IMMUNOGEN INC
Form 10-K
August 27, 2010

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended June 30, 2010

OR

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

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

ImmunoGen, Inc.

Massachusetts	**04-2726691**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $.01 par value	NASDAQ Global Market

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

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

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

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

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

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

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

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

Aggregate market value, based upon the closing sale price of the shares as reported by the NASDAQ Global Market, of voting stock held by non-affiliates at December 31, 2009: $444,794,248 (excludes shares held by executive officers and directors). Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of management or policies of the registrant, or that such person is controlled by or under common control with the registrant. Common Stock outstanding at August 24, 2010: 67,949,840 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement to be delivered to shareholders in connection with the Annual Meeting of Shareholders to be held on November 16, 2010 are incorporated by reference into Part III.

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ImmunoGen, Inc.

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Item 1. ***Business***

In this Annual Report on Form 10-K, ImmunoGen, Inc. (ImmunoGen, Inc., together with its subsidiaries, is referred to in this document as "we", "us", "ImmunoGen", or the "Company"), incorporates by reference certain information from parts of other documents filed with the Securities and Exchange Commission. The Securities and Exchange Commission allows us to disclose important information by referring to it in that manner. Please refer to all such information when reading this Annual Report on Form 10-K. All information is as of June 30, 2010 unless otherwise indicated. For a description of the risk factors affecting or applicable to our business, see "Risk Factors," below.

The Company

We develop novel, targeted therapeutics for the treatment of cancer using our expertise in cancer biology, the development of monoclonal antibodies, the creation of highly potent cytotoxic, or cell-killing, agents, and the engineering of linkers used to attach our cell-killing agents to antibodies.

Most of the product candidates being developed by us and through our collaborations with others utilize our Targeted Antibody Payload, or TAP, technology. A TAP compound consists of a monoclonal antibody that binds specifically to an antigen target found on cancer cells with one of our highly potent cytotoxic agents attached using one of our linkers. Our linkers are engineered to keep the cytotoxic agent stably attached to the antibody while the TAP compound is in the blood stream and then release it in a fully active form after delivery to a cancer cell. Six TAP compounds and one therapeutic antibody are in clinical testing through our own programs and those of our partners, with more expected to enter the clinic in 2010 and 2011.

We develop targeted, antibody-based anticancer compounds for our own proprietary pipeline. Our most advanced wholly owned product candidate is lorvotuzumab mertansine (also known as IMGN901). This TAP compound is a potential treatment for cancers that express CD56, which include small-cell lung cancer, Merkel cell carcinoma, ovarian cancer, and multiple myeloma. We have several clinical trials underway with lorvotuzumab mertansine and expect to initiate additional trials going forward. Our second most advanced compound, IMGN388, is a potential treatment for solid tumors including melanomas, sarcomas and many carcinomas. IMGN388 also is a clinical-stage TAP compound. We have three TAP compounds currently in or positioned to begin preclinical toxicology studies. One of these compounds, IMGN529, is being developed for the treatment of certain liquid tumors and we expect to submit an investigational new drug, or IND, application to the FDA for this product candidate in 2011. We expect to submit an IND for another of these in 2012. In addition to our product programs, we continue to invest in our TAP technology, including the development of additional cytotoxic agents and linkers, to maintain a leadership position in our field.

Part of our business model is to establish collaborations with other companies in order to provide us with cash and revenue short term and potential significant value long term. The collaborations also expand the utilization of our TAP technology. The most advanced TAP compound, Trastuzumab-DM1 or T-DM1, is in development through our collaboration with Genentech, a member of the Roche Group, and it is in Phase III testing for two indications. SAR3419 and SAR650984 are in clinical testing through a collaboration with sanofi-aventis. BIIB015 and BT-062 are in clinical development through our collaborations with Biogen Idec and Biotest, respectively. Companies with licenses to develop TAP compounds to other targets include Amgen, Bayer Schering Pharma, Genentech, and sanofi-aventis.

We were organized as a Massachusetts corporation in 1981. Our principal offices are located at 830 Winter Street, Waltham, Massachusetts (MA) 02451, and our telephone number is (781) 895-0600. We maintain a website at *www.immunogen.com*, where certain information about us is available. Please note that information contained on the website is not a part of this document. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to

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those reports are available free of charge through the "Investor Information" section of our website as soon as reasonably practicable after those materials have been electronically filed with, or furnished to, the Securities and Exchange Commission. We have adopted a Code of Corporate Conduct that applies to all our directors, officers and employees and a Senior Officer and Financial Personnel Code of Ethics that applies to our senior officers and financial personnel. Our Code of Corporate Conduct and Senior Officer and Financial Personnel Code of Ethics are available free of charge through the "Investor Information" section of our website.

Product Candidates

The following table summarizes the status for compounds in development by us and our collaborators. The results from preclinical testing and early clinical trials may not be predictive of results obtained in subsequent clinical trials and there can be no assurance that our or our

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collaborators' clinical trials will demonstrate the level of safety and efficacy of any product candidates necessary to obtain regulatory approval.

Product Candidate	Development Stage	Collaborative Partner, if any
Trastuzumab-DM1 (T-DM1)	For advanced HER2+ breast cancer: 2nd-line use Phase III trial underway 1st-line use Phase III trial underway Adjuvant use described as being under consideration	Genentech/Roche
Lorvotuzumab mertansine (IMGN901)	For CD56+ solid tumors: Merkel cell carcinoma patients with advanced disease being enrolled into expansion phase of a Phase I trial; Go/no go decision to be made regarding initiation of pivotal testing Small-cell lung cancer patients with advanced disease being enrolled into expansion phase of a Phase I elial; Phase I/II trial in 1st-line use expected to start by late 2010 Ovarian cancer patients with advanced disease being recruited into expansion phase of a Phase I trial; next steps to be determined For CD56+ multiple myeloma: Use as monotherapy in advanced disease patients being enrolled into expansion phase of a Phase I trial Use in combination in advanced disease patients being enrolled into Phase I trial	Proprietary to ImmunoGen
SAR3419	For advanced CD19+ non-Hodgkin's lymphoma Phase I	sanofi-aventis
IMGN388	For advanced solid tumors Phase I	Centocor Ortho Biotech has opt-in rights
BIIB015	For advanced solid tumors Phase I	Biogen Idec
BT-062	For advanced multiple myeloma Phase I	Biotest; ImmunoGen has opt-in rights
SAR650984[(1)]	For advanced hematological malignancies Phase I	sanofi-aventis
SAR566658	For advanced solid tumors Preclinical	sanofi-aventis
Other compounds	Research/preclinical	ImmunoGen/collaborators

(1) Therapeutic antibody; the rest of the product candidates are TAP compounds.

Trastuzumab-DM1 (T-DM1)

The most advanced compound in our pipeline is T-DM1, which is in global development by Roche for the treatment of advanced HER2+ breast cancer. T-DM1 consists of our DM1 cell-killing agent attached to trastuzumab, which is the active component of the marketed anticancer compound,

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Herceptin®. T-DM1 was created under a HER2-specific license agreement established in 2000 between ImmunoGen and Genentech.

To date, we have earned $13.5 million of a potential $44 million in milestone payments with Genentech/Roche's advancement of T-DM1: $2 million when the IND became effective in January 2006, $5 million when T-DM1 entered Phase II clinical testing in July 2007, and $6.5 million when it began Phase III evaluation in February 2009. Genentech retained us to develop a commercial-scale manufacturing process for T-DM1 in May 2006 and we have completed and transferred this process.

In early July 2010, Roche announced the submission of a Biologics License Application, or BLA, to the FDA to gain U.S. marketing approval for use of T-DM1 to treat patients with advanced HER2+ breast cancer who had previously received multiple chemotherapies and HER2-targeted medicines; this is also known as 3rd-line use. The basis of the submission is the single-arm Phase II clinical trial that was reported at the San Antonio Breast Cancer Symposium in December 2009. In August 2010, Roche announced that the FDA issued a Refuse to File letter for this BLA. Roche will continue to work with the FDA and expects to submit a new BLA in mid 2012 based on results of the ongoing EMILIA trial described below.

In February 2009, patient dosing began in a Phase III trial, EMILIA, being conducted by Roche to assess T-DM1 for 2nd-line use in advanced HER2+ breast cancer. EMILIA compares T-DM1, used alone, against the marketed anticancer agents, lapatinib and capecitabine, used together. Roche has noted that, if successful, this trial would be used to apply in 2012 for marketing approval of T-DM1 for 2nd-line use in the U.S. It would also be used to apply in 2012 for marketing approval in Europe.

In July 2010, patient dosing began in a Phase III trial, MARIANNE, being conducted by Roche to assess T-DM1 for 1st-line use in advanced HER2+ breast cancer. MARIANNE compares T-DM1, used alone, against the marketed agent, trastuzumab, used together with a taxane, in patients not previously treated for metastatic disease. This trial also includes comparison to T-DM1 used with Roche's experimental agent, pertuzumab. Roche has noted that, if successful, MARIANNE would be used to apply some time after 2013 for marketing approval of T-DM1 for 1st-line use in the U.S. and Europe.

The first findings with T-DM1 used for 1st-line treatment of advanced HER2+ breast cancer are expected to be reported at a medical meeting in October 2010. These data would be from a Phase II trial.

Roche also is assessing T-DM1 used in combination with several approved and experimental agents, and reported the first data on T-DM1 used together with pertuzumab at a medical meeting in June 2010. It expects to report additional data at a medical meeting in December 2010.

Lorvotuzumab mertansine

Our most advanced wholly owned compound is lorvotuzumab mertansine, also known as IMGN901. The target for this TAP compound, CD56, is found on a number of tumor types, including small-cell lung cancer, ovarian cancer, Merkel cell carcinoma, and the liquid tumor, multiple myeloma. We believe lorvotuzumab mertansine has the potential to be the first effective antibody-based therapy for the treatment of these cancers.

There is a need for better therapies for a number of CD56+ cancers. For example, patients with advanced small-cell lung cancer can respond to their first treatment regimen, but typically their disease then recurs fairly quickly and, at that stage, patients usually survive for less than 6 months. There are no approved therapies for metastatic Merkel cell carcinoma, and patients with advanced disease typically survive for less than 7 months. In recent years, several new therapies have become available to treat multiple myeloma; however, patients still die from this disease and we believe there is a need for a treatment, such as lorvotuzumab mertansine, that has a different mechanism of action from the approved therapies.

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We are evaluating lorvotuzumab mertansine for the treatment of CD56+ cancers, focusing initially on small-cell lung cancer, Merkel cell carcinoma, ovarian cancer, and multiple myeloma:

Small-cell lung cancer, or SCLC Patients with recurrent SCLC were enrolled in the first lorvotuzumab mertansine Phase I trial conducted, which has been completed, and are being enrolled in the expansion phase of a second Phase I trial, which is in progress. To assess lorvotuzumab mertansine for 1st-line treatment of SCLC, we plan to commence a Phase I/II trial by late 2010 assessing it used in combination with etoposide/carboplatin, the standard 1st-line treatment for this cancer. We have applied for orphan drug designation in SCLC in the U.S. and Europe and are awaiting the decision.

Merkel cell carcinoma, or MCC A limited number of patients with advanced MCC received lorvotuzumab mertansine in the ongoing Phase I trial referenced previously. Additional patients with advanced MCC are being enrolled in the expansion phase of this trial to gain more experience with lorvotuzumab mertansine in the treatment of this disease. These findings along with other clinical data and input gained from regulatory agencies will be used to determine whether or not we will initiate a pivotal Phase II trial for this use during 2011. We have received orphan drug designation in MCC in the U.S. and Europe.

Ovarian cancer To gain experience with lorvotuzumab mertansine in this disease, patients with CD56+ ovarian cancer are being recruited to the expansion phase of the ongoing Phase I trial referenced previously.

Multiple myeloma, or MM Two Phase I trials are underway in this indication. One evaluates lorvotuzumab mertansine when used as a single agent and is currently in its expansion phase. The other evaluates the compound used in combination with the standard treatment for this cancer, lenalidomide plus dexamethasone. We expect to report interim data from one or both of these trials at the ASH annual meeting in December 2010. The findings from these trials will inform the future development of lorvotuzumab mertansine for MM.

SAR3419

We created this TAP compound for the treatment of non-Hodgkin's lymphoma and other B-cell malignancies and licensed it to sanofi-aventis as part of a broader research collaboration. We earned a $1 million milestone payment from sanofi-aventis in October 2007 with the its advancement into clinical testing. SAR3419 is currently in Phase I testing for the treatment of non-Hodgkin's lymphoma. Encouraging findings from the first Phase I trial conducted were reported at a medical meeting in December 2009. Sanofi-aventis is evaluating the compound using a different dosing schedule in a second Phase I trial, and SAR3419 is expected to advance into Phase II testing in the second half of 2011. Like Genentech for T-DM1, sanofi-aventis retained us to develop a commercial-scale manufacturing process for the compound. We have completed and transferred this process.

IMGN388

We are developing IMGN388 for the treatment of solid tumors. It includes an integrin-targeting antibody developed by Centocor Ortho Biotech, previously Centocor. IMGN388's target occurs on many types of solid tumors and also on vascular endothelial cells in the process of forming new blood vessels, a process that needs to occur for solid tumors to grow. IMGN388 is in Phase I testing and clinical data from this trial were presented at a medical meeting in June 2010. Centocor Ortho Biotech has opt-in rights for this compound.

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Other Compounds in Development by Us

In addition to lorvotuzumab mertansine and IMGN388, we have a number of product candidates at earlier stages in our pipeline. We expect to submit an IND for our third compound, IMGN529, in 2011, and an IND for our fourth compound in 2012. These are both TAP compounds. IMGN529 is a potential treatment for certain types of liquid tumors.

We also continue to invest in our TAP technology, including the development of additional cytotoxic agents and linkers, to maintain our leadership position in our field.

Other Compounds in Development by Our Partners

In addition to T-DM1 and SAR3419, other compounds in clinical testing through our collaborations with other companies are BT-062, BIIB015, and SAR650984. We expect 3 - 4 additional TAP compounds to advance into clinical testing during 2010 and 2011 through our existing collaborative partnerships. Companies with licenses to develop TAP compounds other than those already in the clinic include Amgen, Bayer Schering Pharma, Genentech, and sanofi-aventis.

Incidence of Relevant Cancers

Cancer remains a leading cause of death worldwide, and is the second leading cause of death in the U.S. Based on American Cancer Society estimates, we believe approximately 1.5 million new cases of cancer will be diagnosed in the U.S. in 2010 and that approximately 570,000 people will die from various cancers. The total number of people living with cancer significantly exceeds the number of patients diagnosed with cancer in a given year as patients can live with cancer for a year or longer. Additionally, the potential market for anticancer drugs exceeds the number of patients treated as many types of cancer typically are treated with multiple compounds at the same time. Additionally, patients often receive multiple drug regimens sequentially, either to treat or help prevent recurrence of the disease. In recent years, several antibody-based anticancer drugs have enjoyed considerable commercial success, as have other targeted anticancer agents.

T-DM1 Based on American Cancer Society and Roche estimates, we believe approximately 42,000-50,000 new cases of HER2+ breast cancer will be diagnosed in 2010. These include diagnoses for both localized disease and advanced, or metastatic, disease. The first approvals of T-DM1 are expected to be for advanced disease. Roche has estimated the 2nd-line and later patient population in the U.S. to be approximately 13,700 patients.

Lorvotuzumab mertansine We are assessing this compound for the treatment of CD56+ solid tumors, including small-cell lung cancer, ovarian cancer and Merkel cell carcinoma, as well as the liquid tumor, multiple myeloma. Based on our own studies and scientific literature, we believe that CD56 is expressed on approximately 100% of small-cell lung cancer and Merkel cell carcinoma cases, 70% of multiple myeloma cases, and 58% of ovarian cancer cases. Based on American Cancer Society estimates and other sources, we believe that approximately 28,000 new cases of small-cell lung cancer will be diagnosed in the U.S. in 2010. Based on American Cancer Society estimates, we also believe that approximately 22,000 new cases of ovarian cancer and 20,000 new cases of multiple myeloma will be diagnosed in the U.S. in 2010. Based on other published data, we believe approximately 1,900 new cases of Merkel cell carcinoma will be diagnosed in the U.S. in 2010.

We are assessing our IMGN388 compound for the treatment of solid tumors. Cancers of particular interest include melanoma, lung, breast, and ovarian cancers. Based on American Cancer Society estimates, we believe approximately 522,000 new cases of these cancers will be diagnosed in the U.S. in 2010.

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Out-licenses and Collaborations

As part of our business strategy to expand the use of and financial return from our TAP technology, we enter into license agreements with third parties where we grant the other party the exclusive right to use our TAP technology with their antibodies to specific antigen targets. We also had a research collaboration with sanofi-aventis that provided them access to compounds in our preclinical pipeline. As part of these agreements, we are entitled to receive upfront fees, potential milestone payments and royalties on the sales of any resulting products. Our principal out-licenses and collaborative agreements are described below.

Genentech (a member of the Roche Group)

In May 2000, we entered into two separate agreements with Genentech. The first agreement grants Genentech an exclusive license to our maytansinoid TAP technology for use with antibodies that target HER2, such as trastuzumab. Under the terms of this agreement, Genentech has exclusive worldwide rights to develop and commercialize maytansinoid TAP compounds with antibodies that target HER2. Genentech is responsible for the manufacturing, product development and marketing of any products resulting from the agreement. We are reimbursed for any preclinical and clinical materials that we manufacture under the agreement. We received a $2 million non-refundable payment from Genentech upon execution of the agreement. We also are entitled to receive up to $44 million in milestone payments from Genentech under this agreement, as amended in May 2006, in addition to royalties on the net sales of any resulting products. Genentech and Roche began Phase III evaluation of T-DM1 in February 2009, which triggered a $6.5 million milestone payment to us. Through June 30, 2010, we have received a total of $13.5 million in milestone payments.

In May 2000 we also entered into a "right-to-test" agreement with Genentech. This agreement provided Genentech with the right to test our maytansinoid TAP technology with antibodies to a defined number of targets on an exclusive basis for specified option periods and to take exclusive licenses to use our maytansinoid TAP technology to develop products directed to individual targets on agreed-upon terms. We received non-refundable technology access fees totaling $5 million for the eight-year term of the agreement. Genentech no longer has the right to designate new targets under this "right-to-test" agreement.

Under this agreement, Genentech licensed exclusive rights to use our maytansinoid TAP technology with antibodies to four undisclosed targets. The most recent license was taken in December 2008. Under the terms defined in the 2000 "right-to-test" agreement, for each license we received a $1 million license fee and may receive up to $38 million in milestone payments. We are also entitled to receive royalties on the sales of any resulting products. Genentech is responsible for the development, manufacturing, and marketing of any products resulting from these licenses.

Amgen

In September 2000, we entered into a ten-year "right-to-test" agreement with Abgenix, Inc., which was later acquired by Amgen. The agreement provides Amgen with the right to test our maytansinoid TAP technology with antibodies to a defined number of targets on either an exclusive and non-exclusive basis for specified option periods and to take exclusive or non-exclusive licenses to use our maytansinoid TAP technology to develop products for individual targets on agreed-upon terms. We received a $5 million technology access fee in September 2000. Under the agreement, in September 2009 and November 2009, we entered into two development and license agreements with Amgen and received a $1 million upfront payment with each license taken. In addition to the $1 million upfront payment, we are entitled to earn milestone payments potentially totaling $34 million per target for each compound developed under the "right-to-test" agreement, as well as royalties on the commercial sales of any resulting products. In March 2010, we granted Amgen a non-exclusive option to test our TAP

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technology with antibodies to a specific target, for which Amgen paid us a nominal fee. Under this "right-to-test" agreement, there can be option periods in effect that extend beyond the expiration of the agreement in September 2010.

sanofi-aventis

In July 2003, we entered into a broad collaboration agreement with sanofi-aventis to discover, develop and commercialize antibody-based anticancer therapeutics.

The agreement provides sanofi-aventis with worldwide commercialization rights to new anticancer therapeutics developed to targets that were included in the collaboration, including the right to use our TAP technology and our humanization technology in the creation of therapeutics to these targets. The product candidates (targets) currently in the collaboration include SAR3419 (CD19), SAR650984 (CD38), SAR566658 (CA6) and additional compounds at earlier stages of development that have yet to be disclosed.

The collaboration agreement entitles us to receive milestone payments potentially totaling $21.5 million for each therapeutic now included in the collaboration agreement. Through June 30, 2010, we have earned a total of $4 million in milestone payments related to the three product candidates noted above and one target not yet disclosed. We also earned an aggregate of $8 million of milestone payments related to two product candidates previously in the collaboration that have been returned to us along with the rights to the respective targets.

The agreement also entitles us to royalties on the commercial sales of any resulting products if and when such sales commence. Sanofi-aventis is responsible for the cost of the development, manufacturing and marketing of any products created through the collaboration. We are reimbursed for any preclinical and clinical materials that we make under the agreement. The collaboration agreement also provides us an option to certain co-promotion rights in the U.S. on a product-by-product basis. The terms of the collaboration agreement allow sanofi-aventis to terminate our co-promotion rights if there is a change of control of our company.

The overall term of the agreement extends to the later of the latest patent to expire or twelve years after the latest launch of any product discovered, developed and/or commercialized under the agreement. Sanofi-aventis paid us an upfront fee of $12.0 million in August 2003. Inclusive of all of its allowed extensions, the agreement enabled us to receive committed research funding totaling $79.3 million over the five years of the research collaboration. The two companies subsequently agreed to extend the date of research funding through October 31, 2008 to enable completion of previously agreed-upon research. We recorded the research funding as it was earned based upon its actual resources utilized in the collaboration. We earned $81.5 million of committed funding over the duration of the research program and are now compensated for research performed for sanofi-aventis on a mutually agreed-upon basis.

In October 2006, sanofi-aventis licensed non-exclusive rights to use our proprietary resurfacing technology to humanize antibodies to targets not included in the collaboration, including antibodies for non-cancer applications. This license provides sanofi-aventis with the non-exclusive right to use our proprietary humanization technology through August 31, 2011 with the right to extend for one or more additional periods of three years each by providing us with written notice prior to expiration of the then-current license term. Under the terms of the license, we are entitled to a $1 million license fee, half of which was paid upon contract signing and the second half was paid in August 2008, and in addition, we are entitled to receive milestone payments potentially totaling $4.5 million for each antibody humanized under this agreement and also royalties on commercial sales, if any.

In August 2008, sanofi-aventis exercised its option under a 2006 agreement for expanded access to our TAP technology. The exercise of this option enables sanofi-aventis to evaluate, with certain

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restrictions, our maytansinoid TAP technology with antibodies to targets that were not included in the research collaboration between the companies and to license the exclusive right to use the technology to develop products to specific targets based on the terms in the 2006 agreement. We are entitled to earn upfront and milestone payments potentially totaling $32 million per target for each compound developed under the 2006 agreement, as well as royalties on the commercial sales of any resulting products. We are also entitled to manufacturing payments for any materials made on behalf of sanofi-aventis. We received $500,000 in December 2006 with the signing of the option agreement and we received $3.5 million with the exercise of this option in August 2008. The agreement has a three-year term from the date of the exercise of the option and can be renewed by sanofi-aventis for one additional three-year term by payment of a $2 million fee.

Biogen Idec

In October 2004, we entered into a development and license agreement with Biogen Idec. The agreement grants Biogen Idec exclusive rights to use our maytansinoid TAP technology to develop and commercialize therapeutic compounds to the target Cripto. Biogen Idec is responsible for the research, development, manufacturing, and marketing of any products resulting from the license. We received a $1 million upfront payment upon execution of the agreement. In January 2008, Biogen Idec submitted an IND to the FDA for BIIB015, which was created under this agreement. This event triggered a $1.5 million milestone payment to us. Assuming all benchmarks are met, we could receive up to $42 million in milestone payments under this agreement. We are also entitled to receive royalties on net sales of resulting products. We also receive compensation from Biogen Idec for any product development research done on its behalf, as well as for the production of preclinical and clinical materials.

Biotest

In July 2006, we entered into a development and license agreement with Biotest. The agreement grants Biotest exclusive rights to use our maytansinoid TAP technology to develop and commercialize therapeutic compounds directed to the target CD138. We received a $1 million upfront payment upon execution of the agreement. In September 2008, Biotest began Phase I evaluation of BT-062, which was created under this agreement. This event triggered a $500,000 milestone payment to us. Assuming all benchmarks are met under this agreement, we could receive up to $35.5 million in milestone payments. We are also entitled to receive royalties on net sales of any resulting products. We receive payments for manufacturing any preclinical and clinical materials made at the request of Biotest.

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

Bayer Schering Pharma

In October 2008, we entered into a development and license agreement with Bayer Schering Pharma AG. The agreement grants Bayer Schering Pharma exclusive rights to use our maytansinoid TAP technology to develop and commercialize therapeutic compounds directed to a specific target. Bayer Schering Pharma is responsible for the research, development, manufacturing and marketing of any products resulting from the license. We received a $4 million upfront payment upon execution of the agreement, and for each compound developed and marketed by Bayer Schering Pharma under this collaboration we could potentially receive up to $170.5 million in milestone payments;

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additionally, we are entitled to receive royalties on the net sales of any resulting products. In September 2009, Bayer Schering Pharma reached a preclinical milestone which triggered a $1 million payment to us. We also are entitled to receive payments for manufacturing any preclinical and clinical materials at the request of Bayer Schering Pharma as well as for any related process development activities.

In-Licenses

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

Centocor Ortho Biotech

In December 2004, we entered into a development and license agreement with a predecessor to Centocor Ortho Biotech, a wholly owned subsidiary of Johnson & Johnson. Under the terms of this agreement, Centocor was granted exclusive worldwide rights to develop and commercialize anticancer therapeutics that consist of our maytansinoid cell-killing agent attached to an αv integrin-targeting antibody that was developed by Centocor. Under the terms of the agreement, we received an upfront payment of $1 million upon execution of the agreement.

In December 2007, we licensed from Centocor the exclusive, worldwide right to develop and commercialize a TAP compound, IMGN388, that consists of an αv integrin-targeting antibody developed by them and one of our maytansinoid cell-killing agents. This license reallocates the parties' respective responsibilities and financial obligations from the license referenced above. Centocor has the right to opt-in on future development and commercialization of IMGN388 at an agreed-upon stage in early clinical testing. Should Centocor not exercise this right, Centocor would be entitled to receive milestone payments potentially totaling $30 million, with the first payment due upon the completion of a successful Phase III trial, and also royalties on IMGN388 sales, if any. In this event, ImmunoGen has the right to obtain a new partner for IMGN388, with certain restrictions. Should Centocor exercise its opt-in right, ImmunoGen would receive an opt-in fee and be released from its obligation to pay Centocor any milestone payments or royalties on sales. Both companies would contribute to the costs of developing the compound. The two companies would share equally any profits on the sales of the compound in the U.S. and ImmunoGen would receive royalties on any international sales. The companies have agreed to share certain third-party payments. In June 2008, the FDA approved the IND application for IMGN388. This event triggered a $1 million milestone payment to a third-party, half of which was paid by ImmunoGen. As of June 30, 2010, the maximum amount that may be payable in the future to such third-parties under this agreement is $11 million.

Other Licenses

We also have licenses with third parties, including other companies and academic institutions, to gain access to techniques and materials for drug discovery and product development and the rights to use those techniques and materials to make our product candidates. These licenses include rights to certain antibodies.

Patents, Trademarks and Trade Secrets

Our intellectual property strategy centers on obtaining patent protection for our proprietary technologies and product candidates. As of June 30, 2010, our patent portfolio had a total of 299 issued patents worldwide and 463 pending patent applications worldwide that we own or license from third parties. We seek to protect our TAP technology and our product candidates through a multi-pronged

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approach. In this regard, we have patents and patent applications covering antibodies and other cell-binding agents, linkers, maytansinoid and other cell-killing agents, and complete antibody-drug conjugates, or immunoconjugates, comprising these components and methods of making and using each of the above. Typically, multiple issued patents and pending patent applications cover various aspects of each product candidate.

We consider our maytansinoid technology to be a key component of our overall corporate strategy. We currently own 21 issued U.S. patents covering various embodiments of our maytansinoid technology including claims directed to certain maytansinoids, antibody-maytansinoid conjugates and other cell-binding agents used with maytansinoids, and methods of making and using the same. In all cases, we have received or are applying for comparable patents in other jurisdictions including Europe and Japan. We have issued patents that cover numerous aspects of the manufacture of both our DM1 and DM4 cell-killing agents. These issued patents remain in force until various times between 2020 and 2026. We also have a composition of matter patent on our DM4 cell-killing agent that is expected to remain in force until 2024.

Our intellectual property strategy also includes pursuing patents directed to linkers, antibodies, conjugation methods, immunoconjugate formulations and the use of specific antibodies and immunoconjugates to treat certain diseases. In this regard, we have issued patents and pending patent applications related to many of our linker technologies. These issued patents, expiring in 2021-2023, and any patents which may issue from the patent applications, cover antibody-maytansinoid conjugates using these linkers. We also have issued U.S. patents and pending patent applications covering methods of assembling immunoconjugates from their constituent antibody, linker and cell-killing agent moieties. These issued patents will expire in 2021, while any patents that may issue from pending patent applications also covering various aspects of these technologies will, if issued, expire between 2021 and 2030. We also have issued patents and pending patent applications related to monoclonal antibodies that may be a component of a TAP compound or may be developed as a therapeutic, or "naked," antibody anticancer compound. Among these patents is an issued U.S. patent claiming a method of humanizing murine antibodies to avoid their detection by the human immune system. We have received patents in other jurisdictions, including Europe and Japan, that correspond to our antibody humanization U.S. patent. These patents will expire between 2013 and 2014.

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

As described elsewhere in this annual report on Form 10-K under the heading "In-Licenses *Centocor Ortho Biotech,*" we have in-licensed certain technology from Centocor Ortho Biotech in connection with the development of our IMGN388 product candidate. In addition, we have in-licensed intellectual property relating to our lorvotuzumab mertansine product candidate from Dana-Farber Cancer Institute. We do not believe that the terms of this license are material to our business or prospects.

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

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

Competition

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

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

- the safety and efficacy of products;
- the timing of regulatory approval and commercial introduction;
- special regulatory designation of products, such as Orphan Drug designation; and
- the effectiveness of marketing, sales, and reimbursement efforts.

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

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

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

Such new technologies include, but are not limited to:

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

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

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

the use of therapeutic vaccines.

Regulatory Matters

Government Regulation and Product Approval

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

U.S. Drug Development Process

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

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

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

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

submission to the FDA of an NDA or BLA;

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

FDA review and approval of the NDA or BLA.

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

Once a pharmaceutical candidate is identified for development it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as

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

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with good clinical practice regulations. These regulations include the requirement that all research subjects provide informed consent. Further, an institutional review board, or IRB, must review and approve the plan for any clinical trial before it commences at any institution. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative and must monitor the study until completed.

Each new clinical protocol must be submitted to the FDA for its review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety.

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

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

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

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

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

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

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, under the Pediatric Research Equity Act of 2007, or PREA, an NDA, BLA and certain types of supplements to an NDA or BLA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted. PREA sunsets on October 1, 2012.

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

NDAs or BLAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the

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drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Priority review and accelerated approval do not change the standards for approval, but may expedite the approval process.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require us to conduct Phase IV testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA or BLA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized.

Patent Term Restoration and Marketing Exclusivity

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

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

Pediatric exclusivity is another type of exclusivity in the U.S. Pediatric exclusivity, if granted, provides an additional six months to an existing