to option exercise by GSK, Bayer or Celgene is highly dependent on achieving certain development milestones in these programs and triggering related milestone fee payments to us.

Under our collaboration with GSK, during certain time periods through completion of proof-of-concept trials, or in the case of one scenario, with respect to the brontictuzumab program, during certain time periods through completion of Phase I trials, GSK is entitled to exercise an option to obtain an exclusive license for further development and commercialization of the applicable product candidate on a worldwide basis. GSK may decide not to exercise its option for tarextumab and/or brontictuzumab at all, or may decide, under the scenario where GSK is entitled to exercise its option on brontictuzumab during certain time periods through completion of Phase I trials, to delay exercise of that option until completion of proof-of-concept trials.

Under the agreement with GSK, we are eligible to receive from GSK, (1) with respect to tarextumab, aggregate payments of up to \$344.5 million, including an option exercise fee and development, regulatory and commercialization milestones, in addition to percentage royalties in the low double digits to high teens on net product sales, and (2) with respect to brontictuzumab, aggregate payments of up to \$349.5 million, including an option exercise fee and development, regulatory and commercialization milestones, in addition to percentage to \$349.5 million, including an option exercise fee and development, regulatory and commercialization milestones, in addition to percentage

royalties in the low double digits to high teens on net product sales. We have received milestone payments related to these programs to date. However, there is no guarantee that we will be able to successfully continue to advance programs and receive milestone payments related to tarextumab or brontictuzumab on our anticipated timelines or at all. Even if we successfully advance these product candidates through Phase II proof-of-concept trials, GSK is under no obligation to exercise its option to progress either tarextumab or brontictuzumab development, and even if one or both of these product candidates are progressed, there is no guarantee that either product candidate will achieve the relevant regulatory filing or approval milestones. Further, in the event that GSK is required to obtain Hart-Scott-Rodino, or HSR, clearance after exercising any of its options, and such clearance is not obtained, GSK will not participate in further development of these product candidates and the product rights would revert to us. We would then have worldwide rights to those assets and be responsible for funding the development of the assets.

GSK may terminate the entire collaboration agreement or any collaboration program on a program-by-program basis for any or no reason upon written notice to us after expiration of a defined notice period. The agreement or any program under the agreement may also be terminated by either party for material breach by the other party that remains uncured after a specified notice period. The agreement may also be terminated by either party for insolvency of the other party, or by us if GSK challenges the licensed patents. Depending on the timing of any such termination we may not be entitled to receive the option exercise fees, or potential milestone payments, as these payments terminate with termination of the agreement.

There are similar provisions in our Bayer Wnt pathway agreement. In this collaboration, Bayer has the option to obtain an exclusive license to Wnt pathway biologic product candidates within defined classes at any point up through the completion of certain Phase I trials. Bayer may decide not to exercise its options.

As our product candidates targeting the Wnt pathway advance, we would be entitled to receive, per product candidate, (1) an aggregate of up to \$387.5 million for each biologics program in development, regulatory, and commercial milestones and option fees, plus royalties on net product sales, and (2) for each small molecule product candidate, up to \$112.0 million in the aggregate for development, regulatory, and commercial milestones and advancement fees, plus single-digit percentage royalties on net product sales. Percentage royalties for certain biologic product candidates are in the low double digits to high teens. For certain other biologic product candidates, percentage royalties are in the mid-single digits to low double digits. We have received milestone payments related to the biologic programs to date. However, there is no guarantee that we will be able to successfully continue to advance programs and receive milestone payments related to vantictumab, ipafricept or any other Wnt pathway product candidates on our anticipated timelines or at all. Even if we are able to successfully complete Phase I trials with vantictumab, ipafricept or our other Wnt pathway product candidates, Bayer is under no obligation to exercise its option to obtain an exclusive license to develop and commercialize any such product candidate, and there is no guarantee that any such product candidate will achieve the relevant further development, regulatory filing or approval, or commercial milestones. Furthermore, in the event that Bayer is required to obtain HSR clearance with respect to such options, and such clearance is unable to be obtained, Bayer will not participate in further development of the relevant product candidates.

Bayer may terminate, for any or no reason, the collaboration agreement in its entirety, or may terminate with respect to a therapeutic class or specified product candidate, in each case upon prior written notice to us. The agreement may also be terminated in its entirety, or with respect to a therapeutic class, by either party for material breach by the other party that is not cured within a specified cure period. Either party may terminate the agreement for insolvency by the other party, and we may terminate the agreement if Bayer challenges the licensed patents. Depending on the timing of any such termination we may not be entitled to receive the option fees, or potential milestone payments, as these payments terminate with termination of the agreement.

Under our agreement with Celgene, Celgene has options to obtain an exclusive license to develop further and commercialize biologic therapeutics in specified programs, which may be exercised during specified time periods through completion of certain clinical trials, provided that such completion occurs within a specified time

period. Celgene s options may be exercised on a program-by-program basis for up to six biologic programs, including the demcizumab program, the anti-DLL4/VEGF bispecific program, the anti-RSPO3 program, and up to three additional programs targeting the RSPO-LGR signaling pathway and/or targets in the undisclosed pathway. Celgene also has a seventh option, which, if exercised at any time until the fourth anniversary of the date of the Agreement, would permit Celgene to discover, develop and commercialize small molecule therapeutics directed to targets in an undisclosed pathway under the collaboration. Celgene may decide not to exercise any or all of its options.

In addition to the upfront payment of \$177.3 million, including a \$22.3 million equity investment, we are eligible to receive option fees upon Celgene s exercise of the option for each biologic therapeutic program (for up to six biologic therapeutic programs). The collaboration also includes milestone payments for achievement of specified development, regulatory and commercial milestones, paid on a per-product and per-program basis. The option exercise payments and payments for achievement of development, regulatory and commercial milestones may total up to (1) approximately \$791.0 million for products in the demcizumab program, including a payment of \$70.0 million upon the achievement of certain pre-determined safety criteria in Phase II clinical trials with respect to demcizumab, (2) \$505.0 million for products in the anti-DLL4/VEGF bispecific program, and (3) approximately \$440.0 million for products achieving regulatory approval that are directed to targets in each of the RSPO-LGR signaling pathway and the undisclosed pathway programs for which Celgene exercises its option. However, there is no guarantee that any programs under our collaboration with Celgene will successfully advance to achieve the development, regulatory and commercial milestones and that we will receive the associated milestone payments on our anticipated timelines or at all.

For programs in which we are co-developing and co-commercializing biologic therapeutic products in the United States, we are also entitled to share 50% of all product profits and losses in the United States. For such programs outside the United States, we are eligible to receive tiered royalties equal to a percentage of net product sales outside of the United States for each biologic program as follows: tiered royalties in the double-digits for demcizumab and royalties in the mid-single digits to the mid-teens for other biologics programs. If we elect not to co-develop or co-commercialize biologic therapeutic products or do not have the right to do so for a given program, Celgene is required to pay us tiered royalties in the high-single digits to the mid-teens for other biologic so roor and co-commercialize biologics programs and royalties in the high-single digits to the high-teens for other biologics programs), with such royalties being increased where we had the right to co-develop and co-commercialize such biologic therapeutics under the collaboration prior to Celgene s exercise of the option for such program. We are also entitled to receive payments from Celgene upon exercise of its option for the small molecule program, as well as certain development and regulatory milestone payments through regulatory approval totaling over \$100.0 million. We will receive royalties equal to a percentage of worldwide net sales of small molecule products in the low- to mid-single digits.

The agreement with Celgene will terminate upon the expiration of all of Celgene s payment obligations under all license or co-development and co-commercialization agreements entered into with respect to programs following Celgene s exercise of an option for a given program, or if Celgene fails to exercise its options within its option period. The agreement may be terminated by either party for the insolvency of, or an uncured material breach of the agreement by, the other party. In addition, Celgene may terminate the agreement in its entirety or with respect to one or more programs subject to the collaboration, for any reason, with prior written notice to us. We may also terminate the agreement with respect to one or more programs in the event that Celgene challenges the licensed patents with respect to such program. Depending on the timing of any such terminate with termination of the agreement.

If (1) GSK does not exercise its options with respect to tarextumab or brontictuzumab, or terminates its rights and obligations with respect to a program or the entire agreement, (2) Bayer does not exercise its options with respect to vantictumab, ipafricept or other development candidates under its agreement with us, or terminates its rights and obligations with respect to a program or the entire agreement, or (3) Celgene does not exercise its options with respect to demcizumab or other development candidates under its agreement with us, or terminates its rights and obligations with respect to a program or the entire agreement, or (3) Celgene does not exercise its options with respect to demcizumab or other development candidates under its agreement with us, or terminates its rights and obligations with respect to a program or the entire agreement, then depending on the timing of such event:

in the case of GSK, under certain circumstances, we may owe GSK single-digit percentage royalties with respect to product candidates covered by our agreement with GSK that we elect to continue to commercialize, dependent upon the stage of development at which such product commercialization rights reverted back to us, or additional payments if we license such product candidates to third parties;

in the case of Bayer, under certain circumstances, we may owe Bayer single-digit percentage royalties on Wnt product candidates that we elect to continue to commercialize and are successfully commercialized;

in the case of Celgene, under certain circumstances, we may owe Celgene single-digit percentage royalties on product candidates covered by our agreement with Celgene that we elect to continue to commercialize and are successfully commercialized;

the development of our product candidates subject to the GSK agreement, Bayer agreement, or Celgene agreement, as applicable, may be terminated or significantly delayed;

our cash expenditures could increase significantly if it is necessary for us to hire additional employees and allocate scarce resources to the development and commercialization of product candidates that were previously funded by GSK, Bayer, or Celgene, as applicable;

we would bear all of the risks and costs related to the further development and commercialization of product candidates that were previously the subject of the GSK agreement, Bayer agreement, or Celgene agreement, as applicable, including the reimbursement of third parties; and

in order to fund further development and commercialization of new product candidates or programs, we may need to seek out and establish alternative collaboration arrangements with third-party partners; this may not be possible, or we may not be able to do so on terms which are acceptable to us, in which case it may be necessary for us to limit the size or scope of one or more of our programs or increase our expenditures and seek additional funding by other means.

Any of these events would have a material adverse effect on our results of operations and financial condition.

The commercial success of our partnered product candidates that are part of our collaboration agreements with GSK, Bayer, and Celgene, will depend in large part on the development and marketing efforts of our collaboration partners, if and when our collaboration partners exercise their options on those programs. If our partners are

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# unable to perform in accordance with the terms of our agreements, our potential to generate future revenue from these programs would be significantly reduced and our business would be materially and adversely harmed.

If GSK, Bayer or Celgene opt to exercise their options to license any product candidates under their respective agreements (and, with respect to Celgene, we do not co-develop and co-commercialize the license product candidate), we will have limited influence and/or control over their approaches to development and commercialization. While we will have potential milestone and royalty streams payable as these collaboration partners or their sublicensees advance development of the product candidates that are not being co-developed and co-commercialized with us, we are likely to have limited ability to influence our collaboration partners development and commercialization efforts. Even if Celgene exercises its option to license a product candidate under its agreement to which we have global co-development rights and co-commercialization rights in the United States and we co-develop and co-commercialize such product candidate with Celgene, our ability to

influence Celgene s development and commercialization plans may still be limited. Moreover, transitioning a product candidate to a collaboration partner after exercise of the partner s option can be a complex process and may cause delays in the development program for that product candidate. If GSK, Bayer, Celgene, or any potential future collaboration partners do not perform in the manner that we expect or fulfill their responsibilities in a timely manner, or at all, or if significant delays arise from the transition of a product candidate to a collaboration partner after option exercise, the clinical development, regulatory approval and commercialization efforts related to product candidates we have licensed to such collaboration partners could be delayed or terminated.

If we terminate any of our collaborations, or any program thereunder due to a material breach by GSK, Bayer, or Celgene we have the right to assume the responsibility at our own expense for the development of the applicable biologic product candidates. Assumption of sole responsibility for further development will greatly increase our expenditures, and may mean we need to limit the size and scope of one or more of our programs, seek additional funding and/or choose to stop work altogether on one or more of the affected product candidates. This could result in a limited potential to generate future revenue from such product candidates, and our business could be materially and adversely affected. Further, under certain circumstances, we may owe GSK, Bayer, or Celgene, as applicable, a single-digit percentage royalty on a product candidate successfully commercialized, subject to a cap.

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

Although we conduct certain preclinical studies, we currently do not have the ability to independently conduct preclinical studies that comply with good laboratory practices, or GLP. We also do not currently have the ability to independently conduct any clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as CROs, to conduct GLP compliant preclinical studies and clinical trials on our product candidates. The third parties with which we contract for execution of our GLP preclinical studies and our clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our GLP compliant preclinical studies and clinical trials, we remain responsible for ensuring that each of our GLP preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, commonly referred to as current good clinical practices, or cGCPs, for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials.

Many of the third parties with whom we contract may also have relationships with other commercial entities, some of which may compete with us. If the third parties conducting our GLP preclinical studies or our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical trial protocols or to cGCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be costly, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated, and we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, or to commercialize such product candidate being tested in such studies or trials.

We rely on single source third-party contract manufacturing organizations to manufacture and supply our product candidates for us. If one of our suppliers or manufacturers fails to perform adequately or fulfill our needs, or if these agreements are terminated by the third parties, we may be required to incur significant costs and devote significant efforts to find new suppliers or manufacturers. We may also face delays in the development and commercialization of our product candidates.

We currently have limited experience in, and we do not own facilities for, manufacturing our product candidates. We rely upon single source third-party contract manufacturing organizations to manufacture and supply large quantities of our product candidates. We currently utilize Lonza Sales AG, or Lonza, for the bulk manufacturing of our product candidates, except for our ipafricept (OMP-54F28, Fzd8-Fc) program, for which Bayer provides bulk manufacturing. We have also used Synco Bio Partners B.V. for fill/finish services (e.g., filling vials with drug substance, sealing and inspecting vials and performance of release assays). In addition, a number of our clinical trials require us to source and supply our clinical trial sites with other medications that are administered in conjunction with our product candidates, or co-medications. We rely upon third-party suppliers for the manufacture and supply of these co-medications, which are subject to the same risks as the manufacture and supply of our product candidates.

The manufacture of pharmaceutical products in compliance with current good manufacturing practice, or cGMP, regulations requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, or shortages of qualified personnel. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates or the supply of co-medications will not occur in the future. If the manufacturers of our product candidates or co-medications were to encounter any of these difficulties or otherwise fail to comply with their obligations to us or under applicable regulations, or if we were unable to timely identify third party suppliers of co-medications or enter into agreements with these third party suppliers for the supply of co-medications, our ability to provide study materials in our preclinical studies and clinical trials would be jeopardized. Any delay or interruption in the supply of preclinical study or clinical trial materials could delay the initiation of, enrollment in, and/or completion of our preclinical studies and clinical trials, increase the costs associated with maintaining our preclinical study and clinical trial programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the studies and trials completely.

All manufacturers of our product candidates must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our component materials may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any product supplied is compromised due to our manufacturers failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of our product candidates or entail higher costs or impair our reputation.

Our current agreements with our suppliers do not provide for the entire supply of the bulk drug necessary for additional clinical trials or for full-scale commercialization. In the event that we and our suppliers cannot agree to the terms and conditions for them to provide some or all of our bulk drug clinical and commercial supply needs, or if any

single-source supplier terminates the agreement in response to a breach by us, we would not be

able to manufacture the bulk drug on a commercial scale until a qualified alternative supplier is identified, which could also delay the development of, and impair our ability to commercialize, our product candidates.

Although we believe that appropriate alternative sources of supply exist for each of our current product candidates, the number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities is limited, and it could be expensive and take a significant amount of time to arrange for alternative suppliers, which could have a material adverse effect on our business. New suppliers of any bulk drug would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing such ingredients. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs which may be passed on to us. In addition, we may be required to pay potential fees and royalties to Lonza if we utilize other suppliers for bulk drug, given that we have used their proprietary production cell lines in our programs.

The failure of third-party manufacturers or suppliers to perform adequately or the termination of our arrangements with any of them may negatively and adversely affect our business.

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

An important element of our clinical development strategy for certain of our product candidates such as demcizumab (OMP-21M18, anti-DLL4), tarextumab (OMP-59R5, anti-Notch2/3), brontictuzumab (anti-Notch1, OMP-52M51), vantictumab (OMP-18R5, anti-Fzd7), and ipafricept (OMP-54F28, Fzd8-Fc) is that we seek to identify patient subsets within a disease category who may derive selective and meaningful benefit from the product candidates we are developing. In collaboration with our partners, we plan to develop companion diagnostics for selected product candidates to help us to more accurately identify patients within a particular subset. Such companion diagnostics would be used during our clinical trials as well as in connection with the commercialization of our product candidates. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and therefore require separate regulatory clearance or approval prior to commercialization. The clinical development of novel therapeutics with a companion diagnostic is complex from an operational and regulatory perspective because of the need for both the drug and the diagnostic to receive regulatory clearance or approval.

We will be dependent on identifying suitable third-party development partners, and on entering into appropriate agreements with such third parties, and on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. Failure to overcome these hurdles would have an adverse effect on our ability to derive revenues from sales of our diagnostic products. Any delay or failure by us or our future collaborators to develop or obtain regulatory approval of the companion diagnostics where required in connection with obtaining approval of our product candidates could delay or prevent approval of our product candidates. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and

commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into

arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

### Even if our product candidates do obtain regulatory approval they may never achieve market acceptance or commercial success.

Even if we obtain FDA or other regulatory approvals, and are able to launch our product candidates commercially, our product candidates may not achieve market acceptance among physicians, patients and third-party payors and, ultimately, may not be commercially successful. Market acceptance of our product candidates for which we receive approval depends on a number of factors, including:

the efficacy and safety of the product candidates as demonstrated in clinical trials;

the clinical indications for which the product candidate is approved;

acceptance by physicians, operators of treatment facilities and parties responsible for reimbursement of the product as a safe and effective treatment;

the potential and demonstrable advantages of our product candidates, including the cost of treatment and benefits over alternative treatments;

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

the cost of treatment in relation to alternative treatments;

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

relative convenience and ease of administration;

the tolerance of the products by patients, including prevalence and severity of adverse side effects; and

the effectiveness of our sales and marketing efforts.

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

If any of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by the product candidate, our ability to market and derive revenue from the product candidates could be compromised.

In the event that any of our product candidates receive regulatory approval and we or others identify undesirable side effects caused by one of our products, any of the following adverse events could occur:

regulatory authorities may withdraw their approval of the product or seize the product;

we may be required to recall the product or change the way the product is administered to patients;

additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;

we may be subject to fines, injunctions or the imposition of civil or criminal penalties;

regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication;

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

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

the product may become less competitive; and

our reputation may suffer.

Any of the foregoing events could result in the loss of significant revenues to us, which would materially and adversely affect our results of operations and business.

#### We currently have no sales and marketing staff or distribution organization. If we are unable to develop a sales and marketing and distribution capability on our own or through our collaborations with GSK, Bayer, Celgene or other potential marketing partners, we will not be successful in commercializing our future products.

We currently have no sales or marketing staff or distribution organization. If our Notch or Wnt product candidates that are part of our collaborations with GSK and Bayer are approved for sale, we intend to rely on GSK and/or Bayer to market and distribute our products for which they have exercised an option under our agreements, but there is no guarantee that GSK or Bayer will elect to market and distribute our products or that either party will not elect to terminate our collaboration arrangement, which they have a right to do at any time with prior notice under our agreements with them. Similarly, if Celgene elects to exercise its option for a program under its agreement, including a program we are co-commercializing in the United States with Celgene, then although we intend to exercise our right to participate in specified promotion activities in the United States by contributing up to half of the overall sales force for the applicable program products, as well as to perform certain marketing and other commercial activities, Celgene will be responsible for booking sales of products. There is no guarantee that Celgene will elect to market and distribute our products or that Celgene will not elect to terminate our collaboration arrangement, which they have a right to do at any time with prior notice under our agreement. Further, we are likely to have limited control over the marketing and distribution activities of GSK, Bayer, or Celgene for products for which our partner is solely responsible for development and commercialization of a product candidate. This will be the case under our agreements with GSK and Bayer. It is also the case under our agreement with Celgene for all biologic products outside the United States, and for all biologic products within the United States for which we either do not have, or for which we opt out of, our right to co-develop and co-commercialize such product candidates, and for all small molecule product candidates throughout the world. On the other hand, if GSK, Bayer or Celgene do not exercise their respective options, and we develop the product candidates under the GSK, Bayer and/or Celgene agreements ourselves, or if we develop unpartnered product candidates to the point of commercialization, we may need to enter into distribution or co-marketing arrangements with other third parties. Further, if Celgene exercises its options for product candidates under its agreement to which we have co-commercialization rights in the United States and we choose to exercise our right to co-commercialize such product candidates, we will need to build certain sales and marketing capabilities. If we need to rely on third parties for marketing and distributing our independently developed approved products, any revenue we receive will depend upon the efforts of third parties, which may not be successful and are only partially within our control and our product revenue may be lower than if we directly marketed or sold our products. If we are unable to enter into arrangements with third parties to sell, market and distribute product candidates for which we have received regulatory approval on acceptable terms or at all, we will need to market these products ourselves. Marketing products ourselves or co-commercializing products with Celgene is likely to be expensive and logistically difficult, as it would require us to build our own sales force. We have no experience as a company in this area. If such efforts were necessary, we may not be able to successfully commercialize our future products. If we are not successful in commercializing our future products, either on our own or through collaborations with GSK, Bayer, Celgene, or one or more third parties, or by co-promoting products with marketing partners, any future product revenue will be materially and adversely affected.

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

As of December 31, 2014, we had 108 employees. We will need to expand our managerial, operational, financial and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize our product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our business strategy requires that we:

manage our clinical trials effectively, including two Phase Ib/II trials for tarextumab (OMP-59R5, anti-Notch2/3), a Phase Ib/II trial and two Phase II trials for demcizumab (OMP-21M18, anti-DLL4), three Phase Ib trials each for vantictumab (OMP-18R5, anti-Fzd7) and ipafricept (OMP-54F28, Fzd8-Fc), and Phase I trials for brontictuzumab (anti-Notch1, OMP-52M51) and anti-DLL4/VEGF bispecific (OMP-305B83), most of which are being conducted, or are expected to be conducted, at multiple trial sites, as well as additional clinical trials we expect to initiate in the future, including additional clinical trials we expect to initiate in 2015;

manage our internal research and development efforts effectively while carrying out our contractual obligations to licensors, contractors, collaborators, government agencies and other third parties;

continue to improve our operational, financial and management controls, reporting systems and procedures; and

identify, recruit, maintain, motivate and integrate additional employees. If we are unable to expand our managerial, operational, financial and other resources to the extent required to manage our development and commercialization activities, our business will be materially adversely affected.

# If we are not successful in discovering, developing and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives, or receive payments from our collaboration partners, would be impaired.

Although a substantial amount of our efforts will focus on the continued clinical testing and potential approval of our most advanced product candidates, which include demcizumab (OMP-21M18, anti-DLL4), tarextumab (OMP-59R5, anti-Notch2/3), vantictumab (OMP-18R5, anti-Fzd7), ipafricept (OMP-54F28, Fzd8-Fc), brontictuzumab (anti-Notch1, OMP-52M51) and anti-DLL4/VEGF bispecific (OMP-305B83), a key element of our strategy is to discover, develop and potentially commercialize a portfolio of antibody-based products and other biologics useful in the treatment of cancer. We are seeking to do so through our internal research programs. Additional product candidates may be part of our existing collaborations, such as our Celgene collaboration, which involves up to another three biologic programs in addition to demcizumab, OMP-305B83 and OMP-131R10, and potentially certain small molecule therapeutic product candidates, or may arise out of unpartnered programs. We may explore strategic partnerships for the development of new products or develop new unpartnered product candidates on our own. All of our potential product candidates other than our six product candidates currently in clinical trials remain in the discovery and preclinical study stages. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates for clinical

development for many reasons, including the following:

the research methodology used may not be successful in identifying potential product candidates;

competitors may develop alternatives that render our product candidates obsolete;

a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;

a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and

a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If we are unsuccessful in identifying and developing additional product candidates, our potential for growth, or our ability to receive payments from our collaboration partners, may be impaired.

## Key elements of our product discovery technologies, such as our human tumor xenograft models, antibody display technology and single-cell analysis platform, are new approaches to the discovery and development of new product candidates and may not result in the discovery of any products of commercial value.

We have developed a suite of discovery technologies to enable generation and testing of novel product candidates. For example, we have created a bank of over 200 patient-derived human tumors that we routinely utilize in human tumor xenograft models to screen our product candidates for evidence of activity. We have also developed a mammalian display antibody technology that we use routinely to select antibody product candidates for in vivo testing. In addition, we have created a single-cell gene expression analysis platform that we are utilizing to identify genes that are critical to CSC self-renewal and differentiation. We cannot assure you that any of these technologies will yield product candidates of commercial value.

### We face substantial competition and our competitors may discover, develop or commercialize products faster or more successfully than us.

The biotechnology and pharmaceutical industries are highly competitive, and we face significant competition from companies in the biotechnology, pharmaceutical and other related markets that are researching and marketing products designed to address solid tumors and hematologic malignancies. Established pharmaceutical and biotechnology companies that are known to be involved in oncology research and currently sell or are developing drugs in our markets of interest include AbbVie, Amgen, Astellas, AstraZeneca, Bayer, BMS, Celgene, Genentech (Roche), GSK, Johnson & Johnson, Lilly, Merck, MerckSerono, Novartis, Pfizer, Regeneron, Sanofi, Teva and others. There are also biotechnology companies of various sizes that are developing therapies against CSCs, including Stemline Therapeutics, Inc. and Verastem, Inc., among others.

It is possible that our competitors will develop and market drugs or other treatments that are less expensive and more effective than our product candidates, or that will render our product candidates obsolete. It is also possible that our competitors will commercialize competing drugs or treatments before we or our collaboration partners can launch any products developed from our product candidates. If approved for marketing by the FDA or other regulatory agencies worldwide, demcizumab (OMP-21M18, anti-DLL4), or our other product candidates, would compete against existing cancer treatments such as Avastin<sup>®</sup>, Erbitux<sup>®</sup>, Yervoy , chemotherapies and potentially against other novel drug candidates or treatments that are currently in development. Additionally, there are several additional monoclonal antibodies in development for cancer, such as anti-DLL4 antibodies from Regeneron (REGN421, also known as SAR153192 and enoticumab) and MedImmune (MEDI0639), both of which we believe are in Phase I development. In the Notch pathway, several companies, including Merck, Lilly, Pfizer, Roche and others, have attempted to advance small molecule gamma-secretase inhibitors, or GSIs, in clinical development. With respect to the Wnt pathway, we believe that there may be some early stage small molecules programs from other companies. See

Business Competition. We also anticipate that we will face increased competition in the future as new companies enter into our target markets and scientific developments surrounding the cancer stem cell field continue to develop.

Many of our competitors have materially greater name recognition and financial, manufacturing, marketing, research and drug development resources than we do. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Large

pharmaceutical companies in particular have extensive expertise in preclinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors.

### We may form additional strategic alliances in the future with respect to our independent programs, and we may not realize the benefits of such alliances.

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties with respect to our independent programs that we believe will complement or augment our existing business. For example, we may attempt to find a partner for licensing, development and/or commercialization of our unpartnered research and preclinical assets. We routinely engage in partnering discussions with a range of pharmaceutical and biotechnology companies and could enter into new collaborations at any time. We face significant competition in seeking appropriate strategic partners, and the negotiation process to secure appropriate terms is time-consuming and complex. Any delays in identifying suitable development partners and entering into agreements to develop our product candidates could also delay the commercialization of our product candidates, which may reduce their competitiveness even if they reach the market. Moreover, we may not be successful in our efforts to establish such a strategic partnership for any future product candidates and programs on terms that are acceptable to us, or at all. This may be because our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort, our research and development pipeline may be viewed as insufficient, and/or third parties may not view our product candidates and programs as having sufficient potential for commercialization, including the likelihood of an adequate safety and efficacy profile. Even if we are successful in entering into a strategic alliance or license arrangement, there is no guarantee that the collaboration will be successful, or that any future partner will commit sufficient resources to the development, regulatory approval, and commercialization effort for such products, or that such alliances will result in us achieving revenues that justify such transactions.

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

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases, and out-licensing or in-licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

exposure to unknown liabilities;

disruption of our business and diversion of our management s time and attention in order to develop acquired products, product candidates or technologies;

incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;

higher-than-expected acquisition and integration costs;

write-downs of assets or goodwill or impairment charges;

increased amortization expenses;

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

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

inability to retain key employees of any acquired businesses. Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks, could have a material adverse effect on our business, results of operations, financial condition and prospects.

# We are highly dependent on the services of our Chairman and Chief Executive Officer, Paul J. Hastings, our Executive Vice President and Chief Scientific Officer, John Lewicki, Ph.D., our Senior Vice President and Chief Medical Officer, Jakob Dupont, M.D., and other key executives, and if we are not able to retain these members of our management or recruit additional management, clinical and scientific personnel, our business will suffer.

We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Francisco Bay area. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We are highly dependent on the principal members of our management and scientific staff. The loss of service of any of our management could harm our business. In addition, we are dependent on our continued ability to attract, retain and motivate highly qualified additional management, clinical and scientific personnel. The competition for qualified personnel in the pharmaceutical industry is intense. Due to our limited resources, we may not be able to effectively attract and recruit additional qualified personnel. If we are not able to retain our management, particularly our Chairman and Chief Executive Officer, Mr. Hastings, our Executive Vice President and Chief Scientific Officer, Dr. Lewicki, and our Senior Vice President and Chief Medical Officer, Dr. Dupont, and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow. Although we have executed employment agreements with each member of our current executive management team, including Mr. Hastings and Drs. Lewicki and Dupont, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. In addition to the competition for personnel, the San Francisco Bay area in particular is characterized by a high cost of living. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

In addition, we have scientific and clinical advisors who assist us in formulating our product development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours.

# We may be subject to costly product liability claims related to our clinical trials and product candidates and, if we are unable to obtain, or maintain, adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage, a material liability claim could adversely affect our financial condition.

Because we conduct clinical trials with human patients, we face the risk that the use of our product candidates may result in adverse side effects to patients in our clinical trials. We face even greater risks upon any commercialization

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of our product candidates. Although we have product liability insurance, which covers our

clinical trials, for up to \$10.0 million, our insurance may be insufficient to reimburse us for any expenses or losses we may suffer, and we will be required to increase our product liability insurance coverage for our advanced clinical trials that we plan to initiate. We do not know whether we will be able to continue to obtain product liability coverage and obtain expanded coverage if we require it, on acceptable terms, or at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage. Where we have provided indemnities in favor of third parties under our agreements with them, there is also a risk that these third parties could incur liability and bring a claim under such indemnities. An individual may bring a product liability claim against us alleging that one of our product candidates or products causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any product liability claim brought against us, with or without merit, could result in:

withdrawal of clinical trial volunteers, investigators, patients or trial sites;

the inability to commercialize our product candidates;

decreased demand for our product candidates;

regulatory investigations that could require costly recalls or product modifications;

loss of revenues;

substantial costs of litigation;

liabilities that substantially exceed our product liability insurance, which we would then be required to pay ourselves;

an increase in our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, if at all;

the diversion of management s attention from our business; and

damage to our reputation and the reputation of our products. Product liability claims may subject us to the foregoing and other risks, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

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Our third-party manufacturers activities and our own activities involve the controlled storage, use and disposal of hazardous materials, including the components of our pharmaceutical product candidates, test samples and reagents, biological materials and other hazardous compounds. We and our manufacturers are subject to federal, state, local and foreign laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these hazardous materials. We currently carry no insurance specifically covering environmental claims relating to the use of hazardous materials. Although we believe that our safety procedures for handling and disposing of these materials and waste products comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of an accident, state or federal or other applicable authorities may curtail our use of these materials and/or interrupt our business operations. In addition, if an accident or environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages and fines. If such unexpected costs are substantial, this could significantly harm our financial condition and results of operations.

### Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural

disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

### Our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations, including those laws that require the reporting of true, complete and accurate information to the FDA, (ii) manufacturing standards, (iii) federal and state healthcare fraud and abuse laws and regulations, and (iv) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

### Requirements associated with being a public company have increased our costs significantly and have diverted significant company resources and management attention.

Prior to our initial public offering in July 2013, we had not been subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or the other rules and regulations of the SEC or any securities exchange relating to public companies. We are continuing to work with our legal, independent accounting and financial advisors to identify those areas in which changes should be made to our financial and management control systems to manage our growth and our obligations as a public company. These areas include corporate governance, corporate control, disclosure controls and procedures and financial reporting and accounting systems. We have made, and will continue to make, changes in these and other areas. However, the expenses that will be required in order to operate as a public company could be material, particularly after we cease to be an emerging growth company. Compliance with the various reporting and other requirements applicable to public companies will also require considerable time and attention of management. In addition, the changes we make may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis.

However, for as long as we remain an emerging growth company as defined in the Jumpstart our Business Startups Act, or the JOBS Act, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including

not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. Because the JOBS Act has only recently been enacted, it is not yet clear whether investors will accept the more limited disclosure requirements that we may be entitled to follow while we are an emerging growth company. If they do not, we may end up electing to comply with disclosure requirements as if we were not an emerging growth company, in which case we would incur the greater expenses associated with such disclosure requirements.

We will remain an emerging growth company for up to five years from our initial public offering in July 2013, although if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of any June 30 before that time or if we have total annual gross revenues of \$1 billion or more during any fiscal year before that time, we would cease to be an emerging growth company as of the end of that fiscal year, or if we issue more than \$1 billion in non-convertible debt in a three-year period, we would cease to be an emerging growth company immediately.

In addition, being a public company made it more difficult or more costly for us to obtain certain types of insurance, including directors and officers liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

### If we are not able to implement the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 in a timely manner or with adequate compliance, we may be subject to sanctions by regulatory authorities.

Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal controls over financial reporting and, beginning with our annual report for fiscal year 2014, provide a management report on the internal control over financial reporting. If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We will be evaluating our internal controls systems to allow management to report on, and eventually allow our independent auditors to attest to, our internal controls. We will be performing the system and process evaluation and testing (and any necessary remediation) required to comply with the management certification and eventual auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. The aforementioned auditor attestation requirements will not apply to us until we are not an emerging growth company.

We cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, we may be subject to sanctions or investigation by regulatory authorities, such as the SEC or The NASDAQ Stock Market LLC, or NASDAQ. Any such action could adversely affect our financial results or investors confidence in us and could cause our stock price to fall. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls that are deemed to be material weaknesses, we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources and could materially adversely affect our stock price. Inferior internal controls could also cause us to fail to meet our reporting obligations or cause investors to lose confidence in our reported financial information, which could have a negative effect on our stock price.

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

We have incurred substantial losses during our history and do not expect to become profitable in 2015 and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. We may be unable to use these losses to offset income before such unused losses expire. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an ownership change (generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a three-year period), the corporation s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be further limited. We have experienced ownership changes in the past. We may experience additional ownership changes in the future. As of December 31, 2014, we had federal and California net operating loss carryforwards of \$69.0 million and \$116.5 million, respectively, that could be limited if we experience an ownership change, which could have an adverse effect on our results of operations.

#### We may be adversely affected by the current global economic environment.

Our ability to attract and retain collaboration partners or customers, invest in and grow our business and meet our financial obligations depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic conditions and financial, business and other factors beyond our control, such as the rate of unemployment, the number of uninsured persons in the United States and inflationary pressures. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. We cannot anticipate all the ways in which the current global economic climate and global financial market conditions could adversely impact our business.

We are exposed to risks associated with reduced profitability and the potential financial instability of our collaboration partners or customers, many of which may be adversely affected by volatile conditions in the financial markets. For example, unemployment and underemployment, and the resultant loss of insurance, may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage, our collaboration partners or customers may experience reductions in revenues, profitability and/or cash flow that could lead them to reduce their support of our programs or financing activities. If collaboration partners or customers are not successful in generating sufficient revenue or are precluded from securing financing, they may not be able to pay, or may delay payment of, accounts receivable that are owed to us. In addition, the volatility in the financial markets could cause significant fluctuations in the interest rate and currency markets. We currently do not hedge for these risks. The foregoing events, in turn, could adversely affect our financial condition and liquidity. To the extent economic challenges result in fewer individuals pursuing or being able to afford our product candidates once commercialized, our business, results of operations, financial condition and cash flows could be adversely affected.

### Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our corporate headquarters is located in California and certain clinical sites for our product candidates, operations of our existing and future partners and suppliers are or will be located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant partners, suppliers

and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural or manmade disaster.

#### **Risks Related to Intellectual Property**

We or our collaborators may become subject to third parties claims alleging infringement of their patents and proprietary rights or seeking to invalidate our patents or proprietary rights, or we may need to become involved in lawsuits to protect or enforce our patents, which could be costly, time-consuming, delay or prevent the development and commercialization of our product candidates, or put our patents and other proprietary rights at risk.

Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical and biotechnology industries is common. We or our collaborators may be subject to third-party claims in the future that would cause us to incur substantial expenses and which, if successful, could cause us to pay substantial damages, if we or our collaborators are found to be infringing a third party s patent rights. These damages potentially include increased damages and attorneys fees if we are found to have infringed such rights willfully. Further, if a patent infringement suit is brought against us or our collaborators, our research, development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated. As a result of patent infringement claims, or in order to avoid potential infringement claims, we or our collaborators may choose to seek, or be required to seek, a license from the third party, which would be likely to include a requirement to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if a license can be obtained on acceptable terms, the rights may be nonexclusive, which would give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we or our collaborators could be prevented from commercializing one or more of our product candidates, or to cease some aspect of our business operations, which could harm our business significantly.

We are aware of U.S. and foreign issued patents and pending patent applications controlled by third parties that may relate to the areas in which we are developing product candidates. Because all issued patents are entitled to a presumption of validity in many countries, including the United States and many European countries, issued patents held by others that claim our products or technology may limit our freedom to operate unless and until these patents expire or are declared invalid or unenforceable in a court of applicable jurisdiction, if we do not obtain a license or other right to practice the claimed inventions. Pending patent applications controlled by third parties may result in additional issued patents claiming our products and technology. In addition, the publication of patent applications occurs with a certain delay after the date of filing, so we may not be aware of all relevant patent applications of third parties at a given point in time. Further, publication of discoveries in the scientific or patent literature often lags behind actual discoveries, so we may not be able to determine whether inventions claimed in patent applications of third parties have been made before or after the date on which inventions claimed in our patent applications and patents have been made. If U.S. patent applications filed by third parties claim technology or therapeutics that are also claimed by our patent applications or patents, we may, under certain circumstances, have to participate in interference proceedings in the U.S. Patent and Trademark Office, or USPTO, to determine the priority of invention. We may also become involved in opposition proceedings in the European Patent Office, or EPO, or other proceedings before patent offices in the U.S. or foreign countries, regarding the intellectual property rights of third parties. An unfavorable outcome in these proceedings regarding the intellectual property rights of a third party could require us to attempt to license rights from the prevailing party, or to cease using the related technology or developing or commercializing the related product candidate.

Competitors may infringe our patents, or misappropriate or violate our other intellectual property rights. To counter infringement or unauthorized use, we may find it necessary to file infringement or other claims to protect our intellectual property rights. In addition, in any infringement proceeding brought by us against a third party to enforce our rights, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the basis that our patents do not cover the technology in question. In patent

litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. An adverse result in any patent litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could open us up to additional competition and have a material adverse effect on our business.

Third parties may also raise claims alleging the invalidity or unenforceability of our patents in other forms of proceedings, including proceedings before administrative bodies in the U.S. or abroad, even outside the context of patent litigation. The use of administrative proceedings for challenging patents, including interference, derivation, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions is common in the biotechnology and pharmaceutical industries. For instance, we may be involved in opposition proceedings in the EPO regarding our intellectual property rights with respect to our product candidates. Due to recent changes in U.S. patent law, new procedures including inter partes review and post-grant review have been implemented and are now also available for use in patent challenges.

The cost to us of any patent litigation or other proceedings regarding our patents and/or third party patents, even if resolved in our favor, could be substantial. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, there could be a substantial adverse effect on the price of our common stock. Uncertainties resulting from the initiation and continuation of patent litigation and other proceedings may also require significant time and attention of management and technical staff, which may materially and adversely impact our financial position and results of operations. Furthermore, because of the substantial amount of discovery required in connection with any intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

# Our proprietary rights may not adequately protect our technologies and product candidates. If we are unable to protect our product candidates and our intellectual property rights, it may materially and adversely affect our position in the market.

Our commercial success will depend on our ability to obtain patents and maintain adequate protection for our technologies, intellectual property and product candidates in the United States and other countries. As of December 31, 2014, our patent estate, including the patents and patent applications that we have exclusively licensed from the University of Michigan, included approximately 304 issued patents or allowed patent applications and approximately 134 additional pending patent applications on a worldwide basis, which, as a whole, include claims relating to our current clinical stage product candidates. There is no guarantee that any of our patent applications will result in issued patents, or that any patents, if issued, will include claims that are sufficiently broad to cover our product candidates or products, or to provide meaningful protection from our competitors. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and future products are covered by valid and enforceable patents or are effectively maintained as trade secrets within our organization. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely impact our position in the market.

We apply for patents covering both our technologies and product candidates, as we deem appropriate. However, we may fail to apply for patents on important technologies or product candidates in a timely fashion, or at all. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies. Moreover, the patent positions of numerous biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. As a result, the validity and enforceability of our patents cannot be predicted with certainty. In addition, we cannot guarantee you that:

we were the first to make the inventions covered by each of our issued patents and pending patent applications;

we were the first to file patent applications for these inventions;

others will not independently develop similar or alternative technologies or duplicate any of our technologies by inventing around our claims;

a third party will not challenge our proprietary rights, and, if challenged, that a court or patent office, as applicable, will hold that our patents are valid and enforceable;

any patents issued to us or our collaboration partners will cover our product as ultimately developed, or provide us with any competitive advantages, or will not be challenged by third parties;

we will develop additional proprietary technologies or product candidates that are patentable; or

the patents of others will not have an adverse effect on our business. Our issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign authority. For instance, we may become involved in opposition proceedings before the EPO, proceedings such as interferences, re-examination, inter partes review, or post-grant review before the USPTO, and/or legal proceedings before the courts in the U.S. or foreign countries regarding patents in our portfolio, and the outcome of any such proceedings may be uncertain. The outcome regarding legal assertions of invalidity and unenforceability is unpredictable. If a third party challenging one or more of our patents were to prevail on a legal assertion of invalidity and/or enforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

In addition, there are numerous recent changes to the patent laws and proposed changes to the rules of the USPTO which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, on September 16, 2011, President Obama signed the Leahy-Smith America Invents Act which codifies several significant changes to the U.S. patent laws, including, among other things, changing from a first to invent to a first inventor to file system, limiting where a patentee may file a patent suit, eventually eliminating interference proceedings while maintaining derivation actions, and creating a set of procedures to challenge patents in the USPTO after they have issued. The effects of these changes are currently uncertain as the USPTO has only recently implemented regulations related to these changes and the courts have yet to address many of these provisions in the context of a dispute. Further, we have not assessed the applicability of the act and new regulations on the specific patents discussed herein. The U.S. Supreme Court has also recently issued multiple decisions regarding patent law, the full impact of which is not yet known. In some instances, the rulings have narrowed the scope of patent protection available under certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to the ability to obtain patents in the future, these events have created uncertainty with respect to the value of patents once obtained. For example, on March 20, 2012 in Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc., the Court held that several claims drawn to measuring drug metabolite levels from patient samples and correlating them to drug doses were not patentable subject matter. The decision appears to impact diagnostics patents that merely apply a law of nature via a series of routine steps and it has created uncertainty around the ability to patent certain biomarker-related method claims. Additionally, on June 13, 2013 in Association for Molecular Pathology v. Myriad Genetics, Inc., the Court held that claims to isolated genomic DNA are not patentable, but claims to complementary DNA (cDNA) molecules were held to be valid. The effect of the decision on patents for other isolated natural products is uncertain. Depending on decisions by the U.S. Congress, the federal courts, the USPTO, and foreign courts and patent offices, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents

or to enforce our existing patents and patents that we might obtain in the future.

### Restrictions on our patent rights relating to our product candidates may limit our ability to prevent third parties from competing against us.

Our success will depend, in part, on our ability to obtain and maintain patent protection for our product candidates, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others. Composition-of-matter patents on the biological

or chemical active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. We have filed composition-of-matter patent applications for all of our product candidates. However, we cannot be certain that the claims in our patent applications to inventions covering our product candidates will be considered patentable by the USPTO and courts in the United States or by the patent offices and courts in foreign countries.

In addition to composition-of-matter patents and patent applications, we also have filed method-of-use patent applications. This type of patent protects the use of the product only for the specified method. However, this type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if these competitors do not actively promote their product for our targeted indication, physicians may prescribe these products off-label. Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Patent applications in the United States and most other countries are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags behind actual discoveries by several months or more. As a result, we cannot be certain that we and the inventors of the issued patents and applications that we may in-license were the first to conceive of the inventions covered by such patents and pending patent applications or that we and those inventors were the first to file patent applications covering such inventions.

Also, we have a number of issued patents and numerous patent applications pending before the USPTO and foreign patent offices and the patent protection may lapse before we manage to obtain commercial value from them, which might result in increased competition and materially affect our position in the market. Even if our patents do not lapse before we are able to obtain at least some commercial value from them, the life of any patent, and the protection it affords, is limited. Although the term of a U.S. patent may be increased to compensate for certain delays caused by the USPTO, this increase may also be reduced or offset entirely by delays caused by the patent applicant during patent prosecution. Once the patent life has expired for any of our product candidates, we may be open to competition from biosimilars, which may potentially reduce our market share, and our business and results of operations will be adversely affected.

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our other patent applications at risk of not issuing and could provoke third parties to assert counter claims of infringement or misappropriation against us. We may not be able to obtain injunctive relief in foreign jurisdictions to

prevent ongoing infringement while we enforce our patent rights and we may not

prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property.

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

We are a party to intellectual property license agreements with third parties, including with respect to demcizumab (OMP-21M18, anti-DLL4), tarextumab (OMP-59R5, anti-Notch2/3), brontictuzumab (anti-Notch1, OMP-52M51), vantictumab (OMP-18R5, anti-Fzd7), and anti-DLL4/VEGF bispecific (OMP-305B83) and the production of all of our biologic product candidates, and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, milestone payment, royalty, insurance, indemnification and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements, in which event we, or our collaborators, might not be able to develop and market any product candidate that is covered by these agreements. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms, or in the inability to obtain access to the licensed technology at all. The occurrence of such events could materially harm our business.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process. In addition, periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In the event that noncompliance leads to abandonment or lapse of a patent or patent application given the able to enter the market earlier than would otherwise have been the case, which could have a material adverse effect on our business.

### If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. Litigation may be necessary to protect our rights to our trademarks or trade names. Such litigation may be costly and be a distraction to management. Also, an adverse result in any such litigation proceedings could put our trademarks or trade names at risk. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

### We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees or consultants former employers or their clients. These claims may be costly to

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### defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.

Many of our employees were previously employed at universities or biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or

disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to commercialize, or prevent us from commercializing our product candidates, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

### If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States, including in foreign jurisdictions, are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitive position would be harmed.

#### **Risks Related to Government Regulation**

# The regulatory approval process is expensive, time-consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of some or all of our product candidates.

The development, research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug and biologic products are subject to extensive and evolving regulation by federal, state and local governmental authorities in the United States, principally by the FDA, and foreign regulatory authorities, which regulations differ from country to country. Neither we nor our collaboration partners are permitted to market our product candidates in the United States until we receive regulatory approval from the FDA. Our product candidates are subject to regulation as biologics, and we will require approval of a BLA from the FDA before we may market our product candidates. Neither we nor our collaboration partners have submitted an application for or received marketing approval for any of our product candidates. Obtaining approval of a BLA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including:

warning letters;

civil and criminal penalties;

injunctions;

withdrawal of approved products;

product seizure or detention;

product recalls;

total or partial suspension of production; and

#### refusal to approve pending BLAs or supplements to approved BLAs.

Prior to receiving approval to commercialize any of our product candidates in the United States or abroad, we and our collaboration partners must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and other regulatory authorities abroad, that such product candidates are safe and effective for their intended uses. Preclinical testing and clinical trials are long, expensive and uncertain processes. We may spend several years completing our testing for any particular product candidate, and failure can occur at any stage. Negative or inconclusive results or adverse medical events during a clinical trial could also cause the FDA or us to terminate a clinical trial or require that we repeat it or conduct additional clinical trials. Additionally, data obtained from preclinical studies and clinical trials can be interpreted in different ways and the FDA or other regulatory authorities may interpret the results of our studies and trials less favorably than we do. Even if we and our collaboration partners believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any of our product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials of our product candidates and result in the FDA or other regulatory authorities denying approval of our product candidates for any or all targeted indications.

Regulatory approval of our product candidates is not guaranteed, and the approval process is expensive and may take several years. The FDA and foreign regulatory entities also have substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials, or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. The FDA can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to, the following:

a product candidate may not be deemed safe or effective;

FDA officials may not find the data from preclinical studies and clinical trials sufficient;

the FDA might not approve our or our third-party manufacturer s processes or facilities; or

the FDA may change its approval policies or adopt new regulations. If any of our product candidates fails to demonstrate safety and efficacy in clinical trials or does not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

Even if we or our collaboration partners receive regulatory approval for a product candidate, we and our collaboration partners will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.

Once regulatory approval has been granted, the approved product and its manufacturer are subject to continual review by the FDA and/or non-U.S. regulatory authorities. Any regulatory approval that we or our collaboration partners receive for our product candidates may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and efficacy of the product. In addition, if the FDA and/or non-U.S. regulatory authorities approve any of our product candidates, we will be subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products. Manufacturers of our products are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture our products, and these

facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we, a collaboration partner or a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the collaboration partner, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and/or other non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

warning letters;

civil or criminal penalties;

injunctions;

suspension of or withdrawal of regulatory approval;

suspension of any ongoing clinical trials;

voluntary or mandatory product recalls and publicity requirements;

refusal to approve pending applications for marketing approval of new products or supplements to approved applications filed by us;

restrictions on operations, including costly new manufacturing requirements; or

#### seizure or detention of our products or import bans.

The regulatory requirements and policies may change and additional government regulations may be enacted for which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we or our collaboration partners are not able to maintain regulatory compliance, we or our collaboration partners, as applicable, will not be permitted to market our future products and our business will suffer.

The availability of adequate third-party coverage and reimbursement for newly approved products is uncertain, and failure to obtain adequate coverage and reimbursement from third-party payors could impede our ability to market any future products we may develop and could limit our ability to generate revenue.

There is significant uncertainty related to the third-party payor coverage and reimbursement of newly approved medical products. The commercial success of our future products in both domestic and international markets depends on whether such third-party coverage and reimbursement is available for our future products. Governmental payors, including Medicare and Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to manage their healthcare expenditures by limiting both coverage and the level of reimbursement of new drugs and biologics and, as a result, they may not cover or provide adequate reimbursement for our future products. These payors may not view our future products as cost-effective, and coverage and reimbursement may not be available to our customers or may not be sufficient to allow our future products to be marketed on a competitive basis. Third-party payors are exerting increasing influence on decisions regarding the use of, and coverage and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, are challenging the prices charged for medical products and services, and many third-party payors limit or delay coverage and reimbursement for newly approved healthcare products. In particular, third-party payors may limit the covered indications. Cost-control initiatives could cause us to decrease the price we might establish for products, which could result in lower than anticipated product revenues. If we decrease the prices for our product candidates because of competitive pressures or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer.

# Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our product candidates internationally.

We may seek a distribution and marketing partner for our unpartnered programs outside North America and may market future products in international markets. In order to market our product candidates in the European Economic Area, or EEA (which is comprised of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein), and many other foreign jurisdictions, we or our collaboration partners must obtain separate regulatory approvals. More concretely, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations:

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

National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

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

We have had limited interactions with foreign regulatory authorities, and the approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We or our collaboration partners may not be able to file for regulatory approvals and even if we or our collaboration partners file, we may not receive necessary approvals to commercialize our product candidates in any market.

## Healthcare reform measures could hinder or prevent our product candidates commercial success.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenues and profitability and the future revenues and

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profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that results in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, in March 2010, the President signed one of the most significant healthcare reform measures in decades, the Affordable Care Act. It contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and

fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The Affordable Care Act, among other things:

imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell branded prescription drugs ;

increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;

extends the rebate program to individuals enrolled in Medicaid managed care organizations;

addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

expands the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer s Medicaid rebate liability;

expands access to commercial health insurance coverage through new state-based health insurance marketplaces, or exchanges; and

requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation s automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future or

their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of health care may adversely affect:

our ability to set a price we believe is fair for our products;

our ability to generate revenues and achieve or maintain profitability; and

the availability of capital.

In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Governmental Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials and the drug approval process. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or

additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought. In, addition, because of the serious public health risks of high profile adverse safety events with certain products, the FDA may require, as a condition of approval, costly risk management programs which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising.

# Our therapeutic product candidates for which we intend to seek approval as biologic products may face competition from biosimilars and may face such competition sooner than anticipated.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Affordable Care Act, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as interchangeable, based on their similarity to existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The 12 years of data exclusivity afforded to biologics under the BPCIA does not prevent another company from developing a product that is highly similar to the innovative product, generating its own data, and seeking approval. Data exclusivity only assures that another company cannot rely upon data within the innovator s application to support the biosimilar product s application. The law is complex and is subject to continuing interpretation and implementation by the FDA. In January 2015, however, an FDA advisory panel recommended the approval of the first biosimilar drug in the United States, reflecting that the Agency is moving forward with a simplified pathway for biosimilars despite some uncertainty surrounding the specifics of the biosimilar regulatory pathway. As a result, its ultimate impact, implementation and meaning are subject to continuing uncertainty. The FDA s processes for biosimilars could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of data exclusivity. However, there is a risk that the U.S. Congress could amend the BPCIA to significantly shorten this exclusivity period, which has been proposed by President Obama. In addition President Obama has also proposed to prohibit additional periods of exclusivity due to minor changes in formulations, a practice known as evergreening. It is possible that Congress may take this or other measures to reduce or eliminate periods of exclusivity. There is also a risk that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In addition, foreign regulatory authorities may also provide for exclusivity periods for approved biological products. For example, biological products in Europe may be eligible for a 10-year period of exclusivity. Biosimilar products have been approved under the centralized procedure since 2006. The pathway allows sponsors of a biosimilar product to seek and obtain regulatory approval based in part on the clinical trial data of an originator product to which the biosimilar product has been demonstrated to be similar. In many cases, this allows biosimilar products to be brought to market without conducting the full suite of clinical trials typically required of originators. It is unclear whether we would face competition to our products in European markets sooner than anticipated.

# If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud

and abuse and patients rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, without limitation:

the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities that provide coding and billing advice to customers;

federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by physicians (as defined above) and their immediate family members and payments or other transfers of value to such physician owners. Manufacturers are required to report such data to the government by the 90<sup>th</sup> calendar day of each year;

the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The Affordable Care Act, among other things, also amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

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

# Risks Related to the Securities Market and Investment in Our Common Stock

# The price of our common stock may be volatile, and you may not be able to resell your shares at prices that are attractive to you.

There was no public market for our common stock prior to our initial public offering in July 2013, the trading volume of our common stock on The NASDAQ Global Select Market has been limited since then, and there can be no assurance that an active and liquid trading market for our common stock will be sustained. We cannot predict the extent to which investor interest in our company will sustain an active trading market on The NASDAQ Global Select Market or otherwise or how liquid that market might become. If an active and liquid market is not sustained, it may be difficult for stockholders to sell their shares of common stock at prices that are attractive to them, or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products, product candidates or technologies by using our shares of common stock as consideration. Stockholders may also be unable to sell their shares of common stock at prices that are attractive to them due to fluctuations in the market price of our common stock. Factors that could cause volatility in the market price of our common stock include, but are not limited to:

ability to commercialize or obtain regulatory approval for our product candidates, or delays in commercializing or obtaining regulatory approval;

results from, or any delays in, clinical trial programs relating to our product candidates, including the ongoing and planned clinical trials for demcizumab (OMP-21M18, anti-DLL4), tarextumab (OMP-59R5, anti-Notch2/3), vantictumab (OMP-18R5, anti-Fzd7), ipafricept (OMP-54F28, Fzd8-Fc), brontictuzumab (anti-Notch1, OMP-52M51), anti-DLL4/VEGF bispecific (OMP-305B83) and other product candidates;

failure to achieve anticipated research and development milestones and obtain the applicable milestone payments under our agreements with our collaboration partners, on our anticipated timelines or at all;

any need to suspend or discontinue clinical trials due to side effects or other safety risks, or any need to conduct studies on the long-term effects associated with the use of our product candidates;

announcements relating to future collaborations or our existing collaborations with GSK, Bayer and/or Celgene, including decisions regarding the exercise by GSK, Bayer and/or Celgene of their options or any termination by them of any development program under their partnerships with us;

manufacturing issues related to our product candidates for clinical trials or future products for commercialization;

commercial success and market acceptance of our product candidates following regulatory approval;

undesirable side effects caused by product candidates after they have entered the market;

ability to discover, develop and commercialize additional product candidates;

success of our competitors in discovering, developing or commercializing products;

strategic transactions undertaken by us;

additions or departures of key personnel;

product liability claims related to our clinical trials or product candidates;

prevailing economic conditions;

business disruptions caused by external factors, such as natural disasters and other crises;

disputes concerning our intellectual property or other proprietary rights;

FDA or other U.S. or foreign regulatory actions affecting us or our industry;

healthcare reform measures in the United States;

sales of our common stock by our officers, directors or significant stockholders;

future sales or issuances of equity or debt securities by us;

fluctuations in our quarterly operating results; and

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

# Together with their affiliates, our directors and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Based on the beneficial ownership of our outstanding common stock as of December 31, 2014, our officers and directors, together with their respective affiliates, beneficially own approximately 40.5% of our outstanding common stock. Accordingly, these stockholders will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors perception that conflicts of interest may exist or arise.

# We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including not being required to comply with the auditor attestation requirements of section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, Section 102 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we are choosing to opt out of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such

standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

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

If our existing stockholders or holders of our options or warrants sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. The perception in the market that these sales may occur could also cause the trading price of our common stock to decline. As of December 31, 2014, we have a total of 29,847,577 shares of common stock outstanding.

Our officers, directors and certain stockholders were also subject to lock-up agreements with OncoMed that expired as to 25% of the shares subject thereto at market close on January 17, 2014, as to another 50% at market close on July 17, 2014 and as to the remaining 25% at 11:59 pm Pacific Standard Time on January 17, 2015. As the lock-up agreements expired, these shares of common stock became eligible for sale in the public market. In addition, based on the number of shares subject to outstanding awards under our 2004 Stock Incentive Plan and 2013 Equity Incentive Award Plan, or available for issuance under our 2013 Equity Incentive Award Plan and Employee Stock Purchase Plan as of December 31, 2014, 4,369,174 shares of common stock that are either subject to outstanding options, outstanding but subject to vesting, or reserved for future issuance under our employee benefit plans will be eligible for sale in the public market, subject to, in the case of shares issued to directors, executive officers and other affiliates, the volume limitations under Rule 144 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Certain holders of 12,326,000 shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. In addition, our directors, executive officers and other affiliates may establish, and certain executive officers, directors and affiliates have established, programmed selling plans under Rule 10b5-1 of the Exchange Act, for the purpose of effecting sales of our common stock. Any sales of securities by these stockholders, or the perception that those sales may occur, including the entry into such programmed selling plans, could have a material adverse effect on the trading price of our common stock.

# Future sales and issuances of equity and debt securities could result in additional dilution to our stockholders and could place restrictions on our operations and assets, and such securities could have rights, preferences and privileges senior to those of our common stock.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may from time to time issue additional shares of common stock at a discount from the then-current trading price of our common stock. As a result, our common stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. Whether or not we issue additional shares of common stock at a discount, any issuance of common stock will, and any issuance of other equity securities or of options, warrants or other rights to purchase common stock may, result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to decline. New investors could also gain rights, preference and privileges senior to those of holders of our common stock, which could cause the price of our common stock to decline. Debt securities may also contain covenants that restrict our operational flexibility or impose liens or other restrictions on our assets, which could also cause the price of our common stock to decline.

Pursuant to our equity incentive plan, we are authorized to grant equity-based incentive awards to our employees, directors and consultants. As of December 31, 2014, there were 1,768,645 shares of our common stock reserved for future issuance under our 2013 Equity Incentive Award Plan, or the 2013 Plan. The number of shares of our common stock reserved for issuance under our 2013 Plan will be increased (i) from time to time by the number of shares of our common stock forfeited upon the expiration, cancellation, forfeiture, cash settlement or other termination of awards under our 2004 Stock Incentive Plan, or the 2004 Plan, and (ii) annually on the first day of the year by the lesser of (x) a number of additional shares of our common stock representing 4% of our then-outstanding shares of common stock on the last day of the immediately preceding fiscal year; (y) 1,500,000 shares of our common stock; and (z) such smaller number of shares as determined by our board of directors. As a result of this increase, an additional 1,193,903 shares of our common stock became available for future issuance under our 2013 Plan as of January 1, 2015. Future option grants and issuances of common stock under our 2013 Plan may have an adverse effect on the market price of our common stock.

In addition, pursuant to our 2013 Employee Stock Purchase Plan, or ESPP, as of December 31, 2014, 528,070 shares of our common stock were available for issuance to our employees. The number of shares of our common stock reserved for issuance under our ESPP will be increased annually on the first day of the year by the lesser of (x) a number of additional shares of our common stock representing 1% of our then-outstanding shares of common stock on the last day of the immediately preceding fiscal year; (y) 350,000 shares of our common stock; and (z) such number of shares as determined by our board of directors. As a result of this increase, an additional 298,475 shares of our common stock became available for future issuance under our ESPP as of January 1, 2015. Future issuances of common stock under our ESPP may have an adverse effect on the market price of our common stock.

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

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

variations in the level of expenses related to our product candidates or future development programs;

if any of our product candidates receives regulatory approval, the level of underlying demand for these product candidates and wholesalers buying patterns;

addition or termination of clinical trials or funding support;

our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements or existing such arrangements, such as our collaboration agreements with GSK, Bayer and Celgene;

any intellectual property infringement lawsuit or opposition, interference, or cancellation proceeding in which we may become involved; and

regulatory developments affecting our product candidates or those of our competitors. If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

# Provisions of our charter documents or Delaware law could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our stockholders, and could make it more difficult for you to change management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider

favorable, including transactions in which stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or remove our current management by making it more difficult to replace or remove our board of directors. These provisions include:

a classified board of directors so that not all directors are elected at one time;

a prohibition on stockholder action through written consent;

a requirement that special meetings of stockholders be called only by the board of directors, the chairman of the board of directors, the chief executive officer or, in the absence of a chief executive officer, the president;

an advance notice requirement for stockholder proposals and nominations;

the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine; and

a requirement of approval of not less than 66 2/3% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our certificate of incorporation.

In addition, Delaware law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with its affiliates, owns or within the last three years has owned 15% or more of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Delaware law may discourage, delay or prevent a change in control of our company. Furthermore, our amended and restated certificate of incorporation will specify that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders. We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in such action.

Provisions in our charter and other provisions of Delaware law could limit the price that investors are willing to pay in the future for shares of our common stock.

# Our employment agreements with our officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change of control of us, which could harm our financial condition or results.

Our officers are parties to employment agreements providing for aggregate cash payments of up to approximately \$5.5 million for severance and other benefits and acceleration of vesting of stock options with a value of approximately \$16.2 million (as of December 31, 2014) in the event of a termination of employment in connection with a change of control of us. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

# We do not anticipate paying any cash dividends on our capital stock in the foreseeable future; therefore capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We have never declared or paid cash dividends on our capital stock. We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. In addition, the terms of any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

# If securities or industry analysts publish inaccurate or unfavorable research about our business, or fail to publish research about our business regularly, our stock price and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. A limited number of securities and industry analysts currently publish research on our company. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of the analysts covering us or our business cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

# Changes in, or interpretations of, accounting rules and regulations could result in unfavorable accounting charges or require us to change our compensation policies.

Accounting methods and policies for biopharmaceutical companies, including policies governing revenue recognition, research and development and related expenses and accounting for stock-based compensation, are subject to further review, interpretation and guidance from relevant accounting authorities, including the SEC. Changes to, or interpretations of, accounting methods or policies may require us to reclassify, restate or otherwise change or revise our financial statements, including those contained in this filing.

Item 1B. UNRESOLVED STAFF COMMENTS None.

## Item 2. **PROPERTIES**

Our corporate headquarters are located in Redwood City, California, where we lease 45,690 square feet of office and laboratory space. In May 2006, we entered into a lease agreement for office and laboratory facilities in Redwood City, California. The lease term commenced in February 2007 for a period of seven years with options to extend the lease for two additional five-year terms. On December 22, 2010, the lease agreement was amended to extend the lease term for an additional five years, which expires in January 2019, with options to further extend the lease for two additional three-year terms.

We believe that our existing facilities are adequate for our current needs, as the facilities have sufficient laboratory space to house additional scientists to be hired as we expand. When our lease expires, we may exercise our renewal options or look for additional or alternate space for our operations and we believe that suitable additional or alternative space will be available in the future on commercially reasonable terms.

# Item 3. LEGAL PROCEEDINGS

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

Item 4. MINE SAFETY DISCLOSURES Not applicable.

# PART II

# ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock has been listed on The NASDAQ Global Select Market under the symbol OMED since July 18, 2013. Prior to that date, there was no public trading market for our common stock. The following table sets forth for the periods indicated the high and low sales price per share of our common stock as reported on The NASDAQ Global Select Market for the quarterly periods indicated:

	High	Low
Year Ended December 31, 2014:		
First Quarter	\$42.34	\$27.92
Second Quarter	\$ 34.75	\$18.75
Third Quarter	\$24.79	\$16.57
Fourth Quarter	\$ 22.50	\$16.91

	High	Low
Year Ended December 31, 2013:		
Third Quarter (from July 18, 2013)	\$31.00	\$15.25
Fourth Quarter	\$ 32.39	\$12.07
Common Stool		

# Holders of Common Stock

As of December 31, 2014, there were approximately 71 holders of record of our common stock. In addition, a substantially greater number of stockholders may be street name or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

# **Dividend Policy**

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors.

# **Performance Graph**

This graph is not soliciting material, is not deemed filed with the Securities and Exchange Commission, or SEC, and is not to be incorporated by reference into any filing of OncoMed Pharmaceuticals, Inc. under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following graph shows the total stockholder return of an investment of \$100 in cash at market close on July 18, 2013 (the first day of trading of our common stock), through December 31, 2014 for (i) our common stock, (ii) the NASDAQ Composite Index (U.S.) and (iii) the NASDAQ Biotechnology Index. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends, however no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

	7/18/13	9/30/13	12/31/13	3/31/14	6/30/14	9/30/14	12/31/14
OncoMed Pharmaceuticals, Inc.	100.00	56.33	108.61	123.80	85.72	69.65	80.06
NASDAQ Composite	100.00	111.61	124.09	123.38	129.53	132.03	139.16
NASDAQ Biotechnology	100.00	120.55	131.73	136.17	148.16	157.69	175.25
Depart Color of Unnerstand Committee							

## **Recent Sales of Unregistered Securities**

None.

# Use of Proceeds from Registered Securities

On July 23, 2013, we closed our IPO, in which we sold an aggregate of 5,520,000 shares of common stock at a price to the public of \$17.00 per share. The aggregate offering price for shares sold in the offering was \$93.9 million. The offer and sale of all of the shares in the IPO were registered under the Securities Act pursuant

to a registration statement on Form S-1 (File No. 333-181331), which was declared effective by the SEC on July 17, 2013. After deducting underwriting discounts, commissions and offering expenses paid or payable by us, the net proceeds from the offering were approximately \$82.7 million.

There has been no material change in the planned use of proceeds from our IPO as described in the Registration Statement. We invested the funds received in short-term, interest-bearing investment-grade securities and government securities.

## **Issuer Purchases of Equity Securities**

Not applicable

# ITEM 6. SELECTED FINANCIAL DATA.

The selected statement of operations data for the years ended December 31, 2014, 2013 and 2012 and the selected balance sheet data as of December 31, 2014 and 2013 are derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The selected statement of operations data for the years ended December 31, 2011 and 2010 and the selected balance sheet data as of December 31, 2012, 2011 and 2010 are derived from our audited financial statements which are not included in this Annual Report on Form 10-K.

Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the selected historical financial data below in conjunction with the section titled Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations and the financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

(In thousands, except share and per share data)	e data) Year Ended December 31,							
		2014		2013		2012	2011	2010
Statement of Operations Data:								
Revenue:								
Collaboration revenue related party	\$		\$		\$	15,970	\$ 3,365	\$ 13,363
Collaboration revenue		39,559		37,779		8,689	28,000	4,355
Grant revenue						22	44	
Total revenue		39,559		37,779		24,681	31,409	17,718
Operating expenses:								
Research and development <sup>(1)</sup>		76,430		50,048		39,893	40,058	39,703
General and administrative <sup>(1)</sup>		13,753		11,630		7,157	6,591	6,552
Total operating expenses		90,183		61,678		47,050	46,649	46,255
Loss from operations		(50,624)		(23,899)		(22,369)	(15,240)	(28,537)
Interest and other income (expense), net		105		(228)		134	206	1,522
				. ,				·
Loss before income taxes		(50,519)		(24,127)		(22,235)	(15,034)	(27,015)
Income tax (provision) benefit		509						,
Loss from operations Interest and other income (expense), net		(50,624) 105 (50,519)		(23,899) (228)		(22,369) 134	(15,240) 206	(28,53 1,52

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Net loss	\$	(50,010)	\$	(26,071)	\$	(22,235)	\$ (15,034)	\$ (	(27,015)
Net loss per common share, basic and diluted <sup>(2)</sup>	\$	(1.69)	\$	(1.93)	\$	(21.30)	\$ (15.40)	\$	(30.47)
Shares used to compute net loss per common share, basic and diluted <sup>(2)</sup>	29	,664,326	1	3,530,239	]	,044,059	976,299	8	86,484

(1) Included in the statement of operations data above are the following non-cash stock-based compensation expenses (in thousands):

		Year Ended December 31,						
	2014	2013	2012	2011	2010			
Research and development	\$3,600	\$ 957	\$497	\$499	\$453			
General and administrative	2,594	779	339	347	396			
Total stock-based compensation	\$6,194	\$1,736	\$836	\$846	\$ 849			

(2) See Notes 2 and 14 to our audited financial statements included elsewhere in this Annual Report on Form 10-K for an explanation of the calculations of our basic and diluted net loss per common share.

	As of December 31,							
(In thousands)	2014	2013	2012	2011	2010			
Balance Sheet Data:								
Cash, cash equivalents and short-term								
investments	\$ 231,966	\$ 316,194	\$ 66,239	\$ 100,410	\$ 114,400			
Working capital	202,264	256,727	51,256	82,096	103,753			
Total assets	247,842	333,685	79,768	107,205	129,894			
Notes payable				346	1,048			
Convertible preferred stock warrant								
liability			182	199	210			
Convertible preferred stock			182,773	182,773	182,773			
Accumulated deficit	(224,436)	(174,426)	(148,355)	(126,120)	(111,086)			
Total stockholders equity (deficit)	76,367	118,122	(144,227)	(122,934)	(108,839)			

# ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

You should read the following discussion in conjunction with our financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as may, could, will, would, should, expect, plan, anticipate, estimate, intend, believe, predict, seek, contemplate, potential or continue or the negative of these terms or other comparable terminology. These forward-looking statements, include, but are not limited to, the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs; our ability to advance product candidates into, and successfully complete, clinical trials; our receipt of future milestone payments and/or royalties, and the expected timing of such payments; our collaborators exercise of their license options; the commercialization of our product candidates; the implementation of our business model, strategic plans for our business, product candidates and technology; the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology; estimates of our expenses, future revenues, capital requirements and our needs for additional financing; the timing or likelihood of regulatory filings and approvals; our ability to maintain and establish collaborations or obtain additional government grant funding; our use of proceeds from our IPO; our financial performance; and developments relating to our competitors and our industry. These statements reflect our current views with respect to future events or our future financial performance, are based on assumptions, and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Item 1A. Risk Factors of this Annual Report on Form 10-K. These forward-looking statements speak only as of the date hereof. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

## Overview

OncoMed is a clinical development-stage biopharmaceutical company focused on discovering and developing first-in-class protein therapeutics targeting cancer stem cells (CSCs). Our approach has been to target CSCs, also known as tumor-initiating cells. Common cancer drugs target bulk tumor cells but have limited impact on CSCs, thereby providing a path for recurrence of the tumor. We utilize our proprietary technologies to identify and validate multiple potential targets critical to CSC self-renewal and differentiation. These targets are in pathways implicated in cancer biology and stem cell biology, including the Notch, Wnt, RSPO-LGR and other fundamental CSC pathways. We believe our product candidates are quite distinct from current generations of chemotherapies and targeted therapies, and have the potential to significantly impact cancer treatment and the clinical outcome of patients with cancer. All of our product candidates were discovered internally in our own research laboratories.

We have six anti-CSC product candidates in clinical development and have treated over 500 patients across all of our clinical trials. Additionally, we have an antibody product candidate, anti-RSPO3 (OMP-131R10) in preclinical development with an Investigational New Drug, or IND, filing planned for the first half of 2015. We are also pursuing discovery of additional novel anti-CSC and immuno-oncology product candidates. The first candidate, demcizumab (anti-DLL4, OMP-21M18), has completed a single-agent Phase Ia safety and dose escalation trial and is currently in Phase Ib combination therapy trials in patients with non-small cell lung cancer (with carboplatin and pemetrexed) and pancreatic cancer (with gemcitabine and Abraxane<sup>®</sup>) and a Phase Ib/II trial combining demcizumab with paclitaxel in ovarian cancer. We initiated a Phase II randomized trial of demcizumab in non-small cell lung cancer (with

carboplatin and pemetrexed) in February 2015 and initiated and

are planning to enroll patients in a Phase II randomized trial of demcizumab in pancreatic cancer (with gemcitabine and Abraxane<sup>®</sup>) in 2015. The second candidate, tarextumab (anti-Notch2/3, OMP-59R5), completed a Phase Ia safety and dose escalation trial and is in the Phase II portion of a Phase Ib/II trial in pancreatic cancer (with gemcitabine and Abraxane<sup>®</sup>) and in a second Phase Ib/II trial in small cell lung cancer (with etoposide and platinum chemotherapy). The third candidate, vantictumab (anti-Fzd7, OMP-18R5), has completed a single-agent Phase Ia trial and is currently in three separate Phase Ib combination trials, one trial each in patients with breast cancer (with paclitaxel), pancreatic cancer (with gemcitabine and Abraxane®) and non-small cell lung cancer (with docetaxel). The fourth candidate, ipafricept (Fzd8-Fc, OMP-54F28), is in a single-agent Phase Ia safety and dose escalation trial in solid tumor malignancies, and is currently in three separate Phase Ib combination trials, one trial each in patients with ovarian cancer (with carboplatin and paclitaxel), pancreatic cancer (with gemcitabine and Abraxane®) and hepatocellular carcinoma (with sorafenib). The fifth candidate, brontictuzumab (anti-Notch1, OMP-52M51), is in two single-agent Phase Ia safety and dose escalation trials in hematologic and solid tumor malignancies. Clinical trials for all six of these product candidates are ongoing, with the intent of gathering additional data required to proceed to later stage clinical trials and product approval. In addition, we recently filed an IND application for a sixth product candidate, anti-DLL4/VEGF bispecific (OMP-305B83), and are currently enrolling patients in a single-agent Phase Ia trial in advanced solid tumor patients. We plan to file an IND application for a seventh product candidate, anti-RSPO3 (OMP-131R10), in the first half of 2015.

# **Financial Operations Overview**

# Revenue

We have not generated any revenue from product sales. Our revenue to date has been primarily derived from upfront payments and development milestones received from GSK, Bayer and Celgene. We recognize revenue from upfront payments ratably over the term of our estimated period of performance under the agreements. In addition to receiving upfront payments, we may also be entitled to milestone and other contingent payments upon achieving predefined objectives or the exercise of options for specified programs by our strategic partners. Such payments are recorded as revenue when we achieve the underlying milestone if there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved.

The following table summarizes our revenue for the years ended December 31, 2014, 2013 and 2012, which is related to the recognition of upfront payments and milestone payments received under our various collaboration arrangements:

	Year Ended December 31,				
(In thousands)	2014	2013	2012		
GSK:					
Recognition of upfront payment	\$ 1,248	\$ 1,971	\$ 1,970		
Milestone revenue	11,000		14,000		
GSK total.	12,248	1,971	15,970		
Bayer:					
Recognition of upfront payment	9,756	9,756	8,689		
Milestone revenue	2,000	25,000			

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Bayer total	11,756	34,756	8,689				
Celgene:							
Recognition of upfront payment	13,055	1,052					
Milestone revenue	2,500						
Celgene total	15,555	1,052					
Grant revenue			22				
Total revenue	\$ 39,559	\$ 37,779	\$24,681				

We expect that any revenue we generate will fluctuate from period to period as a result of the timing and amount of milestones and other payments from our collaborations with GSK, Bayer and Celgene or any new collaboration we may enter into, and any new government grants that we may receive in the future.

# **Research and Development**

Research and development expenses represent costs incurred to conduct research such as the discovery and development of clinical candidates for GSK, Bayer and Celgene as well as discovery and development of our proprietary un-partnered product candidates. We expense all research and development costs as they are incurred. Our research and development expenses consist of employee salaries and related benefits, including stock-based compensation, third-party contract costs relating to research, manufacturing, preclinical studies, clinical trial activities, laboratory consumables, and allocated facility costs.

At any point in time, we typically have various early stage research and drug discovery projects. Our internal resources, employees and infrastructure are not directly tied to any one research or drug discovery project and are typically deployed across multiple projects. As such, we do not maintain information regarding these costs incurred for these early stage research and drug discovery programs on a project-specific basis.

The following table summarizes our research and development expenses for the years ended December 31, 2014, 2013 and 2012. The internal costs include personnel, facility costs, laboratory consumables and discovery and research related activities associated with our pipeline. The external program costs reflect external costs attributable to our clinical development candidates and preclinical candidates selected for further development. Such expenses include third-party contract costs relating to manufacturing, clinical trial activities, translational medicine and toxicology activities.

	Year Ended December 31,				
(In thousands)	2014	2013	2012		
Internal Costs:					
Cancer biology, pathology and toxicology	\$ 14,619	\$11,822	\$11,978		
Molecular and cellular biology	7,283	6,499	6,434		
Process development and manufacturing	5,445	4,611	5,326		
Product development	7,790	5,352	3,469		
Subtotal internal costs	35,137	28,284	27,207		
External Program Costs:					
Manufacturing	14,345	7,129	3,725		
Clinical	21,799	11,229	4,935		
Translational medicine	2,670	2,309	1,340		
Toxicology	2,479	1,097	2,686		
Subtotal external program costs	41,293	21,764	12,686		
Total research and development expense	\$76,430	\$ 50,048	\$ 39,893		

Our research and development expenses have increased as we have progressed our product candidates, and we expect that these expenses may continue to increase with continued pipeline advancement and conduct of our development activities under our agreements with GSK, Bayer and Celgene. The process of conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time-consuming. We or our partners may never succeed in achieving marketing approval for any of our product candidates. The probability of success of each product candidate may be affected by numerous factors, including preclinical data, clinical data, competition, manufacturing capability and commercial viability.

For the biologic programs covered under our strategic alliances with GSK, Bayer and Celgene, we are responsible for development of each product candidate prior to the exercise of GSK s, Bayer s or Celgene s

option to exclusively license such product candidate. GSK and Bayer may exercise such an option on a product-by-product basis, and Celgene may exercise such option on a program-by-program basis, in each case, during certain time periods, which for GSK, Bayer and Celgene are through the end of certain Phase I or Phase II trials, depending on the applicable product candidate or program. If GSK exercises its option for a product candidate, all further development obligations for such product candidate are assumed by GSK. If Bayer exercises its option for a product candidate, all development obligations for such product candidate after such product candidate reaches a defined early development stage are assumed by Bayer. With respect to biologic therapeutic programs, if Celgene exercises its option for a given program, we will have the option to co-develop and co-commercialize up to five of the six such product candidates in the United States. If we do so, we will be responsible for a one-third share of the global development costs of such product candidates, with Celgene bearing the remaining two-thirds of such costs, and we will be entitled to participate in the commercialization activities for such product candidates in the United States, and to share 50% of all profits and losses arising from U.S. sales of such product candidates. Otherwise, we may enter into a license agreement with Celgene for such product candidate whereupon Celgene would be responsible for all further development costs. In addition, if Celgene exercises its option under the Celgene Agreement to further develop and commercialize small molecule therapeutics directed to targets in an undisclosed pathway, all further development obligations with respect to the small molecule therapeutic program will be assumed by Celgene.

Most of our product development programs are at an early stage; therefore, the successful development of our product candidates is highly uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. Given the uncertainty associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical trials of our product candidates or if and to what extent we will generate revenues from the commercialization and sale of any of our product candidates. We anticipate that we and our strategic alliance partners will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment as to each product candidate s commercial potential. We may need to raise additional capital or may seek additional strategic alliances in the future in order to complete the development and commercialization of our product candidates.

# General and Administrative

Our general and administrative expenses consist primarily of personnel costs, allocated facilities costs and other expenses for outside professional services, including legal, human resource, audit, tax and accounting services. Personnel costs consist of salaries, benefits and stock-based compensation. Since becoming a public company in 2013, we have incurred and expect to continue to incur additional expenses required of public companies, including costs to comply with the rules and regulations applicable to companies listed on a national securities exchange and costs related to compliance and reporting obligations pursuant to the rules and regulations of the SEC. Other related public company costs include increased expenses for additional insurance, investor relations and other needs for human resources and professional services.

# Interest and Other Income (Expense), net

Interest income consists primarily of interest received on our cash, cash equivalents and short-term investments balances.

Prior to our IPO in July 2013, other income (expense), net included gains and losses from the remeasurement of our liabilities related to our convertible preferred stock warrants. The outstanding preferred stock warrants were converted to common stock warrants upon the completion of the IPO and were no longer subject to remeasurement following

this time. There were no warrants outstanding during the year ended December 31, 2014.

# **Provision for Income Taxes**

For the year ended December 31, 2014, we recorded an income tax benefit of \$0.5 million due primarily to the recognition of additional tax attributes that can offset alternative minimum tax as a result of the carryback. For the year ended December 31, 2013, we recorded an income tax provision of \$1.9 million due primarily to the accelerated recognition of certain upfront payments for tax purposes that could not be fully offset by tax attributes. For the year ended December 31, 2012 we did not record an income tax provision on pre-tax income because we incurred taxable losses for both state and federal income tax purposes.

We estimate our income tax provision, including deferred tax assets and liabilities, based on significant management judgment. We evaluate the realization of all or a portion of our deferred tax assets on a quarterly basis. We record a valuation allowance to reduce our deferred tax assets to the amounts that are more likely than not to be realized. We consider future taxable income, ongoing tax planning strategies and our historical financial performance in assessing the need for a valuation allowance. If we expect to realize deferred tax assets for which we have previously recorded a valuation allowance, we will reduce the valuation allowance in the period in which such determination is first made. Our future effective income tax rate may be affected by such factors as changes in tax laws, regulations or rates, changing interpretation of existing laws or regulations, the impact of accounting for stock-based compensation and changes in overall levels of income before tax.

We record liabilities related to uncertain tax positions in accordance with the guidance that clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

At December 31, 2014 and 2013, we had total federal and state unrecognized tax benefits of \$5.4 million and \$4.5 million, respectively. Of the total unrecognized tax benefits, \$4.6 million and \$3.7 million at December 31, 2014 and 2013, respectively, if recognized, in the absence of a valuation allowance, would reduce our effective tax rate in the period of recognition. As of December 31, 2014, we believe that it is reasonably possible that our unrecognized tax benefits will not significantly change in the next 12 months.

We file federal income tax return and California franchise tax return in the United States. For federal and California tax purposes, the statute of limitations is open for 2004 and onwards.

# **Critical Accounting Polices and Estimates**

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, costs and expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. In many instances, we could have reasonably used different accounting estimates, and in other instances changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ significantly from the estimates made by our management. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management s judgments and estimates.

# **Revenue Recognition**

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We generate revenue from two principal sources: (1) collaborative research and development agreements with pharmaceutical companies and (2) government contracts and grants. Under collaboration agreements, we may receive non-refundable upfront payments, funding for research and development services, milestones, other contingent payments and royalties. In assessing the appropriate revenue recognition related to a collaboration

agreement, we first determine whether an arrangement includes multiple elements, such as the delivery of intellectual property rights and research and development services. These multiple element arrangements are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting. The determination of stand-alone value is generally based on whether any deliverable has stand-alone value to the customer. We determine how to allocate arrangement consideration to identified units of accounting based on the selling price hierarchy provided under the relevant guidance. The estimated fair value of deliverables under the arrangement may be derived using a best estimate of selling price if vendor-specific objective evidence and third-party evidence are not available. Deliverables under the arrangement will be separate units of accounting provided that a delivered item has value to the customer on a stand-alone basis and if the arrangement does not include a general right of return relative to the delivered item and delivery or performance of the undelivered items is considered probably and substantially in the control of the vendor.

Typically, we have not granted licenses to collaborators at the beginning of our arrangements and thus there are no delivered items separate from the research and development services provided. As such, upfront payments are recorded as deferred revenue in the balance sheet and are recognized as collaboration revenue over the estimated period of performance that is consistent with the terms of the research and development obligations contained in the collaboration agreement. We regularly review the estimated period of performance based on the progress made under each arrangement. Our estimates of our performance period may change over the course of the research term. Such a change could have a material impact on the amount of revenue we record in future periods.

When we enter into an amendment to a collaboration agreement, we evaluate the terms of the amendment relative to the entire arrangement to determine if it constitutes a material modification to the original agreement for financial reporting purposes. We exercise judgment in determining if an amendment is deemed to be a material modification and consider whether there is a change in total consideration, contracted deliverables, the period of the arrangement or the delivery schedule.

Other contingent payments received for which payment is contingent solely on the results of a collaborative partner s performance (e.g., bonus payments) are not accounted for using the milestone method. Such bonus payments will be recognized as revenue when collectability is reasonably assured.

Options are considered substantive if, at the inception of the arrangement, we are at risk as to whether the collaboration partner will choose to exercise the option. Factors that we consider in evaluating whether an option is substantive include the overall objective of the arrangement, the benefit the collaborator might obtain from the arrangement without exercising the option, the cost to exercise the option and the likelihood that the option will be exercised. For arrangements under which an option is considered substantive, we do not consider the item underlying the option to be a deliverable at the inception of the arrangement and the associated option fees are not included in allocable arrangement consideration, assuming the option is not priced at a significant and incremental discount. Conversely, for arrangement and a corresponding amount would be included in allocable arrangement consideration. All of the options included in our collaboration arrangements have been determined to be substantive, and none of the options are priced at a significant and incremental discount.

We recognize revenue under government contracts and grants when the work is performed or the expenses are incurred. Any amounts received in advance of performance are recorded as deferred revenue until earned.

# Preclinical Studies and Clinical Trial Accruals

We estimate our preclinical studies and clinical trial expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations that conduct these activities on our behalf. In recording service fees, we estimate the time period over which the related services will be performed and

compare the level of effort expended through the end of each period to the cumulative expenses recorded and payments made for such services and, as appropriate, accrue additional service fees or defer any non-refundable advance payments until the related services are performed. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust our accrual or deferred advance payment accordingly. If we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. To date, we have not experienced significant changes in our estimates of preclinical studies and clinical trial accruals.

#### Stock-Based Compensation

We recognize compensation costs related to stock options granted to employees based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. Stock-based compensation expense was \$6.2 million, \$1.7 million and \$0.8 million for the years ended December 31, 2014, 2013 and 2012.

The Black-Scholes option-pricing model requires the use of highly subjective and complex assumptions which determine the fair value of stock-based awards, including the expected term and the price volatility of the underlying stock. These assumptions include:

*Expected term* The expected term represents the period that the stock-based awards are expected to be outstanding. We used the simplified method to determine the expected terms as provided by the SEC. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the options.

*Volatility* The volatility is derived from historical volatilities of unrelated publicly listed biopharmaceutical companies over a period approximately equal to the expected term of the award because we have limited information on the volatility of our common stock due to no significant trading history. The comparable companies were chosen based on their similar size, stage in the life cycle, and financial leverage in comparison to us.

*Risk-free interest rate* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.

*Expected dividend* The expected dividend is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on our common stock.

In addition to the assumptions used in the Black-Scholes option-pricing model, we must also estimate a forfeiture rate to calculate the stock-based compensation for our awards. We continue to use judgment in evaluating the expected volatility, expected terms and forfeiture rates used for our stock-based compensation calculations on a prospective basis. As we continue to accumulate additional data related to our common stock, we may have refinements to the estimates of our expected volatility, expected terms, and forfeiture rates, which could materially impact our future

stock-based compensation expense.

Prior to our IPO in July 2013, our board of directors, with the assistance of management and independent consultants, performed fair value analyses for the valuation of our common stock. For grants made on dates for which there was no contemporaneous valuation to utilize in setting the exercise price of our common stock, and given the absence of an active market for our common stock prior to our IPO in July 2013, our board of directors determined the fair value of our common stock on the date of grant based on several factors, including:

progress of our research and development efforts;

our operating results and financial condition, including our levels of available capital resources;

rights and preferences of our common stock compared to the rights and preferences of our other outstanding equity securities;

material risks related to our business;

equity market conditions affecting comparable public companies;

the likelihood of achieving a liquidity event for the shares of common stock, such as an initial public offering given prevailing market and biotechnology sector conditions; and

that the grants involved illiquid securities in a private company. For the options granted subsequent to our July 2013 IPO, the exercise price of stock options is equal to the closing market price of the underlying common stock on the grant date.

#### **Results of Operations**

#### Comparison of the Years Ended December 31, 2014 and 2013

(In thousands)	Year Ended	Dollar Change	
Revenue:			g-
Collaboration revenue	\$ 39,559	\$ 37,779	\$ 1,780
Total revenue	39,559	37,779	1,780
Operating expenses:			
Research and development	76,430	50,048	26,382
General and administrative	13,753	11,630	2,123
Total operating expenses	90,183	61,678	28,505
Loss from operations	(50,624)	(23,899)	(26,725)
Interest and other income (expense), net	105	(228)	333
Loss before income taxes	(50,519)	(24,127)	(26,392)
Income tax (provision) benefit	509	(1,944)	2,453
Net loss	\$ (50,010)	\$ (26,071)	\$ (23,939)

#### Revenue

Total revenue for the year ended December 31, 2014 was \$39.6 million, an increase of \$1.8 million, or 5%, compared to total revenue of \$37.8 million for the year ended December 31, 2013. In 2014, we recognized collaboration revenue

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from payments previously deferred from GSK that resulted from the achievement of a \$11.0 million development milestone for dosing the first patient in the Phase II portion of the tarextumab ALPINE clinical trial. In 2014 we recognized a \$2.5 million milestone for the designation of an anti-RSPO3 antibody as a clinical candidate under our collaboration with Celgene. We achieved a \$2.0 million milestone for the commencement of preclinical development stemming from our small molecule collaboration with Bayer in 2014 compared to \$10.0 million and \$15.0 million dose escalation milestones achieved in 2013 for the vantictumab (anti-Fzd7, OMP-18R5) and the ipafricept (Fzd8-Fc, OMP-54F28) programs respectively. Due to the amortization of upfront fees received in 2013 under the Celgene agreement, we recognized \$13.1 million of collaboration revenues during 2014 compared to \$1.1 million in 2013. The amortization of upfront fees from our partnership with Bayer remained constant at \$9.8 million in 2014 and 2013. In addition, we recognized \$1.2 million in 2014 from the amortization of upfront fees under the GSK agreement compared to \$2.0 million in 2013. This decrease is a result of a revision to the estimated period of performance for the GSK collaboration at the end of 2013, thereby extending the amortization of the upfront payment for an additional year to June 2016.

# **Research and Development**

Research and development expenses were \$76.4 million for the year ended December 31, 2014, an increase of \$26.4 million, or 53%, compared to research and development expenses of \$50.0 million for the year ended December 31, 2013. The increase was comprised of a \$19.5 million increase in our external program costs and a \$6.9 million increase in our internal program costs.

The increase in our external program costs of \$19.5 million was primarily due to an increase of \$10.6 million in clinical costs driven by the start of two Phase II programs and, the preparation for two additional Phase II programs, and higher patient enrollment for various programs. There was also an increase of \$7.2 million in manufacturing costs primarily related to the production of tarextumab (anti-Notch2/3, OMP-59R5), ipafricept (Fzd8-Fc, OMP-54F28) and anti-RSPO3 (OMP-131R10). Costs of toxicology studies primarily related to the anti-RSPO3 program increased by \$0.4 million. We expect that our external program costs will increase in future periods as we continue to advance our pipeline, enroll patients in various programs and initiate new clinical trials, including more costly Phase II studies.

The increase in our internal costs of \$6.9 million was primarily due to an increase of \$4.9 million in personnel costs related to stock-based compensation, including a new restricted stock unit grant and a full year of Employee Stock Purchase Plan and IPO grant expenses in 2014, and also an increase in headcount. The remaining increase of \$2.0 million was due to an increase in consulting and research supplies.

#### General and Administrative

General and administrative expenses were \$13.8 million for the year ended December 31, 2014, an increase of \$2.1 million, or 18%, compared to general and administrative expenses of \$11.6 million for the year ended December 31, 2013. The increase is primarily due to higher employee related costs of \$2.0 million related to stock-based compensation, including a new restricted stock unit grant, non-employee Board of Directors grants, and a full year of Employee Stock Purchase Plan and IPO grant expenses in 2014, and also an increase in headcount. We also incurred higher insurance and consulting fees of \$0.8 million, which was offset by lower legal fees of \$0.7 million primarily associated with activities related to collaboration agreements.

# Interest and Other Income (Expense), net

Interest and other income (expense), net was \$0.1 million for the year ended December 31, 2014, a change of \$0.3 million, compared to interest and other income (expense), net of \$(0.2) million for the year ended December 31, 2013. The change was primarily due to warrant remeasurement ending during 2013. The outstanding preferred stock warrants were converted to common stock warrants upon the completion of the IPO in July 2013 and were no longer subject to remeasurement following this time. There were no warrants outstanding during the year ended December 31, 2014.

# Comparison of the Years Ended December 31, 2013 and 2012

	Year Ended	Year Ended December 31,				
(In thousands)	2013		2012	Change		
Revenue:						
Collaboration revenue related party	\$	\$	15,970	\$(15,970)		
Collaboration revenue	37,779		8,689	29,090		
Grant revenue			22	(22)		
Total revenue	37,779		24,681	13,098		
Operating expenses:						
Research and development	50,048		39,893	10,155		
General and administrative	11,630		7,157	4,473		
Total operating expenses	61,678		47,050	14,628		
Loss from operations	(23,899)		(22,369)	(1,530)		
Interest and other income, net	(228)		140	(368)		
Interest expense			(6)	6		
Loss before income taxes	(24,127)		(22,235)	(1,892)		
Income tax (provision) benefit	(1,944)			(1,944)		
Net loss	\$ (26,071)	\$	(22,235)	\$ (3,836)		

#### Revenue

Total revenue for the year ended December 31, 2013 was \$37.8 million, an increase of \$13.1 million, or 53%, compared to total revenue of \$24.7 million for the year ended December 31, 2012. This increase is mainly due to collaboration revenue from Bayer that resulted from achievement of a \$10.0 million development milestone for dose escalation of vantictumab (OMP-18R5) in Phase Ia as well as agreement on the Phase Ib trial design in August 2013, and a \$15.0 million development milestone related to Phase I dose escalation in our Fzd8-Fc program. We recognized revenue amounting to \$9.8 million in 2013 from the amortization of the upfront fees under the Bayer agreement compared to \$8.7 million in 2012. In addition, we recognized revenue amounting to \$1.1 million from the amortization of the upfront fees received in 2013 under the Celgene agreement. These increases are partially offset due to the timing of collaboration revenue under the GSK agreement received in 2012 from the achievement of milestones, which included \$5.0 million related to proof-of-principle for the tarextumab (anti-Notch2/3, OMP-59R5) program, \$5.0 million related to IND filing for brontictuzumab (anti-Notch1, OMP-52M51) and \$4.0 million related to the initiation of Phase I for brontictuzumab (anti-Notch1, OMP-52M51). There were no milestones achieved under the GSK agreement in 2013. We initiated the second of two Phase Ib/II trials for tarextumab (anti-Notch2/3, OMP-59R5) in 2013, triggering a cash payment of \$8.0 million from GSK, which was recorded as deferred revenue.

#### **Research and Development**

Research and development expenses were \$50.0 million for the year ended December 31, 2013, an increase of \$10.2 million, or 25%, compared to research and development expenses of \$39.9 million for the year ended December 31,

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2012. The increase was comprised of a \$9.1 million increase in our external program costs and a \$1.1 million increase in our internal program cost.

The increase in our external program costs of \$9.1 million was primarily due to an increase of \$7.3 million in clinical costs resulting from higher patient enrollment for various programs, and an increase of \$3.4 million in manufacturing costs primarily related to the production of vantictumab (OMP-18R5). These increases were partially offset by a decrease of \$1.6 million in toxicology studies primarily related to the brontictuzumab (anti-Notch1, OMP-52M51) program. We expect that our external program costs will increase in future periods as we continue to enroll patients in various programs and initiate new clinical trials.

The increase in our internal costs of \$1.1 million was primarily due to an increase of \$2.4 million in personnel costs due to an increase in headcount as well as a bonus payment and option awards and an increase of \$0.2 million in facility and office related expenses. These increases were partially offset by the decrease of \$1.5 million in contracted services.

# General and Administrative

General and administrative expenses were \$11.6 million for the year ended December 31, 2013, an increase of \$4.5 million, or 63%, compared to general and administrative expenses of \$7.2 million for the year ended December 31, 2012. The increase is primarily due to higher employee related costs of \$1.4 million due to bonus payment and option awards, higher legal fees of \$1.6 million associated with SEC filings and collaborations, and higher consulting fees from third party vendors of \$1.1 million.

#### Interest and Other Income (Expense), net

Interest and other income (expense), net was \$(0.2) million for the year ended December 31, 2013, a decrease of \$0.4 million, compared to interest and other income (expense), net of \$0.1 million for the year ended December 31, 2012. The change was primarily due to the increase in the fair value of the convertible preferred stock warrant liability in 2013.

# Liquidity and Capital Resources

As of December 31, 2014, we had cash, cash equivalents, and short term investments totaling \$232.0 million. In connection with our IPO in July 2013, we received cash proceeds of \$82.7 million, net of underwriters discounts and commissions and expenses paid by us. Prior to the IPO, we funded our operations primarily with cash flows from the sales of our convertible preferred stock in private placements and from the upfront and milestone payments and other collaboration related payments received under the GSK and Bayer collaborative arrangements. In December 2013, we signed a collaboration agreement with Celgene, which will provide additional sources of funds through collaboration related payments.

Our primary uses of cash are to fund operating expenses, primarily related to research and development product candidate expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We believe that our existing cash, cash equivalents and short-term investments as of December 31, 2014 will be sufficient to meet our anticipated cash requirements at least through 2016, even without taking into account potential future milestone payments to us. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

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

the achievement of milestones and/or exercise of options under our agreements with GSK, Bayer and Celgene;

the initiation, progress, timing and completion of preclinical studies and clinical trials for our product candidates and potential product candidates;

the number and characteristics of product candidates that we pursue;

the progress, costs and results of our clinical trials;

the outcome, timing and cost of regulatory approvals;

delays that may be caused by changing regulatory requirements;

funding we may receive under any new collaborations we may enter into or new government grants we may be awarded in the future;

the costs and timing of hiring new employees to support our continued growth; and

the costs and timing of procuring clinical supplies of our product candidates. The following table summarizes our cash flows for the periods indicated (in thousands):

	Year Ended December 31,				
	2014 2013 2012				
Cash provided by (used in) operating activities	\$(84,511)	\$144,544	\$ (33,345)		
Cash provided by (used in) investing activities	(98,364)	(57,794)	38,013		
Cash provided by (used in) financing activities	2,082	105,918	(190)		
Cash Flows from Operating Activities					

Cash used in operating activities for the year ended December 31, 2014 was \$84.5 million. The net loss of \$50.0 million was offset by non-cash charges of \$1.4 million for depreciation and amortization and \$6.2 million for stock-based compensation. The change in net operating assets of \$42.1 million was due primarily to a decrease of \$35.1 million in deferred revenue due to the recognition of revenue for the achievement of a \$11.0 million development milestone for dosing the first patient in the Phase 2 portion of the anti-Notch 2/3 ALPINE clinical trial in the second indication of our tarextumab (anti-Notch2/3, OMP-59R5) program and the amortization of upfront and milestone payments from the GSK, Bayer and Celgene arrangements in the amount of \$24.1 million. There was also a \$7.1 million decrease in tax receivable, \$10.8 million in income tax payable, \$1.2 million in prepaid and other assets, and \$0.6 million in deferred rent. These were offset by a \$2.4 million increase in accounts payable and accrued liabilities as a result of the timing of our payments as well as a \$10.3 million increase in deferred tax asset.

Cash provided by operating activities for the year ended December 31, 2013 was \$144.5 million. The net loss of \$26.1 million was offset by non-cash charges of \$1.4 million for depreciation and amortization, \$1.7 million for stock-based compensation and \$0.3 million for the revaluation of the convertible preferred stock warrant liability. The change in net operating assets of \$167.3 million was due to the collection of a related party receivable from GSK of \$4.0 million and an increase in accounts payable and accrued liabilities of \$23.6 million as a result of the timing of our payments. Deferred revenue increased by \$151.9 million due to receipt of \$8.0 million payment from GSK related to the initiation of the Phase Ib clinical trial in the second indication of our tarextumab program and receipt of \$155.0 million upfront payment and \$1.7 million equity investment premium from Celgene related to the collaboration agreement entered in December 2013, partially offset by the amortization of upfront and milestone payments from the GSK, Bayer and Celgene arrangements in the amount of \$12.8 million.

Cash used in operating activities for the year ended December 31, 2012 was \$33.3 million. The net loss of \$22.2 million was partially offset by non-cash charges of \$1.4 million for depreciation and amortization and \$0.8 million for stock-based compensation. The decrease in net operating assets of \$13.2 million was due to the decrease in deferred revenue of \$2.2 million. The decrease in deferred revenue included the amortization of upfront and milestone payments from the GSK and Bayer arrangements in the amount of \$10.7 million, partially offset by the advance payment for a future development milestone of \$3.0 million related to the Phase Ib trial for our tarextumab program with GSK, a payment of \$5.0 million related to the achievement of an IND acceptance for the Fzd8-Fc

program with Bayer and additional funding of \$0.5 million for development activities under the GSK agreement. In addition, accounts payable and accrued liabilities decreased by \$3.2 million as a result of the timing of our payments. Other assets increased by \$2.9 million due to the capitalization of IPO costs related to this offering. Receivables from related parties also increased by \$4.0 million primarily related to achievement of a development milestone under the collaboration agreement with GSK for the initiation of Phase I for brontictuzumab (anti-Notch1, OMP-52M51).

#### **Cash Flows from Investing Activities**

Cash used in investing activities was comprised of maturities of short-term investments amounting to \$340.3 million, \$75.3 million and \$112.7 million, offset by purchases of short-term investments amounting to \$436.9 million, \$132.5 million and \$73.9 million and our acquisition of property and equipment amounting to \$1.8 million, \$0.6 million and \$0.7 million for the years ended December 31, 2014, 2013 and 2012, respectively.

#### Cash Flows from Financing Activities

Cash provided by financing activities of \$2.1 million for the year ended December 31, 2014 was due to the proceeds of \$1.1 million from the issuance of common stock upon the exercise of stock options and \$1.0 million from purchases of common stock under our ESPP.

Cash provided by financing activities for the year ended December 31, 2013 was mainly due to the net proceeds of \$85.1 million from the IPO and \$20.5 million from the purchase of common stock by Celgene in connection with the research and collaboration agreement we entered into with Celgene in December 2013.

Cash used in financing activities for the year ended December 31, 2012 of \$0.2 million was primarily related to repayments on our borrowings of \$0.3 million, partially offset by proceeds of \$0.1 million from the issuance of common stock upon the exercise of stock options.

#### **Contractual Obligations and Other Commitments**

The following table summarizes our contractual obligations as of December 31, 2014 (in thousands):

	Payments Due by Period							
Less than 1 to 3 3 to 5 M								
Contractual Obligations:	1 year	Years	Years	5 Years	Total			
Operating leases <sup>(1)</sup>	\$ 1,942	\$6,186	\$ 177	\$	\$ 8,305			

(1) Operating leases include total future minimum rent payments under non-cancelable operating lease agreements. **Off-Balance Sheet Arrangements** 

As of December 31, 2014, we did not have any off-balance sheet arrangements or any holdings in variable interest entities.

#### **Recent Accounting Pronouncements**

In June 2014, FASB issued final guidance that a performance target that affects vesting of a share-based payment and that could be achieved after the requisite service period is a performance condition under ASC 718, Compensation Stock Compensation. As a result, the target is not reflected in the estimation of the award s grant date fair value. Compensation cost for such an award would be recognized over the required service period, if it is probable that the performance condition will be achieved. The guidance is effective for all entities for annual periods beginning after December 15, 2015 and interim periods within those annual periods. The guidance should be applied on a

prospective basis to awards that are granted or modified on or after the effective date. We do not believe the adoption of this guidance will have a material impact on our financial statements.

In May 2014, the FASB and the International Accounting Standards Board issued ASU 2014-09. This ASU affects any entity that either enters into contracts with customers to transfer goods and services or enters into contracts for the transfer of nonfinancial assets. This ASU will supersede the revenue recognition requirements in Topic 605, and most industry specific guidance. The standard s core principle is that a company will recognize

revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under today s guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective for us for annual periods beginning after December 15, 2016, including interim periods within that period. Entities can choose to apply the standard using either the full retrospective approach or a modified retrospective approach. Entities electing the full retrospective adoption will apply the standard to each period presented in the financial statements. This means that entities will have to apply the new guidance as if it had been in effect since the inception of all its contracts with customers presented in the financial statements. Entities that elect the modified retrospective approach will apply the guidance retrospectively only to the most current period presented in the financial statements. This means that entities will have to recognize the cumulative effect of initially applying the new standard as an adjustment to the opening balance of retained earnings at the date of initial application. Early adoption is not permitted under U.S. GAAP. We are currently evaluating the impact of adoption on our financial statements.

In August 2014, the FASB issued ASU No. 2014-15 (Subtopic 205-40) Presentation of Financial Statements Going Concern: Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern (ASU 2014-15) which provides guidance about management s responsibility to evaluate whether or not there is substantial doubt about the Company s ability to continue as a going concern and to provide related footnote disclosure. ASU 2014-15 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early application is permitted. The adoption of this standard is not expected to have an impact on our financial statements.

#### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. These risks primarily include risk related to interest rate sensitivities and foreign currency exchange rate sensitivity.

#### Interest Rate Sensitivity

We had cash, cash equivalents and short-term investments of \$232.0 and \$316.2 million as of December 31, 2014 and 2013, respectively, which consisted of bank deposits, money market funds and U.S. Treasury Bills. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant. We had no outstanding debt as of December 31, 2014 or 2013.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements. There have been no material quantitative changes in our market risk exposures between the current fiscal year and preceding fiscal years.

#### Foreign Currency Exchange Rate Sensitivity

We face foreign exchange risk as a result of entering into transactions denominated in currencies other than U.S. dollars, particularly in Euro and British Sterling. Due to the uncertain timing of expected payments in foreign currencies, we do not utilize any forward foreign exchange contracts, nor did we in the year ended December 31, 2013. In the years ended December 31, 2014 and 2013, all foreign transactions settled on the applicable spot exchange basis at the time such payments were made.

An adverse movement in foreign exchange rates could have a material effect on payments we make to foreign suppliers. The impact of an adverse change in foreign exchange rates may be offset in the event we receive a milestone payment from a foreign partner. A hypothetical 10% change in foreign exchange rates during any of the preceding periods presented would not have a material impact on our financial statements. There have been no material quantitative changes in our market risk exposures between the current fiscal year and preceding fiscal years.

# Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA ONCOMED PHARMACEUTICALS, INC.

# **Index to Financial Statements**

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# **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders

OncoMed Pharmaceuticals, Inc.

We have audited the accompanying balance sheets of OncoMed Pharmaceuticals, Inc. (the Company) as of December 31, 2014 and 2013, and the related statements of operations, comprehensive loss, convertible preferred stock and stockholders equity (deficit) and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of OncoMed Pharmaceuticals, Inc. at December 31, 2014 and 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Redwood City, California

March 12, 2015

# **OncoMed Pharmaceuticals, Inc.**

# **Balance Sheets**

# (In thousands, except share and per share amounts)

	Decem 2014	ber 31, 2013
Assets	2014	2013
Current assets:		
Cash and cash equivalents	\$ 28,138	\$ 208,931
Short-term investments	203,828	107,263
Receivables related parties	21	23
Tax receivable	7,102	-
Prepaid and other current assets	1,721	2,527
	,	,
Total current assets	240,810	318,744
Property and equipment, net	5,104	4,641
Other assets	1,928	10,300
Total assets	\$ 247,842	\$ 333,685
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	\$ 4,428	\$ 5,706
Income tax payable		10,758
Accrued liabilities	14,683	9,860
Current portion of deferred revenue	18,747	35,059
Current portion of deferred rent	678	624
Liability for shares issued with repurchase rights	10	10
Total current liabilities	38,546	62,017
Deferred revenue, less current portion	130,123	148,871
Deferred rent, less current portion	2,468	3,146
Non-current income tax payable	334	1,515
Liability for shares issued with repurchase rights, less current portion	4	14
Total liabilities	171,475	215,563
Commitments and contingencies (Note 7)		
Stockholders equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2014		
and 2013, respectively; no shares issued and outstanding at December 31, 2014 and		
2013		
Common stock, \$0.001 par value; 145,000,000 shares authorized at December 31,	30	29
2014 and 2013, respectively; 29,847,577 shares and 29,397,964 shares issued and		

outstanding at December 31, 2014 and 2013, respectively		
Additional paid-in capital	300,790	292,505
Accumulated other comprehensive income (loss)	(17)	14
Accumulated deficit	(224,436)	(174,426)
Total stockholders equity	76,367	118,122
Total liabilities and stockholders equity	\$ 247,842	\$ 333,685

See accompanying notes.

# **OncoMed Pharmaceuticals, Inc.**

# **Statements of Operations**

(In thousands, except share and per share amounts)

	Year Ended December 31,					
	2014 2013		2013		2012	
Revenue:						
Collaboration revenue related party	\$		\$		\$	15,970
Collaboration revenue		39,559		37,779		8,689
Grant revenue						22
Total revenue		39,559		37,779		24,681
Operating expenses:						
Research and development		76,430		50,048		39,893
General and administrative		13,753		11,630		7,157
Total operating expenses		90,183		61,678		47,050
Loss from operations		(50,624)		(23,899)		(22,369)
Interest and other income (expense), net		105		(228)		134
Loss before income taxes		(50,519)		(24,127)		(22,235)
Income tax (provision) benefit		509		(1,944)		
Net loss	\$	(50,010)	\$	(26,071)	\$	(22,235)
Net loss per common share, basic and diluted	\$	(1.69)	\$	(1.93)	\$	(21.30)
Shares used to compute net loss per common share, basic and diluted	2	9,664,326	1	3,530,239	1	,044,059

See accompanying notes.

# **OncoMed Pharmaceuticals, Inc.**

# **Statements of Comprehensive Loss**

(In thousands)

	Year Ended December 31,				
	2014	2013	2012		
Net loss	\$ (50,010)	\$(26,071)	\$ (22,235)		
Other comprehensive loss:					
Unrealized gains (losses) on available-for-sale securities, net of tax	(31)	(1)	(34)		
Total comprehensive loss	\$(50,041)	\$ (26,072)	\$ (22,269)		

See accompanying notes.

# **OncoMed Pharmaceuticals, Inc.**

# Statements of Convertible Preferred Stock and Stockholders Equity (Deficit)

(In thousands, except share amounts)

	Convert Preferred		Common S	Stock	Additional (		d i <b>ve</b> umulatedS	Total tockholders
	Shares	Amount	Shares	Amoun	t Capitalnco			
Balances at December 31, 2011 Issuance of common stock upon exercise of	21,180,280	182,773	1,005,104	1	3,136	49	(126,120)	(122,934)
options			67,328		118			118
Vesting of restricted stock Stock-based			11,002		22			22
compensation Unrealized loss on available for sale					836			836
securities Net loss						(34)	(22,235)	(34) (22,235)
1000							(22,233)	(22,233)
Balances at December 31, 2012 Issuance of common stock in connection with initial public	21,180,280	182,773	1,083,434	1	4,112	15	(148,355)	(144,227)
offering, net of offering costs			5,520,000	6	82,662			82,668
Conversion of convertible preferred stock to common stock in connection with initial public								
offering Conversion of preferred stock warrants to common stock warrants in connection with	(21,180,280)	(182,773)	21,180,280	21	182,752 462			182,773 462

initial public offering						
Issuance of						
common stock in						
connection with a						
research and						
collaboration						
agreement	1,470,588	1	20,518			20,519
Issuance of	1,470,500	1	20,510			20,317
common stock						
upon exercise of						
warrants	26,898					
Issuance of	20,070					
common stock						
upon exercise of						
options	113,519		250			250
Vesting of	115,517		250			250
restricted stock	3,245		13			13
Stock-based	5,245		15			15
compensation			1,736			1,736
Unrealized loss on			1,750			1,750
available-for-sale						
securities				(1)		(1)
Net loss				(1)	(26,071)	(26,071)
1011035					(20,071)	(20,071)
Balances at						
December 31, 2013	29,397,964	29	292,505	14	(174,426)	118,122
Issuance of	27,577,701	27	272,505	11	(171,120)	110,122
common stock						
upon exercise of						
options	381,599	1	1,079			1,080
Issuance of	501,577	1	1,079			1,000
common stock for						
ESPP purchase	65,909		1,002			1,002
Vesting of	05,707		1,002			1,002
restricted stock	2,105		10			10
Stock-based	2,105		10			10
compensation			6,194			6,194
Unrealized loss on			0,171			0,171
available for sale						
securities				(31)		(31)
Net loss				(31)	(50,010)	(50,010)
1.00.1055					(50,010)	(30,010)
Balances at						
December 31, 2014	29,847,577	\$ 30	\$ 300,790	\$ (17)	\$ (224,436)	\$ 76,367
		<i>400</i>	÷ 200,170	Ψ ( <b>1</b> 7)	+ ( 1,100)	

# **OncoMed Pharmaceuticals, Inc.**

# **Statements of Cash Flows**

(In thousands)

	Year Ended December 31, 2014 2013 2012		
Operating activities	2014	2013	2012
Net loss	\$ (50,010)	\$ (26,071)	\$ (22,235)
Adjustments to reconcile net loss to net cash provided by (used in)	\$ (30,010)	φ (20,071)	\$ (22,233)
operating activities:			
Depreciation and amortization	1,430	1,378	1,407
Gain on disposal of equipment	(113)	1,570	1,107
Stock-based compensation	6,194	1,736	836
Revaluation of convertible preferred stock warrant liability	0,171	280	(17)
Prepaid convertible preferred stock warrant expense		17	5
Amortization of discount on short-term investments	(14)	(50)	(112)
Changes in operating assets and liabilities:	()	()	()
Accounts receivable related parties	2	4,000	(4,023)
Tax receivable	(7,102)	.,	(.,)
Prepaid and other current assets	(372)	(229)	(540)
Other assets	(781)	(1,096)	(2,871)
Deferred tax assets	10,331	(10,331)	
Accounts payable	(1,278)	4,857	(2,562)
Accrued liabilities and other	3,643	7,952	(622)
Deferred revenue	(35,059)	151,884	(2,165)
Deferred rent	(624)	(541)	(446)
Income tax payable	(10,758)	10,758	
Net cash provided by (used in) operating activities	(84,511)	144,544	(33,345)
Investing activities			
Purchases of property and equipment	(1,809)	(557)	(714)
Proceeds from sale of equipment	30		
Purchases of short-term investments	(436,856)	(132,537)	(73,939)
Maturities of short-term investments	340,271	75,300	112,666
Net cash provided by (used in) investing activities	(98,364)	(57,794)	38,013
Financing activities			
Proceeds from issuance of common stock upon initial public offering,			
net		85,149	
Proceeds from issuance of common stock related to a collaboration			
agreement, net		20,519	
	2,082	250	156

Proceeds from issuance of common stock related to the exercise of options and employee stock plan purchases			
Repayments on notes payable			(346)
Net cash provided by (used in) financing activities	2,082	105,918	(190)
Net increase (decrease) in cash and cash equivalents	(180,793)	192,668	4,478
Cash and cash equivalents at beginning of period	208,931	16,263	11,785
Cash and cash equivalents at end of period	\$ 28,138	\$ 208,931	\$ 16,263
Supplemental cash flow information:			
Cash paid (refund) for income taxes, net	\$ 8,200	\$	\$
Non-cash financing activities:			
Conversion of preferred stock warrants to common stock warrants	\$	\$ 462	\$

See accompanying notes.

# **OncoMed Pharmaceuticals, Inc.**

#### Notes to the Financial Statements

# 1. Organization

OncoMed Pharmaceuticals, Inc. (OncoMed or the Company) is a clinical development-stage biotechnology company focused on discovering and developing first-in-class protein therapeutics targeting cancer stem cells (CSCs). The Company was originally incorporated in July 2004 in Delaware. The Company's operations are based in Redwood City, California and it operates in one segment.

The Company has six anti-CSC product candidates in clinical development and has a seventh anti-CSC product candidate in preclinical development. The first candidate currently in clinical development, demcizumab (anti-DLL4, OMP-21M18), has completed a single-agent Phase Ia safety and dose escalation trial. It is currently in Phase Ib combination therapy trials in patients with non-small cell lung cancer (with carboplatin and pemetrexed) and pancreatic cancer (with gemcitabine and Abraxane®) and a Phase Ib/II trial combining demcizumab with paclitaxel in ovarian cancer. The Company initiated a Phase II randomized trial of demcizumab in non-small cell lung cancer (with carboplatin and pemetrexed) in February 2015. The Company also initiated a Phase II randomized trial of demcizumab in pancreatic cancer and is working to enroll patients. The second candidate, tarextumab (anti-Notch2/3, OMP-59R5), completed a Phase Ia safety and dose escalation trial. It is currently in the Phase II portion of a Phase Ib/II trial in pancreatic cancer (with gemcitabine and Abraxane®) and also in the Phase II portion of a Phase Ib/II trial in small cell lung cancer (with etoposide and platinum chemotherapy). The third candidate, vantictumab (anti-Fzd7, OMP-18R5), has completed a single-agent Phase Ia trial and is currently in three separate Phase Ib combination trials, one trial each in patients with breast cancer (with paclitaxel), pancreatic cancer (with gemcitabine and Abraxane<sup>®</sup>) and non-small cell lung cancer (with docetaxel). The fourth candidate, ipafricept (Fzd8-Fc, OMP-54F28), is in a single-agent Phase Ia safety and dose escalation trial in solid tumor malignancies and is currently in three separate Phase Ib combination trials, one trial each in patients with ovarian cancer (with carboplatin and paclitaxel), pancreatic cancer (with gemcitabine and Abraxane<sup>®</sup>) and hepatocellular carcinoma (with sorafenib). The fifth candidate, brontictuzumab (anti-Notch1, OMP-52M51), is in two single-agent Phase Ia safety and dose escalation trials in hematologic and solid tumor malignancies. In 2014 the Company filed an IND for a sixth product candidate, anti-DLL4/VEGF bispecific (OMP-305B83), and are currently enrolling patients in a single-agent Phase Ia trial in advanced solid tumor patients.

# Initial Public Offering

On July 17, 2013, the Company s registration statement on Form S-1 (File No. 333-181331) relating to the initial public offering (the IPO) of its common stock was declared effective by the SEC. The IPO closed on July 23, 2013 at which time the Company sold 5,520,000 shares of its common stock, which included 720,000 shares of common stock purchased by the underwriters upon the full exercise of their option to purchase additional shares of common stock to cover over-allotments. The Company received net cash proceeds of \$82.7 million from the IPO, net of underwriting discounts and commissions and expenses paid by the Company.

On July 23, 2013, prior to the closing of the IPO, all outstanding shares of convertible preferred stock converted into 21,180,280 shares of common stock with the related carrying value of \$182.8 million reclassified to common stock and additional paid-in capital. In addition, all convertible preferred stock warrants were also thereby converted into common stock warrants. Additionally, all shares of Class B common stock were converted into Class A common stock, and the Class A common stock was redesignated common stock.

# 2. Summary of Significant Accounting Policies

# **Basis of Presentation**

The Company s financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP).

#### Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, preclinical study and clinical trial accruals, fair value of assets and liabilities, income taxes, and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results may differ from those estimates.

# Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of 90 days or less at the date of purchase to be cash and cash equivalents.

#### Short-Term Investments

Short-term investments consist of debt securities classified as available-for-sale and have maturities greater than 90 days, but less than 365 days from the date of acquisition. Short-term investments are carried at fair value based upon quoted market prices. Unrealized gains and losses on available-for-sale securities are excluded from earnings and were reported as a component of accumulated other comprehensive income (loss). The cost of available-for-sale securities sold is based on the specific-identification method.

#### **Concentrations of Credit Risk**

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. Cash and cash equivalents and short-term investments are invested through banks and other financial institutions in the United States. Such deposits may be in excess of insured limits. The Company maintains cash and cash equivalents and investments with various high credit quality and capitalized financial institutions.

# **Property and Equipment**

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization is calculated using the straight-line method over the estimated useful lives of the assets, which range from three to five years. Leasehold improvements are amortized over the shorter of their estimated useful lives or the remaining life of the lease at the time the asset is placed into service.

#### Impairment of Long-Lived Assets

The carrying value of long-lived assets, including property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the asset may not be recoverable. An impairment loss is recognized when the total of estimated future undiscounted cash flows, expected to result from the use of the asset and its eventual disposition, are less than its carrying amount. Impairment, if any, would be assessed using discounted cash flows or other appropriate measures of fair value. Through December 31, 2014, there have been no such impairment losses.

# **Revenue Recognition**

The Company generates substantially all its revenue from collaborative research and development agreements with pharmaceutical companies. The terms of the agreements may include nonrefundable upfront payments, milestone payments, other contingent payments and royalties on any product sales derived from collaborations. These multiple element arrangements are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting.

The determination of stand-alone value is generally based on whether any deliverable has stand-alone value to the customer. The Company determines how to allocate arrangement consideration to identified units of accounting based on the selling price hierarchy provided under the relevant guidance. The selling price used for each unit of accounting is based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available or estimated selling price if neither vendor-specific nor third-party evidence is available. Management may be required to exercise considerable judgment in determining whether a deliverable is a separate unit of accounting and in estimating the selling prices of identified units of accounting for new agreements.

Typically, the Company has not granted licenses to collaborators at the beginning of its arrangements and thus there are no delivered items separate from the research and development services provided. As such, upfront payments are recorded as deferred revenue in the balance sheet and are recognized as collaboration revenue over the estimated period of performance that is consistent with the terms of the research and development obligations contained in the collaboration agreement. The Company regularly reviews the estimated period of performance based on the progress made under each arrangement.

Payments that are contingent upon achievement of a substantive milestone are recognized in their entirety in the period in which the milestone is achieved. Milestones are defined as an event that can only be achieved based on the Company s performance and there is substantive uncertainty about whether the event will be achieved at the inception of the arrangement. Events that are contingent only on the passage of time or only on counterparty performance are not considered milestones. Further, the amounts received must relate solely to prior performance, be reasonable relative to all of the deliverables and payment terms within the agreement and commensurate with the Company s performance to achieve the milestone after commencement of the agreement. Other contingent payments received for which payment is contingent solely on the results of a collaborative partner s performance (bonus payments) are not accounted for using the milestone method. Such bonus payments will be recognized as revenue when collectability is reasonably assured.

Payments related to options to license the Company s program candidates are considered substantive if, at the inception of the arrangement, the Company is at risk as to whether the collaboration partner will choose to exercise the option. Factors that the Company considers in evaluating whether an option is substantive include the overall objective of the arrangement, the benefit the collaborator might obtain from the arrangement without exercising the option, the cost to exercise the option and the likelihood that the option will be exercised. For arrangements under which an option is considered substantive, the Company does not consider the item underlying the option to be a deliverable at the inception of the arrangement and the associated option fees are not included in allocable arrangements under which an option is not considered substantive or if an option is priced at a significant and incremental discount, the Company would consider the item underlying the option to be a deliverable at the inception of an option is not considered substantive or if an option is priced at a significant and incremental discount, the Company would consider the item underlying the option to be a deliverable at the inception of the arrangement would be included in allocable arrangement consideration.

# **Customer Concentration**

Customers whose collaboration revenue accounted for 10% or more of total revenues were as follows:

	Year E	Year Ended December 31,			
	2014	2013	2012		
GlaxoSmithKline LLC ( GSK )	31%	*	65%		
Bayer Pharma AG ( Bayer )	30%	92%	35%		

Celgene Corporation (Celgene) 39% \*

\* less than 10%

#### **Research and Development Expenses**

Research and development costs are expensed as incurred. Research and development costs consist of salaries and other personnel-related expenses, including associated stock-based compensation, consulting fees, lab supplies, and facility costs, as well as fees paid to other entities that conduct certain research, development and manufacturing activities on behalf of the Company.

# **Clinical Trial Accruals**

Clinical trial costs are a component of research and development expenses. The Company accrues and expenses clinical trial activities performed by third parties based upon actual work completed in accordance with agreements established with clinical research organizations and clinical sites. The Company determines the actual costs through discussions with internal personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services.

Nonrefundable advance payments for goods and services that will be used or rendered in future research and development activities, are deferred and recognized as expense in the period that the related goods are delivered or services are performed.

#### Stock-Based Compensation

The Company recognizes compensation expense for all share-based payment awards made to employees and directors based on estimated fair values. For employee stock options, the Company determines the grant date fair value of the awards using the Black-Scholes option-pricing model and generally recognizes the fair value as stock-based compensation expense on a straight-line basis over the vesting period of the respective awards. Stock-based compensation expense is based on the value of the portion of stock-based payment awards that is ultimately expected to vest. As such, the Company s stock-based compensation is reduced for the estimated forfeitures at the date of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. For restricted stock, the compensation cost for these awards is based on the closing price of the Company s common stock on the date of grant and recognized as compensation expense on a straight-line basis over the requisite service period.

The Company accounts for equity instruments issued to nonemployees based on their fair values on the measurement dates using the Black-Scholes option-pricing model. The estimated fair values of the options granted to nonemployees are remeasured as they vest. As a result, the noncash charge to operations for nonemployee options with vesting conditions is affected each reporting period by changes in the fair value of the Company s common stock.

#### Income Taxes

The Company accounts for income taxes using the liability method under which deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amount which is more likely than not to be realizable.

The recognition, derecognition and measurement of a tax position is based on management s best judgment given the facts, circumstances and information available at each reporting date. The Company s policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

# Net Loss per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per common share is computed by dividing the net loss by the weighted-average number of common shares and common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, potentially dilutive securities consisting of convertible preferred stock, common stock subject to repurchase, stock options and warrants are considered to be common stock equivalents and were excluded in the calculation of diluted net loss per common share because their effect would be anti-dilutive for all periods presented.

#### Newly Adopted and Recent Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board (FASB) issued final guidance that a performance target that affects vesting of a share-based payment and that could be achieved after the requisite service period is a performance condition under Accounting Standards Codification (ASC) 718, Compensation Stock Compensation. As a result, the target is not reflected in the estimation of the award s grant date fair value. Compensation cost for such an award would be recognized over the required service period, if it is probable that the performance condition will be achieved. The guidance is effective for all entities for annual periods beginning after December 15, 2015 and interim periods within those annual periods. The guidance should be applied on a prospective basis to awards that are granted or modified on or after the effective date. The Company does not believe the adoption of this guidance will have a material impact on its financial statements.

In May 2014, the FASB and the International Accounting Standards Board issued Accounting Standards Update (ASU) No. 2014-09 (Topic 606) Revenue from Contracts with Customers (ASU 2014-09). This ASU affects any entity that either enters into contracts with customers to transfer goods and services or enters into contracts for the transfer of nonfinancial assets. This ASU will supersede the revenue recognition requirements in Topic 605, and most industry specific guidance. The standard s core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under today s guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective for the Company for annual periods beginning after December 15, 2016, including interim periods within that period. Entities can choose to apply the standard using either the full retrospective approach or a modified retrospective approach. Entities electing the full retrospective adoption will apply the standard to each period presented in the financial statements. This means that entities will have to apply the new guidance as if it had been in effect since the inception of all its contracts with customers presented in the financial statements. Entities that elect the modified retrospective approach will apply the guidance retrospectively only to the most current period presented in the financial statements. This means that entities will have to recognize the cumulative effect of initially applying the new standard as an adjustment to the opening balance of retained earnings at the date of initial application. Early adoption is not permitted under U.S. GAAP. The Company is currently evaluating the impact of adoption of this accounting standards update on its financial statements.

In August 2014, the FASB issued ASU No. 2014-15 (Subtopic 205-40) Presentation of Financial Statements Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (ASU 2014-15) which provides guidance about management's responsibility to evaluate whether or not there is substantial doubt about the Company's ability to continue as a going concern and to provide related footnote disclosure. ASU 2014-15 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early application is permitted. The adoption of this standard is not expected to have an impact on the Company's Financial Statements.

# **3.** Cash Equivalents and Investments

The fair value of securities, not including cash at December 31, 2014 and 2013, were as follows (in thousands):

	Amortized	Decemb Gross U		
	Cost	Gains	Losses	Fair Value
Money market funds	\$ 8,460	\$	\$	\$ 8,460
U.S. treasury bills	203,845	37	(54)	203,828
Total available-for-sale securities	\$212,305	\$ 37	\$ (54)	\$ 212,288
Classified as:				
Cash equivalents				\$ 8,460
Short-term investments				203,828
Total cash equivalents and investments				\$ 212,288

As of December 31, 2014, the Company had a total of \$232.0 million in cash, cash equivalents, and short-term investments, which includes \$19.7 million in cash and \$212.3 million in cash equivalents and short-term investments.

	Amortized	Gross Ui		
	Cost	Gains	Losses	Fair Value
Money market funds	\$ 7,980	\$	\$	\$ 7,980
U.S. treasury bills	267,242	14		267,256
Total available-for-sale securities	\$275,222	\$ 14	\$	\$ 275,236
Classified as:				
Cash equivalents				\$ 167,973
Short-term investments				107,263
Total cash equivalents and investments				\$ 275,236

As of December 31, 2013, the Company had a total of \$316.2 million in cash, cash equivalents, and short-term investments, which includes \$41.0 million in cash and \$275.2 million in cash equivalents and short-term investments.

All available-for-sale securities held as of December 31, 2014 and 2013 had contractual maturities of less than one year. There have been no significant realized gains or losses on available-for-sale securities for the periods presented.

#### 4. Fair Value Measurements

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The Company records its financial assets and liabilities at fair value. The carrying amounts of certain of the Company s financial instruments, including cash and cash equivalents, short-term investments, and accounts payable, approximate their fair value due to their short maturities. The accounting guidance for fair value provides a framework for measuring fair value, clarifies the definition of fair value, and expands disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

Level 1: Inputs which include quoted prices in active markets for identical assets and liabilities.

Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

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

The Company s financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements were as follows (in thousands):

	December 31, 2014				
	Level 1	Level 2	Level 3	Total	
Assets:					
Money market funds	\$ 8,460	\$	\$	\$ 8,460	
U.S. treasury bills		203,828		203,828	
Total	\$ 8,460	\$203,828	\$	\$212,288	

		<b>December 31, 2013</b>			
	Level 1	Level 2	Level 3	Total	
Assets:					
Money market funds	\$ 7,980	\$	\$	\$ 7,980	
U.S. treasury bills		267,256		267,256	
Total	\$ 7,980	\$267,256	\$	\$275,236	

Where quoted prices are available in an active market, securities are classified as Level 1. The Company classifies money market funds as Level 1. When quoted market prices are not available for the specific security, then the Company estimates fair value by using benchmark yields, reported trades, broker/dealer quotes, and issuer spreads. The Company classifies U.S. Treasury securities as Level 2. There were no transfers between Level 1 and Level 2 during the periods presented.

#### 5. Property and Equipment

Property and equipment consist of the following (in thousands):

	December 31,		
	2014	2013	
Computer equipment and software	\$ 1,715	\$ 1,632	
Furniture and fixtures	443	392	

Laboratory equipment	9,739	9,025
Leasehold improvements	8,826	8,624
	20,723	19,673
Less accumulated depreciation and amortization	(15,619)	(15,032)
Property equipment, net	\$ 5,104	\$ 4,641

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# 6. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,		
	2014	2013	
Research and development related	\$ 9,965	\$ 5,949	
Compensation related	4,208	3,446	
Other	510	465	
Total accrued liabilities	\$ 14,683	\$ 9,860	

#### 7. Commitments and Contingencies

#### **Operating Leases**

The Company leases office and laboratory facilities in Redwood City, California under a lease agreement that expires in January 2019 and includes lease extension options for two additional three-year terms.

The operating lease agreement contains rent escalation provisions and tenant improvement allowances. The total rent obligation is being expensed ratably over the term of the agreement.

Minimum annual rental commitments under the lease agreement are as follows (in thousands):

Year ending December 31:	
2015	\$ 1,942
2016	2,002
2017	2,062
2018	2,122
Thereafter	177
Total	\$ 8,305

In 2006, the landlord provided the Company a tenant improvement allowance of \$5.7 million in order for the Company to complete an office and lab build out. In accordance with the lease amendment in December 2010, the landlord funded \$1.6 million of the provided tenant improvement allowance for the Company to complete the lab expansion. The Company has recorded the aggregate tenant improvement allowance received as a leasehold improvement asset and a deferred rent liability on the accompanying balance sheets. The tenant improvement allowance asset is being amortized as depreciation expense and the deferred rent liability balance as a credit to rent expense over the period from which the improvements were placed in service until the end of their useful life, which is the end of the lease term. As of December 31, 2014 and 2013, the Company has an unamortized tenant improvement allowance of \$2.1 million and \$2.7 million, respectively.

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Rent expense for years ended December 31, 2014, 2013 and 2012, was \$1.3 million, \$1.3 million and \$1.3 million, respectively.

#### **Guarantees and Indemnifications**

The Company, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws, and pursuant to indemnification agreements with certain directors, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company s request in such capacity. The term of the indemnification period lasts as long as an officer or director may be subject to any proceeding arising out of acts or omissions of such officer or director in such capacity.

The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance limits the Company s exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations for any period presented.

# 8. License Agreement

In 2004, the Company assumed an exclusive, worldwide license agreement with the University of Michigan relating to the use of certain patents and technology relating to its cancer stem cell technology for which an up-front fee of \$10,000 had been paid and the Company issued 7,796 shares of its common stock. Pursuant to the agreement, the Company is obligated to make low single-digit royalty payments to the University of Michigan on net sales of its or its licensees products and processes covered under the agreement, pay an annual license maintenance fee, and reimburse the University of Michigan for costs of prosecution and maintenance of the licensed patents which reduces future royalty obligations. With respect to one family of licensed patent applications that does not relate to any of the Company is aled therapeutic programs, the Company is also required to pay a tiered, single-digit percentage of any sublicense revenues, including any upfront or milestone payments, received from any sublicensees under such family of patents. Once the University of Michigan has received \$10.0 million in royalties, the Company may at its option convert the license to a fully paid-up license provided the Company transfers additional shares of nonvoting common stock equal to 0.25% of the fully diluted shares then outstanding to the University of Michigan. The amounts incurred for patent legal costs amounted to \$158,000, \$151,000 and \$175,000 for the years ended December 31, 2014, 2013 and 2012, respectively, all of which has been recorded as general and administrative expense in the statements of operations.

# 9. Supply and License Agreements

In June 2006, the Company entered into a subscription and license agreement with MorphoSys AG to obtain a research license and access to certain technology libraries, antibodies and support services. The Company paid technology access and subscription fees from the date of signing through 2008 of 650,000 (approximately \$919,000) and 250,000 (approximately \$350,000) in 2009. The Company also exercised an option to extend an extended research license under the agreement for five years (through 2015). The Company may choose to exercise an annual option to extend the extended research license for up to an additional five years (through 2020), and, upon exercise of such option, must pay an annual fee of 20,000 (approximately \$24,000). These annual fees are capitalized in prepaid and other current assets, and amortized over the relevant one year period. Additionally, the Company may owe MorphoSys AG up to 5.8 million (approximately \$7.1 million) in future milestone payments for each product developed using the licensed antibodies if all milestone events are achieved, primarily in Phase III clinical trials and later development. GSK would reimburse the Company for 50% of such payments for tarextumab (Anti-Notch2/3, OMP-59R5).

The amortization expense for the years ended December 31, 2014, 2013 and 2012 was \$27,000, \$26,000 and \$27,000, respectively, and was recorded as research and development expense in the statements of operations.

In April/May 2008, the Company obtained commercial licenses to two antibodies identified from the licensor s library of antibodies, and must make additional payments to MorphoSys AG for these licenses. GSK reimburses the Company for 50% of the license payments for the first antibody, which is used in the tarextumab program under the Company s collaboration with GSK, while the Company is responsible for all the license payments for the second antibody, which is used in the vantictumab (anti-Fzd7, OMP-18R5) program under its collaboration with Bayer. There were no payments made for the licensed antibodies nor reimbursements received from GSK during the years ended

December 31, 2014, 2013 and 2012.

# **10.** Collaborations

The Company has entered into three collaboration arrangements, each having multiple deliverables under which it received non-refundable upfront payments. For collaborations where the Company has determined that there is a single unit of accounting the Company recognizes revenue related to the upfront payments ratably over its estimated period of performance for each collaboration.

The Company has entered into collaborations arrangements that include contractual milestones, which relate to the achievement of pre-specified research, development, regulatory and commercialization events. The milestone events contained in the Company s alliances coincide with the progression of the Company s product candidates from research and development, to regulatory approval and through to commercialization. The process of successfully discovering a new product candidate, having it selected by the alliance partner for development, having it approved and ultimately sold for a profit is highly uncertain. As such, the milestone payments that the Company may earn from its collaborators involve a significant degree of risk to achieve.

Research and development milestones in the Company s strategic alliances may include the following types of events:

Completion of pre-clinical research and development work leading to selection of product clinical candidates.

Advancement of candidates into clinical development, which may include filing of investigational new drug ( IND ) applications.

Initiation of a Phase I or Phase II clinical trials.

Achievement of certain scientific or development events. Regulatory milestones may include the following types of events:

Filing of regulatory applications for marketing approval such as a New Drug Application in the United States, or a Marketing Authorization Application in Europe.

Marketing approval in a major market, such as the United States, Europe or Japan. Commercialization milestones may include the following types of events:

Product sales in excess of pre-specified thresholds.

# Summary of Collaboration Related Revenue

The Company has recognized the following revenues from its collaboration agreements during the years ended December 31, 2014, 2013 and 2012 (in thousands):

	Year Ended December 31,		
	2014	2013	2012
GSK:			
Recognition of upfront payment	\$ 1,248	\$ 1,971	\$ 1,970
Milestone revenue	11,000		14,000
GSK total	12,248	1,971	15,970
Bayer:			
Recognition of upfront payments	9,756	9,756	8,689
Milestone revenue	2,000	25,000	
Bayer total	11,756	34,756	8,689
Celgene:			
Recognition of upfront payment	13,055	1,052	
Milestone revenue	2,500		
Celgene total	15,555	1,052	
Total collaboration related revenue	\$ 39,559	\$37,779	\$24,659
Total collaboration related revenue	\$ 39,559	\$37,779	\$ 24,659

# **GSK Strategic Alliance**

On December 7, 2007, the Company entered into a Collaboration and Option Agreement with GSK. The agreement was formed to discover, develop and market novel antibody therapeutics to target cancer stem cells (CSCs). The agreement gives GSK the option to obtain an exclusive license for product candidates targeting the Notch signaling pathway.

Under the original agreement, the Company had a research obligation to provide GSK four antibodies that meet specified selection criteria and was responsible for the development of two antibodies through clinical proof-of-concept, or POC, generally considered to be at the end of certain Phase II clinical trials. There is no further obligation by the Company to perform development once these are achieved. Upon exercise of its option, GSK obtains an exclusive worldwide license to the antibody, assume full financial responsibility for funding further clinical development and commercialization and will be obligated to make payments to the Company for further development and commercialization milestones and royalties on product sales.

The Company received an initial payment of \$35.0 million, with half in the form of an equity investment by GSK in the Company s Series B-2 convertible preferred stock and the other half as an up-front cash payment which was initially recorded as deferred revenue. The Company is eligible to earn milestone payments in connection with research and development activities, and contingent consideration in connection with further development, regulatory

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approval and commercialization activities. In addition, the Company can earn royalty payments on all future collaboration product sales, if any.

The 1,441,396 shares of Series B-2 convertible preferred stock sold by the Company to GSK were issued at a premium of \$4.3 million above the estimated fair value of convertible preferred stock at the time of issuance. This premium was considered an additional up-front payment and was added to the \$17.5 million deferred revenue and was being recognized on a ratable basis over the estimated period of performance of five years.

In July 2011, the Company amended the terms of its development agreement with GSK to focus the collaboration entirely on the development of two product candidates, tarextumab (anti-Notch 2/3, OMP-59R5)

and brontictuzumab (anti-Notch1, OMP-52M51). The Company will receive additional funding from GSK to support certain of its development activities conducted in relation to one of these product candidates, up to a maximum of \$2.0 million. There is no further obligation for the Company to continue to progress or fund development once specified Phase II clinical trials are completed for each of the two product candidates. Following exercise of its option for a product candidate, GSK will have an exclusive license to progress further clinical development and commercialization of such product candidate, and will assume full financial responsibility for funding such activities. After exercising its option, GSK will be obligated to make payments to the Company in the form of contingent consideration related to further development and commercialization of such product candidate, as well as royalties on product sales.

The Company evaluated the terms of the July 2011 amendment relative to the entire arrangement and determined the amendment to be a material modification to the original agreement for financial reporting purposes. As a result, the Company evaluated the entire arrangement under the multiple-element accounting guidance. The Company determined that the only undelivered elements were providing certain development services it is obligated to provide for the second product candidate and the continued development work to progress the first product candidate through certain Phase II POC clinical trials. The Company has determined that the undelivered elements are a single unit of accounting. Accordingly, the \$7.9 million deferred revenue balance at the modification date was being recognized as revenue ratably over the estimated period of performance over four years beginning on the date of the material modification of the original agreement. The Company determined that the clinical data it has obtained to date supported a change in study design which extended the estimated completion of the deliverable, certain Phase II POC clinical trials to June 2016. In January 2014, the Company changed its estimate of the period of performance from four years to five years. Accordingly, the Company is recognizing the remaining unamortized portion of the up-front payment over the revised estimated period of performance on a prospective basis.

In July 2012, the Company and GSK entered into the Second Amendment Regarding Payment of Certain Milestone Payments for the tarextumab program. This amendment modified one of the development milestones for advancing the tarextumab program. The restructuring of the milestone payment did not alter the aggregate amount of development milestone payments or the aggregate amount of contingent consideration payments that the Company is eligible to receive in its collaboration with GSK. The Company received a \$3.0 million payment upon the initiation of the Phase Ib portion of the tarextumab program in October 2012, which was not considered to be the achievement of a substantive milestone for accounting purposes. Rather it is an advance payment on a future substantive milestone. Accordingly, the \$3.0 million was recorded as deferred revenue to be recognized upon the achievement of the underlying substantive milestone. This modification was not material to the collaboration taken as a whole.

During the year ended December 31, 2012, the Company recognized a \$5.0 million proof-of-principle development milestone for the tarextumab program, a \$5.0 million development milestone for the IND acceptance for its brontictuzumab program and a \$4.0 million development milestone for the first patient enrollment for its brontictuzumab clinical trial.

In June 2013, the Company received an \$8.0 million advance payment from GSK pursuant to the terms of its tarextumab program. The \$8.0 million was recorded as deferred revenue to be recognized as collaboration revenue upon the achievement of the underlying substantive milestone.

In July 2014 the Company began dosing patients in the randomized, placebo-controlled Phase II portion of its clinical trial of tarextumab in pancreatic cancer. As a result, payments of \$8.0 million and \$3.0 million previously recorded as deferred revenue were recognized as collaboration revenue upon the achievement of this underlying substantive milestone.

As of December 31, 2014, the Company was eligible to receive in its collaboration with GSK up to \$81.0 million in future development milestone payments prior to the completion of certain Phase II POC clinical

trials. These remaining potential development milestones include up to \$5.0 million for the advancement into specified clinical testing related to the brontictuzumab program, up to \$16.0 million for the start of certain Phase II clinical trials, including a \$5.0 million bonus payment, and up to \$60.0 million if GSK exercises its options for the two programs, including a \$10.0 million bonus payment. GSK has the option to license the brontictuzumab program as early as the end of Phase Ia or both programs at Phase II POC, and will be responsible for all further development and commercialization following such option exercise. If GSK successfully develops and commercializes both candidates for more than one indication, the Company could receive contingent consideration payments of up to \$309.0 million for the achievement of regulatory events and up to \$280.0 million upon the achievement of certain levels of worldwide net sales, for a total of \$670.0 million of potential future payments. In addition, the Company can earn royalty payments on all future collaboration product sales, if any. As all contingent consideration payments are based solely on the performance of GSK, the milestone method of accounting will not be applied to such amounts.

As of December 31, 2013, GSK was no longer considered a related party. Previously, GSK was deemed a related party by ownership of more than 10% of the voting common stock of the Company. Accordingly, related party transactions were reported as collaboration revenue related party in the Company s statement of operations for the year ended December 31, 2012.

# **Bayer Strategic Alliance**

On June 15, 2010, the Company entered into a Collaboration and Option Agreement with Bayer. The agreement sets forth an alliance to discover, develop and market novel antibody, protein and small molecule therapeutics targeting CSCs. Specifically, the alliance efforts are directed toward therapeutics affecting targets within the Wnt signaling pathway.

Under the terms of the agreement, Bayer has an exclusive option to license biologic therapeutic product candidates discovered and developed by the Company over a biologics research term that will extend until the later of five years after the effective date of the agreement or the occurrence of certain specified events. In addition, the Company will assist Bayer with its advancement of a specified number of small molecule candidates discovered and developed at Bayer to certain development stages. The Company estimates its period of performance to be approximately five years. The Company is obligated to use commercially reasonable efforts to advance three biologics through to a specified stage of research and two biologics to a specified early clinical development stage.

The option for Bayer to obtain an exclusive license to any of the biologics therapeutic product candidates commences on the effective date of the agreement and extends for a specified time period. The Company is responsible for all preclinical and development costs for each biologic product candidate up to the end of a defined early clinical development stage. Once Bayer exercises its option to obtain an exclusive license to a class of biologic therapeutic products, they assume full financial responsibility for funding further clinical development and commercialization of such product candidates.

The Company received an upfront payment of \$40.0 million and is eligible to receive development, regulatory approval and commercialization milestone or post-option contingent consideration payments up to \$387.5 million for each biologic and \$112.0 million for each small molecule candidate. The upfront payment was recorded as deferred revenue and is being amortized to revenue over the Company s estimated period of performance. Upon product sales, the Company is eligible to receive royalties that adjust depending on sales volume.

The Company achieved a \$20.0 million development milestone related to the acceptance of the IND for the vantictumab (OMP-18R5) product candidate during the year ended December 31, 2011 that was determined to be substantive and at risk at the inception of the arrangement and, as such, was recognized in the period the milestone

was achieved.

In April 2011, the Company entered into a clinical manufacturing agreement which expanded its alliance with Bayer. Pursuant to this agreement, Bayer HealthCare LLC agreed to manufacture ipafricept (Fzd8-Fc, OMP-54F28) at its Berkeley, California site to support the Company s clinical development activities.

In August 2012, the Company and Bayer entered into Amendment 1 to the Collaboration and Option Agreement. This amendment modified the timing of payments under the Company s ipafricept program and another biologic therapeutic product program under the agreement. The modification did not alter the aggregate amount of development milestone payments or the aggregate amount of contingent consideration payments the Company is eligible to receive in its collaboration with Bayer. This modification was not material to the collaboration taken as a whole.

During the year ended December 31, 2012, the Company received a \$5.0 million payment related to the ipafricept program. As the payment was not deemed to be for a substantive milestone under Amendment 1, the Company is recognizing the \$5.0 million payment over the remaining estimated period of performance under the agreement.

In August 2013, the Company and Bayer entered into Amendment 2 to the Collaboration and Option Agreement. The amendment confirms the achievement of a development milestone of \$10.0 million for dose escalation of vantictumab (anti-Fzd7, OMP-18R5) in Phase Ia as well as agreement on the Phase Ib trial design. In addition, the amendment excludes a target that is not being developed under the collaboration. This amendment was not considered a material modification for accounting or reporting purposes. In October 2013, the Company achieved a \$15.0 million development milestone related to Phase I dose escalation in its Fzd8-Fc program under its agreement with Bayer. The two milestones totaling \$25.0 million were determined to be substantive and at risk at the inception of the agreement and, as such, were recognized in the period the milestones were achieved.

In September 2014, the Company earned \$2.0 million in milestone payments from Bayer as a result of the commencement of preclinical development of a small molecule product candidate. The \$2.0 million milestone was determined to be substantive and at risk at the inception of the agreement and, as such, was recognized in the period the milestone was achieved.

As of December 31, 2014, the Company was eligible to receive up to \$10.0 million in future development milestone payments in its collaboration with Bayer for the Company s development of biologic product candidates, prior to the point that Bayer exercises its options. The Company is eligible to receive up to \$55.0 million if Bayer exercises its options for biologic product candidates. Bayer will be responsible for all further development and commercialization following the exercise of an option for a product candidate. The Company is eligible to receive up to \$22.0 million in development milestone payments for the small molecule candidates. If Bayer successfully develops and commercializes all of the product candidates for more than one indication, the Company could receive contingent consideration payments of up to \$185.0 million for the achievement of regulatory events (up to \$135.0 million for biologics and \$50.0 million for small molecules) and up to \$1.0 billion upon the achievement of specified future product sales (up to \$862.5 million for biologics and \$140.0 million for small molecules). As all contingent consideration is based solely on the performance of Bayer, the Company would recognize the contingent payments upon receipt immediately as collaboration revenue if the Company had no further performance obligations under the agreement with Bayer.

# Celgene Strategic Alliance

In December 2013, the Company entered into a Master Research and Collaboration Agreement (the Agreement) with Celgene pursuant to which the Company and Celgene will collaborate on research and development programs directed to the discovery and development of novel biologic therapeutic programs to target CSCs, and, if Celgene exercises an option to do so, the discovery, development and commercialization of novel small molecule therapeutic programs to

target CSCs. Pursuant to the biologic therapeutic programs, the

Company will conduct further development of demcizumab (anti-DLL4, OMP-21M18), anti-DLL4/VEGF bispecific antibodies, biologic therapeutics directed to targets in the RSPO-LGR signaling pathway, including anti-RSPO3 (OMP131R10), and biologic therapeutics directed to targets in an undisclosed pathway. Celgene has options to obtain exclusive licenses to develop further and commercialize biologic therapeutics in specified programs, which may be exercised during time periods specified in the agreement through completion of certain clinical trials, provided that such option exercise occurs within the contractual Option Period of 12 years. The Company at its option may enter into co-commercialization and co-development agreements for five of the six biologic programs. During the Option Period, the Company will provide research and development services and the resultant data to Celgene for analysis in order for Celgene to determine whether or not to exercise its options.

Pursuant to the Agreement, the Company leads the discovery and development of biologic therapeutic products prior to Celgene s exercise of its option. With respect to biologic therapeutics targeting the RSPO-LGR signaling pathway and the undisclosed pathway, prior to Celgene s exercise of its option for a given program, Celgene is required to designate each program for which it wishes to retain the right to exercise its option, based on data generated by the Company, for up to a maximum of four programs. The Company is entitled to receive certain fees for each program that Celgene designates. Celgene has the right to designate programs until December 2, 2017, with an option to extend for another two years upon payment of an extension fee. Following such designation(s), Celgene will have the right to exercise its option for each such program within the Option Period.

With respect to biologic therapeutic programs, with the exception of one program targeting either the RSPO-LGR signaling pathway or the undisclosed pathway, and any program for which the Company elects not to exercise its co-development and co-commercialization right, following Celgene s exercise of its option, the Company and Celgene will enter into an agreed form of co-development and co-commercialization agreement for such program. The Company will have the right to co-develop and to co-commercialize products arising out of such program in the United States, and Celgene will have the exclusive right to develop and commercialize products arising out of such program outside of the United States. The Company s involvement in co-commercialization will include participation in specified promotion activities by means of a dedicated sales force of up to half of the overall sales force for the applicable program products, as well as marketing and other commercial activities, with Celgene recording all product sales. The Company will also bear a one-third share of all development costs, with Celgene bearing the remaining two-thirds. However, for one program targeting either the RSPO-LGR signaling pathway or the undisclosed pathway, and any program for which the Company elects not to co-develop and co-commercialize products arising from such program, the Company and Celgene will instead enter into an agreed form of a license agreement, pursuant to which Celgene retains all rights to develop further and commercialize biologic therapeutic products arising from such program on a worldwide basis, with certain support for development from the Company. The Company may elect not to co-develop and co-commercialize any products arising under such programs at any time, either prior to, or following Celgene s option exercise, with the exception of a defined period of time near commercial launch of a product under a program. If the Company opts out of its co-development and co-commercialization rights with respect to a program, Celgene will have the exclusive right to develop and commercialize products arising out of such program, at Celgene s expense.

With respect to small molecule therapeutics targeting an undisclosed pathway, following Celgene s exercise of its option, the Company will collaborate with Celgene on the discovery of and research on small molecule therapeutics, but Celgene will be solely responsible for development and commercialization of such therapeutics.

Under the terms of the Agreement, the Company received an upfront cash payment of \$155.0 million. In addition, Celgene purchased 1,470,588 shares of the Company s common stock at a price of \$15.13 per share, resulting in gross proceeds of \$22.2 million. The price paid by Celgene for the common stock represented a premium over the closing price of the Company s common stock on the date of the Agreement. The Company accounted for the \$1.7 million

premium as additional consideration under the Agreement and the common stock was recorded at its fair market value of \$20.5 million. The Company is also eligible to receive option fees upon

Celgene s exercise of the option for each biologic therapeutic program. The collaboration also includes milestone payments for achievement of specified development, regulatory and commercial milestones, paid on a per-product and per-program basis. The payments for option exercise, program designation and achievement of development, regulatory and commercial milestones may total up to (1) \$791.0 million for products in the demcizumab program, including a \$70.0 million payment upon the achievement of certain pre-determined safety criteria in Phase II clinical trials with respect to demcizumab, (2) \$505.0 million for products in the anti-DLL4/VEGF bispecific program, (3) up to \$442.8 million for each of the four products achieving regulatory approval that are directed to targets in each of the RSPO-LGR signaling pathway and the undisclosed pathway programs for which Celgene exercises its option, and (4) \$107.0 million for products in the small molecule therapeutic program.

For programs in which the Company is co-developing and co-commercializing biologic therapeutic products in the United States, the Company is also entitled to share 50% of all product profits and losses in the United States. For such programs outside the United States, the Company is eligible to receive tiered royalties equal to a percentage of net product sales outside of the United States. If the Company elects not to co-develop or co-commercialize biologic therapeutic products or does not have the right to do so for a given program, Celgene is required to pay the Company tiered royalties equal to a percentage of net product sales worldwide, with such royalties being increased where the Company had the right to co-develop and co-commercialize such biologic therapeutic products under such program but elected not to do so. The Company is responsible for funding all research and development activities for biologic therapeutics under the collaboration prior to Celgene s exercise of the option for such program.

In addition to the development and regulatory milestone payments the Company will be entitled to receive if Celgene exercises its option for the small molecule program, the Company may also receive royalties equal to a percentage of worldwide net sales of small molecule products in the low- to mid-single digits.

The Agreement will terminate upon the expiration of all of Celgene s payment obligations under all license or co-development and co-commercialization agreements entered into with respect to programs following Celgene s exercise of an option for a given program, or if Celgene fails to exercise any of its options within the Option Period. The Agreement will also terminate, on a program-by-program basis, on the expiration of the option term, if Celgene fails to exercise its option for such program. The Company may also terminate the Agreement with respect to one or more programs in the event that Celgene challenges the licensed patents with respect to such program.

If Celgene does not exercise its option with respect to a biologic therapeutic program within the Option Period, the Company retains worldwide rights to such program(s), except that if Celgene exercises its option to obtain a license for either the demcizumab program or the anti-DLL4/VEGF bispecific program, then for so long as such license is in effect, the Company cannot develop or commercialize products under the other of such two programs. In addition, under certain termination circumstances, the Company would also have worldwide rights to the terminated biologic therapeutic programs.

The Company s deliverables under the arrangement with Celgene are research and development services, including the obligation that the Company provides the resultant data to Celgene, which are accounted for as a single unit of accounting. The Company has determined that the options to license programs are substantive options. Additionally, as a result of the uncertain outcome of the discovery, research and development activities, the Company is at risk with regard to whether Celgene will exercise the options. Accordingly, the options are not considered deliverables at the inception of the arrangement and the associated option fees are not included in allocable arrangement consideration. The Company has identified the initial arrangement consideration to be approximately \$156.7 million which will be recognized on a straight-line basis over the estimated period of performance of 12 years. Due to the uncertain timeline associated with the deliverables at the outset of the Agreement, the Company determined it will use 12 years, which is the maximum period under the Agreement for Celgene to exercise its options. The Company will reevaluate the

estimated performance period at each reporting period.

In November 2014, the Company received a designation notice from Celgene relating to the Company s anti-RSPO3 product candidate, OMP-131R10, which is currently in preclinical testing. This designation triggered a \$2.5 million payment due to the Company from Celgene under the Celgene Agreement.

As of December 31, 2014, the Company was eligible to receive in its collaboration with Celgene up to \$87.5 million in future development milestones across all programs, prior to the point that Celgene exercises its options. The Company is also eligible to receive up to \$240.0 million of contingent consideration if Celgene exercises all its options for the biologic and small molecule therapeutic programs. Celgene will be responsible for all further development and commercialization following the exercise of the options for specified programs. If Celgene successfully develops and commercializes all of the product candidates, the Company could receive additional contingent consideration of up to \$2.8 billion for the achievement of regulatory events (up to \$2.7 billion for biologics and \$95.0 million for small molecules). As all contingent consideration is based solely on the performance of Celgene, the Company would recognize the contingent payments upon receipt immediately as collaboration revenue if the Company had no further performance obligations under the Agreement.

#### 11. Lonza Sales AG Agreement

In August 2012, the Company entered into a multi-product license agreement and a collaboration agreement with Lonza Sales AG (Lonza). These agreements cover the process development and manufacturing of the Company s biologics portfolio with Lonza. Under the collaboration agreement, Lonza will be the Company s preferred supplier of process development and manufacturing services for the Company s bulk drug substances in Lonza s Slough, United Kingdom facility. The parties also agreed to establish a joint steering committee to oversee, coordinate and expedite the performance of the collaboration agreement, resolve disputes arising between the parties; monitor the progress of the relevant services; and plan and assess needs for future services. Under the multi-product license agreement, the Company receives licenses to utilize Lonza s glutamine synthetase gene expression system and related technologies for commercial production of the Company s product candidates. Under this license agreement, the Company paid an upfront payment of \$488,000 which was recorded to research and development expense during 2012 and is obligated to pay Lonza certain payments up to up to £1.4 million (approximately \$2.3 million) on achievement of specified events for each licensed product, and royalties up to the very low single digits on sales of its licensed products. There has been no further payment made by the Company to Lonza pursuant to either the license agreement or collaboration agreement as of the year ended December 31, 2013 or 2014.

The multi-product license agreement shall remain in force on a product by product and country by country basis until expiration of the Company s obligation to make payments to Lonza with respect to such product in such country. The agreement can otherwise be terminated by the Company for any reason or no reason upon advance written notice to Lonza, or by either the Company or Lonza upon the other party s material breach of the agreement, or if the other party ceases to carry on business. Lonza may also terminate the licenses granted under the agreement if the Company challenges any of the Lonza patent rights.

The collaboration agreement shall remain in force for five years, unless either party elects to terminate the collaboration agreement by prior written notice effective on the date that is two and a half years after the effective date of the agreement, or unless the parties mutually agree in writing to extend the term of the collaboration agreement prior to the end of the five year term for an additional two years. Either the Company or Lonza may elect to terminate the collaboration agreement upon advance written notice for material breach by the other party, or if the other party ceases to carry on business. The collaboration agreement can also be terminated by either party by advance written notice in the event that Lonza is no longer obligated to provide manufacturing services to the Company.

#### **12. Stock Incentive Plans**

#### 2004 Plan

The Company granted options under its 2004 Stock Incentive Plan (the 2004 Plan ) until July 2013 when it was terminated as to future awards, although it continues to govern the terms of options that remain outstanding under the 2004 Plan. The 2004 Plan provided for the award of restricted shares, grants of incentive and nonstatutory stock options, and sales of shares of the Company s common stock. Awards can be made to employees, outside directors, and consultants of the Company. Stock options granted generally vest over a period of five years from the date of grant, with 20% of the total grant vesting on the first anniversary of the option vesting commencement date and 1/48 of the remaining grant vesting each month thereafter. Restricted stock issuances and early exercise of stock options were subject to the Company s right of repurchase at the original issuance price, which right lapses over the vesting period of the stock. In connection with the Board of Directors and stockholders approval of the 2013 Plan, all remaining shares available for future award under the 2004 Plan were transferred to 2013 Plan, and the 2004 Plan was terminated as to future awards.

#### 2013 Plan

In July 2013, the Company's Board of Directors and stockholders approved the 2013 Equity Incentive Award Plan (the 2013 Plan ). Under the 2013 Plan, the Company initially reserved 500,000 shares of common stock for issuance as of its effective date of July 17, 2013, plus 90,125 shares which were then available for issuance under the Company s 2004 Plan. The number of shares reserved for issuance under the 2013 Plan will increase by the number of shares represented by awards outstanding under the 2004 Plan that are forfeited or lapse unexercised and which following July 17, 2013 are not issued under the 2004 Plan. Additionally, on the first day of each calendar year, beginning in 2014 and ending in 2023, the number of shares in the reserve will increase by the least of 1,500,000 shares, 4% of the shares of the Company s common stock outstanding (on an as-converted basis) on the last day of the immediately preceding fiscal year or such smaller number of shares of stock as determined by the Company s Board of Directors. The 2013 Plan authorizes discretionary grants of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, performance awards, dividend equivalents, stock payments, deferred stock, deferred stock units, and stock appreciation rights to employees and consultants of the Company, or any of its qualifying affiliates, and to members of the Board of Directors. The exercise price per share subject to each option shall not be less than 100% of the fair value of the common stock on the date of grant. In addition, in the case of incentive stock options granted to a greater than 10% stockholder, such price shall not be less than 110% of the fair value on the date the option is granted. The term of the options shall not be more than 10 years from the grant date, or 5 years from the date an incentive stock option is granted to a greater than 10% stockholder. Stock options granted generally vest over a period of four years from the date of grant, with 25% of the total grant vesting on the first anniversary of the option vesting commencement date and 1/48th of the original grant vesting each month thereafter for stock options granted upon hiring, and with 1/48th of the total grant vesting each month after the option vesting commencement date for any stock options granted after the hiring date.

As of December 31, 2014, a total of 1,768,645 shares of common stock have been authorized under the 2013 Plan, including the additional 1,175,918 shares of common stock that became available for future issuance under the 2013 Plan as of January 1, 2014 as a result of an annual automatic increase provision in the 2013 Plan. As of December 31, 2014, a total of 1,743,484 shares are subject to options outstanding under the 2013 Plan. There are 2,078,526 shares subject to options outstanding under the 2013 Plan as of December 31, 2014, which will become available for issuance under the 2013 Plan to the extent the options are forfeited or lapse unexercised without issuance of such shares under the 2004 Plan. As of January 1, 2015 an additional 1,193,903 shares of our common stock became available for future issuance as a result of the annual increase provision in the 2013 Plan.

# Summary of Activity

The following table summarizes activity under 2004 Plan and 2013 Plan during the twelve months ended December 31, 2014, including grants to nonemployees and restricted stock units ( RSUs ) granted:

(In thousands, except per share amounts)	Shares Available for Grant of Options and Awards	Options and Awards Outstanding	Av Exerc	eighted verage cise Price • Share	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Balances at December 31, 2011	207	2,529	\$	2.91		
Options granted	(129)	129		8.41		
Options exercised		(76)		2.06		
Options forfeited Balances at December 31, 2012 Options authorized	133 211 500	(133) 2,449		2.29 3.48		
Options granted	(597)	597		15.10		
Options exercised		(113)		2.19		
Options forfeited	3	(3)		6.75		
Balances at December 31, 2013 Options authorized Options granted	117 1,176 (1,027)	2,930 0 1,027		5.90 22.50		
RSUs granted	(294)	294				
Options exercised	(_, .)	(382)		2.83		
Options forfeited	47	(47)		22.28		
Balances at December 31, 2014	19	3,822	\$	10.84	6.29	\$ 46,039
Vested and Expected to vest December 31, 2014		3,773	\$	10.72	6.25	\$ 45,904
Vested December 31, 2014		2,011	\$	4.66	4.65	\$ 34,392

The intrinsic value of options exercised was \$8.9 million, \$3.1 million and \$490,000 for the years ended December 31, 2014, 2013, and 2012. The intrinsic value of outstanding options was calculated as the difference between the exercise price of the options and the closing price of the Company s common stock of \$21.76 per share, \$29.52 per share and \$1.50 per share as of December 31, 2014, 2013 and 2012. The weighted-average grant date estimated fair values of options and RSUs granted during the year ended December 31, 2014 were \$13.90 per share and \$31.03 per share, respectively. RSUs were only granted in 2014. The weighted-average grant date estimated fair value of options was \$9.48 per share for the year ended December 31, 2013 and \$5.14 per share for the year ended December 31, 2012.

# Liability for Shares with Repurchase Rights

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The 2004 Plan allowed for the granting of options that may be exercised before the options have vested. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser s employment or services, at the price paid by the purchaser. The amounts received in exchange for these shares have been recorded as a liability on the accompanying balance sheets and will be reclassified into common stock and additional paid-in-capital as the shares vest.

At December 31, 2014 and 2013, there were 2,983 shares and 5,088 shares of common stock outstanding, respectively, subject to the Company s right of repurchase at a price of \$4.56 per share. At December 31, 2014 and 2013, the Company recorded \$14,000 and \$24,000, respectively, as liabilities associated with shares issued with repurchase rights.

# **Employee Stock Purchase Plan**

As of December 31, 2014, a total of 593,979 shares of common stock have been authorized and 528,070 shares of common stock are available for future issuance under the Company s Employee Stock Purchase Plan (the ESPP). This authorized number includes the additional 293,979 shares of common stock that became available for future issuance under the ESPP as of January 1, 2014 as a result of an annual automatic increase provision in the ESPP. The ESPP allows eligible employees to purchase shares of the Company s common stock at a discount through payroll deductions of up to 15% of their eligible compensation, subject to any plan limitations. The ESPP provides for six-month offering periods, and at the end of each offering period, employees are able to purchase shares at 85% of the lower of the fair market value of the Company s common stock on the first trading day of the offering period or on the last day of the offering period.

There were no shares issued during the year ended December 31, 2013 under the ESPP. During the year ended December 31, 2014, the Company issued 65,909 shares under the ESPP. The Company used the following assumptions to estimate the fair value of the ESPP offered for the twelve months ended December 31, 2014: expected term of 0.5 years, weighted-average volatility from 65.7% to 115.4%, risk-free interest rate from 0.05% to 0.08% and expected dividend yield of zero. As of January 1, 2015 an additional 298,475 shares of our common stock became available for future issuance as a result of the annual increase provision in the ESPP.

# **Restricted Stock Units**

In March 2014, the Company awarded 293,980 RSUs under the 2013 Plan. Each vested RSU represents the right to receive one share of common stock. The fair value of the RSU awards was calculated based on the NASDAQ quoted stock price on the date of the grant with the expense being recognized over the vesting period. The RSUs are generally scheduled to vest at the end of three years at March 31, 2017. However, the vesting will be accelerated to 25% of the awarded RSUs upon the payment by Celgene of a designated milestone payment related to Phase II clinical trials of demcizumab (anti-DLL4, OMP-21M18). The stock-based compensation expense for these RSUs is being amortized on the straight-line basis over the three-year vesting period. The Company continues to assess at each reporting date whether achievement of any performance condition is probable and would begin recognizing compensation costs based on the accelerated vesting if and when achievement of the performance condition becomes probable. The Company has recognized the stock-based compensation expense of \$2.3 million related to these RSUs for the year ended December 31, 2014.

#### **Stock-Based Compensation**

Employee stock-based compensation expense was calculated based on awards expected to vest and has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Stock-based compensation expense recognized was as follows (in thousands):

	Year l	Year Ended December 31,			
	2014	2013	2012		
Research and development	\$ 3,600	\$ 957	\$497		
General and administrative	2,594	779	339		

Total	\$6,194	\$1,736	\$836

As of December 31, 2014, the Company had \$15.9 million and \$6.8 million of unrecognized compensation expense related to unvested stock options and RSUs, respectively, which are expected to be recognized over an estimated weighted-average period of 3.16 years and 2.25 years, respectively.

The estimated grant date fair value of employee stock options was calculated using the Black-Scholes option-pricing model, based on the following assumptions:

	Year End	Year Ended December 31,		
	2014	2013	2012	
Weighted-average volatility	66.3%	68.3%	66.9%	
Weighted-average expected term (years)	6.2	6.2	6.2	
Risk-free interest rate	2.06%	1.82%	1.09%	
Expected dividend yield				

#### Volatility

Since the Company has limited information on the volatility of its common stock due to no significant trading history, the expected stock price volatility was calculated based on the average volatility for comparable publicly traded biopharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle, and financial leverage to the Company.

# Expected Term

The Company has very limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock-option grants. As such, the expected term was estimated using the simplified method.

# Risk-Free Rate

The risk-free interest rate assumption is based on the zero-coupon U.S. Treasury instruments on the date of grant with a maturity date consistent with the expected term of the Company s stock option grants.

# Expected Dividend Yield

To date, the Company has not declared or paid any cash dividends and does not have any plans to do so in the future. Therefore, the Company used an expected dividend yield of zero.

# 13. Income Taxes

For the year ended December 31, 2014, the Company recorded an income tax benefit of \$0.5 million due primarily to the recognition of additional tax attributes that can offset alternative minimum tax as a result of the carryback. For the year ended December 31, 2013, the Company recorded an income tax provision of \$1.9 million due primarily to the accelerated recognition of certain upfront payments for tax purposes that could not be fully offset by tax attributes. For the year ended December 31, 2012, the Company did not record an income tax provision on pre-tax income because we incurred taxable losses for both state and federal income tax purposes.

Income (loss) before income taxes for the years ended December 31, 2014, 2013 and 2012 was from the United States.

The components of the provision for income taxes are as follows (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Current			
Federal	\$(10,841)	\$ 12,275	\$
State	1	1	
Total	(10,840)	12,276	
Deferred			
Federal	10,331	(10,331)	
State			
Total	10,331	(10,331)	
Income tax provision (benefit)	\$ (509)	\$ 1,944	\$

The reconciliation of the statutory federal income tax rate to the Company s effective tax rate is as follows:

	Year Ended December 31,		
	2014	2013	2012
Tax at statutory federal rate	35%	35%	34%
State tax net of federal benefit			
Research and development credit	12%	6%	
Change in valuation allowance	(45%)	(54%)	(34%)
Federal tax rate differential		6%	
Other	(1%)	(1%)	
Income tax (provision) benefit	1%	(8%)	%

Net deferred tax assets as of December 31, 2014 and 2013 consist of the following (in thousands):

	Year Ended December 31,	
	2014	2013
Deferred tax assets:		
Net operating loss carryforwards	\$ 28,414	\$ 16,678
Accruals	911	853
Research and development credits	19,249	4,694
Deferred revenue	52,054	64,270
Other	2,378	929

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Gross deferred tax assets	103,006	87,424
Deferred tax liability	(143)	
Valuation allowance	(102,863)	(77,093)
Net deferred tax assets	\$	\$ 10,331

The valuation allowance increased by \$25.8 million and \$11.4 million for the year ended December 31, 2014 and 2013, respectively. ASC Topic 740 requires that the tax benefit of deductible temporary differences or carryforwards be recorded as a deferred tax asset to the extent that management assesses the realization is more likely than not. Future realization of the tax benefit ultimately depends on the existence of sufficient taxable income within the carryback or carryforward period available under the tax law. At December 31, 2013 the Company had concluded that it was more likely than not that \$10.3 million deferred tax assets at the year ended December 31, 2013 would be realizable as a result of carryback potential. At December 31, 2014, the Company

has reclassified the carryback potential from deferred tax assets to tax receivable expected to be claimed as result of the carryback. At December 31, 2014, the Company has set up valuation allowances against all federal and state deferred tax assets because based on all available evidence, these deferred tax assets are not more likely than not to be realizable.

At December 31, 2014, the Company had federal and state net operating loss carryforwards aggregating approximately \$69.0 million and \$116.5 million, respectively. These federal and California net operating loss carryforwards will begin to expire in 2023 and 2017, respectively, if not utilized. At December 31, 2014, the Company also had federal and California research and development credit carryforwards aggregating approximately \$13.1 million and \$12.0 million, respectively. The federal credits will expire in 2024, if not utilized. California research and development credits will expire in 2024, if not utilized.

Utilization of the net operating loss and tax credits carryforwards may be limited by ownership change rules, as defined in Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. This annual limitation may result in the expiration of the net operating losses and credits before utilization. The Company has performed an analysis to determine whether an ownership change has occurred from inception to December 31, 2014. Based on this analysis, management has determined that \$0.7 million in federal and \$0.7 million in California net operating losses generated during that period will expire without being used.

On January 1, 2009, the Company adopted the Financial Accounting Standards Board Interpretation No. 48 (ASC 740-10), Accounting for Uncertainties in Income Taxes (formerly known as FIN 48). ASC 740 requires the Company to recognize the financial statements effects of a tax position when it is more likely than not, based on technical merits, that the position will be sustained upon examination.

A reconciliation of the Company s unrecognized tax benefits is as follows (in thousands):

	December 31,		
	2014	2013	2012
Balance at beginning of year	\$4,464	\$ 3,404	\$ 2,996
Increase related to current year tax provision	1,539	708	338
Increase related to prior year tax provision		354	70
Decrease related to current year tax provision		(2)	
Decrease related to prior year tax provision	(569)		
Balance at end of year	\$ 5,434	\$4,464	\$3,404

The unrecognized tax benefits, if recognized and in absence of full valuation allowance, would impact the income tax provision by \$4.6 million and \$3.7 million as of December 31, 2014 and 2013, respectively.

The Company has elected to include interest and penalties as a component of tax expense. The Company accrued approximately \$37,000 of interest and penalties during 2014. As of December 31, 2013 and 2014, the Company had recognized a liability for interest and penalties of approximately \$0 and \$37,000, respectively.

The Company files federal and state income tax returns in the U.S. Tax years from 2004 forward remain open to examination due to the carryover of net operating losses and other tax attributes.

# 14. Net Loss per Common Share

The following outstanding common stock equivalents were excluded from the computation of diluted net loss per common share for the periods presented because including them would have been antidilutive:

	Year Ended December 31,		
	2014	2013	2012
Convertible preferred stock	0		21,180,280
Options to purchase common stock	3,528,032	2,930,381	2,449,441
RSUs	293,980		
Warrants to purchase convertible preferred stock	0		47,859
	3,822,012	2,930,381	23,677,580

#### 15. Selected Quarterly Financial Data (Unaudited)

Selected quarterly results from operations for the years ended December 31, 2014 and 2013 are as follows (in thousands, except per share amounts):

	2014 Quarter End			
	March 31	June 30	September 30	December 31
Total revenue	\$ 6,015	\$ 6,015	\$ 19,015	\$ 8,514
Operating expenses	19,922	21,607	24,515	24,139
Net loss	(13,871)	(15,597)	(5,486)	(15,056)
Basic and diluted net loss per				
common share	(0.47)	(0.53)	(0.18)	(0.50)

	2013 Quarter End			
	March 31	June 30	September 30	December 31
Total revenue	\$ 2,932	\$ 2,932	\$ 12,932	\$ 18,983
Operating expenses	(11,561)	(12,427)	(16,301)	(21,389)
Net loss	(8,598)	(9,644)	(3,486)	(4,343)
Basic and diluted net loss per common				
share	(7.92)	(8.83)	(0.15)	(0.15)
. Subsequent Events				

On January 15, 2015 the Company announced the enrollment of the first biomarker-selected patient in its brontictuzumab (anti-Notch1, OMP-52M51) Phase Ia solid tumor clinical trial. The advancement to the predictive biomarker expansion stage triggered a \$5.0 million milestone from OncoMed s partner, GlaxoSmithKline (GSK).

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure None.

# Item 9A. Controls and Procedures Evaluation of Disclosure Controls and Procedures

Management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2014. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2014, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

# Management s Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Management conducted an evaluation of the effectiveness of our internal controls over financial reporting utilizing the principles of the 2013 framework established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO Framework). Based on that evaluation, management believes that our internal control over financial reporting was effective as of December 31, 2014.

# **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

# Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for emerging growth companies.

# Item 9B. Other Information None.

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## PART III

### Item 10. Directors, Executive Officers and Corporate Governance

Information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission on Schedule 14A in connection with our 2015 Annual Meeting of Stockholders (the Proxy Statement ), which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2014, under the headings Executive Officers, Election of Directors, Corporate Governance, and Section 16(a) Beneficial Ownership Reporting Compliance, and is incorporated herein by reference.

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

#### Item 11. Executive Compensation

Information required by this item will be contained in the Proxy Statement under the headings Executive Compensation and Director Compensation, and is incorporated herein by reference.

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

Information required by this item will be contained in the Proxy Statement under the headings Security Ownership of Certain Beneficial Owners and Management and Equity Compensation Plan Information, and is incorporated herein by reference.

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

Information required by this item will be contained in the Proxy Statement under the headings Certain Relationships and Related Party Transactions and Corporate Governance, and is incorporated herein by reference.

## Item 14. Principal Accounting Fees and Services

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

## PART IV

# Item 15. *Exhibits and Financial Statement Schedules* (a) The following documents are filed as part of this report:

1. Financial Statements

See Index to Financial Statements at Item 8 herein.

2. Financial Statement Schedules

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

3. Exhibits

See the Exhibit Index immediately following the signature page of this Annual Report on Form 10-K.

#### SIGNATURES

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

#### **ONCOMED PHARMACEUTICALS, INC.**

By: /s/ Paul J. Hastings Paul J. Hastings Chairman and Chief Executive Officer

Date: March 12, 2015

## **POWER OF ATTORNEY**

Each person whose individual signature appears below hereby authorizes and appoints Paul J. Hastings and Sunil Patel, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Paul J. Hastings	/s/ Paul J. Hastings Chairman, Chief Executive Officer and President ( <i>Principal Executive Officer</i> )	
Paul J. Hastings		
/s/ Sunil Patel	Chief Financial Officer, Senior Vice President, Corporate Development and Finance ( <i>Principal</i>	March 12, 2015
Sunil Patel	Financial and Accounting Officer)	
/s/ Jack W. Lasersohn	Lead Director	March 12, 2015
Jack W. Lasersohn, J.D.		
/s/ Terry Gould	Director	March 12, 2015
Elisha P. ( Terry ) Gould III		

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/s/ Laurence Lasky	Director	March 12, 2015
Laurence Lasky, Ph.D.		
/s/ Deepa R. Pakianathan	Director	March 12, 2015
Deepa R. Pakianathan, Ph.D.		
/s/ Denise Pollard-Knight	Director	March 12, 2015
Denise Pollard-Knight, Ph.D.		
/s/ Jonathan D. Root	Director	March 12, 2015
Jonathan D. Root, M.D.		
/s/ Michael S. Wyzga	Director	March 12, 2015
Michael S. Wyzga		

# EXHIBIT INDEX

**Incorporated by Reference** 

#### Exhibit

Exhibit	Incorporated by Reference				
Number	Exhibit Description	Form	Date	Number	Filed Herewith
1.1	Form of Underwriting Agreement	S-1/A	07/08/2013	1.1	
3.1	Amended and Restated Certificate of Incorporation	8-K	07/28/2013	3.1	
3.2	Amended and Restated Bylaws	8-K	07/28/2013	3.2	
4.1	Form of Common Stock Certificate	S-1/A	07/03/2013	4.1	
4.2(A)	Amended and Restated Investor Rights Agreement, dated October 7, 2008, by and among the registrant and certain stockholders	S-1	05/11/2012	4.4(A)	
4.2(B)	Amendment and Consent, dated September 16, 2010, by and among the registrant and certain stockholders	S-1	05/11/2012	4.4(A)	
4.3	Registration Rights Agreement, dated as of December 2, 2013, by and between the registrant and Celgene Corporation	8-K	12/03/2013	4.1	
10.1(A)	Research and Development Collaboration, Option and License Agreement, dated December 7, 2007, by and between the registrant and SmithKline Beecham Corporation	S-1/A	07/05/2012	10.1(A)	
10.1(B)	Amendment No. 1 to the Research and Development Collaboration, Option and License Agreement, dated July 28, 2011, by and between the registrant and GlaxoSmithKline LLC	S-1/A	07/05/2012	10.1(B)	
10.1(C)	Second Amendment regarding Payment of Certain Milestone Payments for the Anti-Notch 2/3 Program (OMP-59R5), dated July 27, 2012, by and between the registrant and GlaxoSmithKline LLC	S-1/A	10/25/2012	10.1(C)	
10.2(A)	Collaboration and Option Agreement, dated June 15, 2010, by and between the registrant and Bayer Schering Pharma AG	S-1/A	07/05/2012	10.2	
10.2(B)	Amendment 1 to the Collaboration and Option Agreement, dated August 1, 2012, by and between the registrant and Bayer Schering Pharma AG	S-1/A	10/25/2012	10.2(B)	
10.2(C)		10-Q	11/13/2013	10.9	

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Amendment 2 to the Collaboration and Option Agreement, dated August 27, 2013, by and between the registrant and Bayer Schering Pharma AG.

10.3(A)	Subscription and License Agreement, dated June 1, 2006, by and between the registrant and MorphoSys AG	S-1/A	07/05/2012	10.3(A)
10.3(B)	Commercial License Requests under the Subscription and License Agreement, dated April 28, 2008 and May 6, 2008, by and between the registrant and MorphoSys AG	S-1	05/11/2012	10.3(B)

Exhibit		Incorporated by Reference			
Number	Exhibit Description	Form	Date	Number	Filed Herewith
10.3(C)*	Extended Research License under the Subscription and License Agreement, dated September 30, 2014, by and between the registrant and MorphoSys AG				Х
10.4(A)	License Agreement, dated January 5, 2001, by and between the registrant (as successor in interest to Cancer Stem Cell Genomics, Inc.) and the Regents of the University of Michigan	S-1	05/11/2012	10.4(A)	
10.4(B)	Amendment Number 1 to License Agreement, dated July 21, 2004, by and between the registrant (as successor in interest to Cancer Stem Cell Genomics, Inc.) and the Regents of the University of Michigan	S-1	05/11/2012	10.4(B)	
10.4(C)	Amendment Number 2 to License Agreement, dated August 13, 2004, by and between the registrant and the Regents of the University of Michigan	S-1	05/11/2012	10.4(C)	
10.4(D)	Amendment No. 3 to License Agreement, dated March 31, 2005, by and between the registrant and the Regents of the University of Michigan	S-1	05/11/2012	10.4(D)	
10.4(E)	Amendment No. 4 to License Agreement, dated December 12, 2005, by and between the registrant and the Regents of the University of Michigan	S-1	05/11/2012	10.4(E)	
10.4(F)	Amendment No. 5 to License Agreement, dated March 12, 2007, by and between the registrant and the Regents of the University of Michigan	S-1	05/11/2012	10.4(F)	
10.4(G)	Amendment No. 6 to License Agreement, dated October 6, 2008, by and between the registrant and the Regents of the University of Michigan	S-1	05/11/2012	10.4(G)	
10.4(H)	Letter, dated September 4, 2008, from the University of Michigan to the registrant regarding the License Agreement	S-1	05/11/2012	10.4(H)	
10.4(I)	Memorandum of Understanding, dated May 8, 2009, by and between the registrant and the Regents of the University of Michigan	S-1	05/11/2012	10.4(I)	
10.5(A)	Lease, dated May 30, 2006, by and between the registrant and Slough Redwood City, LLC	<b>S-</b> 1	05/11/2012	10.5(A)	
10.5(B)		<b>S-</b> 1	05/11/2012	10.5(B)	

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First Amendment to Lease, dated November , 2006, by and between the registrant and Slough Redwood City, LLC

10.5(C)	Second Amendment to Office Lease, dated December 22, 2010, by and between the registrant and HCP LS Redwood City, LLC	S-1	05/11/2012	10.5(C)
10.6(A)#	2004 Stock Incentive Plan, as amended	S-1	05/11/2012	10.6(A)
10.6(B)#	Form of Stock Option Agreement under 2004 Stock Incentive Plan	S-1	05/11/2012	10.6(B)

Exhibit		Incorporated by Reference			
Number	Exhibit Description	Form	Date	Number	Filed Herewith
10.7(A)#	2013 Equity Incentive Award Plan	S-1/A	07/08/2013	10.7	
10.7(B)#	Form of Stock Option Agreement under 2013 Equity Incentive Award Plan	S-1/A	07/03/2013	10.7(B)	
10.7(C)#	Form of Restricted Stock Unit Award Agreement under the OncoMed Pharmaceuticals, Inc. 2013 Equity Incentive Award Plan	S-8	03/28/2014	10.3	
10.8#	Employee Stock Purchase Plan	S-1/A	07/03/2013	10.8	
10.9#	Offer Letter, dated November 12, 2005, by and between the registrant and Paul Hastings	S-1	05/11/2012	10.9	
10.9(B)#	Amendment to Employment Agreement, dated July 2, 2013, by and between the registrant and Paul Hastings	S-1/A	07/03/2013	10.9(B)	
10.10#	Offer Letter, dated May 27, 2004, by and between the registrant (as successor in interest to Cancer Stem Cell Genomics, Inc.) and John A. Lewicki	S-1	05/11/2012	10.10	
10.11#	Offer Letter, dated October 15, 2007, by and between the registrant and William D. Waddill	S-1	05/11/2012	10.11	
10.12#	Offer Letter, dated June 18, 2009, by and between the registrant and Sunil Patel	S-1	05/11/2012	10.12	
10.13#	Offer Letter, dated July 14, 2005, by and between the registrant and Tim Hoey	S-1	05/11/2012	10.13	
10.14#	Offer Letter, dated September 27, 2004, by and between the registrant and Austin Gurney	S-1	05/11/2012	10.14	
10.15#	Form of Indemnity Agreement for directors and officers	S-1/A	07/03/2012	10.16	
10.16#	Form of Change in Control and Severance Agreement for officers	S-1	05/11/2012	10.17	
10.17#	Offer Letter, dated July 28, 2011, by and between the registrant and Jakob Dupont	S-1/A	06/15/2012	10.18	
10.18#	Offer Letter, dated April 24, 2008, by and between the registrant and Alicia J. Hager	S-1/A	06/15/2012	10.19	
10.19	Collaboration Agreement, dated August 22, 2012, by and between the registrant and Lonza Sales AG	S-1/A	10/25/2012	10.20	
10.20(A)	Multi-Product License Agreement, dated August 22, 2012, by and between the registrant and Lonza Sales AG	S-1/A	10/25/2012	10.21	

10.20(B)\* Amendment No. 1 to the Multi-Product License Agreement, dated January 22, 2014, by and between the registrant and Lonza Sales AG
10.21 Non-Employee Director Compensation Policy, adopted August 28, 2013, as amended October 14, 2013 and February 28, 2014

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#### Exhibit

Incorporated	by	Reference
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		P			Filed		
Number	Exhibit Description	Form	Date	Number	Herewith		
10.22	Master Research and Collaboration Agreement, by and between the registrant and Celgene Corporation	10-K	03/18/2014	10.23			
10.23	Securities Purchase Agreement, dated as of December 2, 2013, by and between the registrant and Celgene Corporation	8-K	12/03/2013	10.1			
23.1	Consent of independent registered public accounting firm				Х		
24.1	Power of Attorney (included on signature page to this Annual Report on Form 10-K)				Х		
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended				Х		
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended				Х		
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350				Х		
101.INS	XBRL Instance Document				Х		
101.SCH	XBRL Taxonomy Extension Schema Document				Х		
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				Х		
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				Х		
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document				Х		
101 DDE							

101.PRE XBRL Taxonomy Extension Presentation Linkbase

Confidential treatment has been granted for certain information contained in this exhibit. Such information has been omitted and filed separately with the Securities and Exchange Commission.

- # Indicates management contract or compensatory plan.
- \* Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the Securities and Exchange Commission.
- \*\* The certifications attached as Exhibit 32.1 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of OncoMed Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general

incorporation language contained in such filing.