

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

Form 10-K/A  
Amendment No. 1

(Mark One)

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 transaction period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 000-53127

**Lion Biotechnologies, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

**Nevada**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**75-3254381**  
(I.R.S. Employer  
Identification No.)

**21900 Burbank Blvd, Third Floor, Woodland Hills**  
(Address of Principal Executive Offices)

**91367**  
(Zip Code)

**(818) 992-3126**

(Registrant's Telephone Number, Including Area Code)

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

<u>Title of Each Class</u>	<u>Name Of Each Exchange On Which Registered</u>
<b>Common Stock, \$0.000041666 Par Value per Share</b>	<b>The Nasdaq Global Market</b>

Securities 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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) 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, accelerated filer or non-accelerated filer (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

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 Exchange Act). Yes  No

The aggregate market value of the registrant's common stock held by non-affiliates on June 30, 2014, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$87,400,000. Shares of common stock held by directors and executive officers and any ten percent or greater stockholders and their respective affiliates have been excluded from this calculation, because such stockholders may be deemed to be "affiliates" of the Registrant. This is not necessarily determinative of affiliate status of other purposes. As of March 16, 2015, there were 44,082,138 shares of the registrant's common stock outstanding.



## EXPLANATORY NOTE

Lion Biotechnologies, Inc. is filing this Amendment No. 1 on Form 10-K/A (this “Amendment”) to its Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed on March 16, 2015 (the “From 10-K”), for the purpose of amending Items 10 through 14 in Part III and Item 15 in Part IV, and to file two exhibits. The information in Part III was previously omitted from the From 10-K in reliance on General Instruction G(3) to Form 10-K, which permits such information to be incorporated in the From 10-K by reference to a definitive proxy statement if such proxy statement is filed no later than 120 days after our fiscal year end.

This Amendment hereby amends Part III, Items 10 through 14, and Part IV, Item 15 of the From 10-K. Also filed with this Amendment are two patent license agreements for which confidential treatment has been requested. A new Exhibit Index has been included to reflect the filing of the two patent license agreements and to list two previously filed agreements that were inadvertently omitted from the Exhibit Index of the From 10-K. Additionally, the reference on the cover page of the From 10-K to the Definitive Proxy Statement for the 2015 Annual Meeting of Stockholders is hereby deleted.

Except as described above, no other changes have been made to the From 10-K. Other than the information specifically amended and restated herein, this Amendment does not reflect events occurring after March 16, 2015, the date the From 10-K was filed, or modify or update those disclosures that may have been affected by subsequent events.

References in this Annual Report to “we,” “us,” “our” or the “company” refer to this company, now known as Lion Biotechnologies, Inc. We are a Nevada corporation that, until September 26, 2013, was known as Genesis Biopharma, Inc.

*All references to the number of shares issued or outstanding in this Annual Report, and all per share and other similar data, reflect a 1-for-100 reverse stock split that we effected on September 26, 2013.*

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## PART III

### Item 10. Directors, Executive Officers and Corporate Governance

The following table sets forth the name, age and position held by each of our executive officers and directors. Directors are elected for a period of one year and thereafter serve until the next annual meeting at which their successors are duly elected by the stockholders.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Elma Hawkins	45	Chief Executive Officer, President and Director
Merrill A. McPeak <sup>(3)</sup>	79	Director
Sanford J. Hillsberg <sup>(1)(2)</sup>	66	Director
Jay Venkatesan <sup>(1)(2)(3)</sup>	41	Director
Ryan Maynard <sup>(3)</sup>	45	Director
Michael Handelman	56	Chief Financial Officer
James Bender, Ph.D.	63	Vice President--Manufacturing
Laszlo Radvanyi	54	Chief Scientific Officer

(1) Member of our Compensation Committee

(2) Member of our Nominating and Corporate Governance Committee

(3) Member of our Audit Committee

#### **Business Experience and Directorships**

The following sets forth the business experience and directorships of our current Board of Directors and our executive officers.

#### **Current Directors**

**Elma Hawkins, Ph.D.** Dr. Hawkins was appointed as a director effective December 12, 2014, and as our Chief Executive Officer effective January 1, 2015. From August 21, 2014 until her appointment as our Chief Executive Officer on December 12, 2014, Dr. Hawkins was our President and Chief Operating Officer. From February 2014 until her appointment as President and Chief Operating Officer, Dr. Hawkins served as this Company's Head of Clinical Development under a consulting agreement. Since 2006 Dr. Hawkins has been an independent consultant to various biotechnology companies and financial institutions. Dr. Hawkins started her career at Warner-Lambert/Parke-Davis in Clinical Research. Later she joined the Center for the Study of Drug Development at Tufts Medical School. Following that, she held various positions at BioSurface Technology and Genzyme Corporation, and at Antigenics, most recently as that company's Vice Chairman. Later, she was President and CEO of Advanced Viral Research. She also serves on the Health Care Advisory Board for the Partnership for New York City. Dr. Hawkins has BSc in Mathematics and Chemistry, BSc (Hons) in Chemistry, MSc in Organic Chemistry, a PhD in Organic Chemistry and an MBA with specialization in entrepreneurship.

**Merrill A. McPeak.** General (Ret.) McPeak has served as a member of our Board of Directors since July 2011. Since February 2015, General McPeak has served as the lead director on our Board of Directors. In addition, General McPeak served as our unpaid, interim Chief Executive Officer from January 14, 2013 until July 24, 2013. General McPeak currently is the President of McPeak and Associates, a consulting firm that he founded in 1995. He has previously served as a director of several public companies, including Tektronix, Inc., Trans World Airlines, Inc., and ECC International Corp., where he was for many years the chairman of the Board. General McPeak has served as a director of DGT Holdings, Corp., a real estate business, since April 2005, of Research Solutions, Inc., a company engaged in developing systems to reuse published content, since November 2010, of GenCorp, an aerospace and defense contractor, since March 2013, and of Lilis Energy, an independent oil and gas producer, since, since January, 2015. He was Chairman of the Board of Coast Plating, Inc., a privately held turnkey provider of metal processing and metal finishing services, from January 2009 until the company was acquired by Trive Capital and renamed Valence Surface Technologies, now the country's largest independently owned aerospace and defense metal processing company. He continues to be a Director of the company. He helped found, and from December 2003 to February 2012 was Chairman of the Board of EthicsPoint, Inc., a provider of risk management and compliance software-as-a-service that was acquired in 2012 and restyled Navex Global. General McPeak remained a member of the board of directors of Navex Global until that company was sold in 2014. In 2010, General McPeak was a director of Point Blank Solutions, Inc., a former public company that on April 14, 2010 filed a voluntary petition for relief under Chapter 11 of the United States Code in the U.S. Bankruptcy Court for the District of Delaware.

From 1990 until his retirement from active military service in late-1994, General McPeak was Chief of Staff of the United States Air Force. As a member of the Joint Chiefs of Staff, General McPeak was a military advisor to the Secretary of Defense and the President of the United States. General McPeak received a Bachelor of Arts degree in economics from San Diego State College and a Master of Science degree in international relations from George Washington University, and is a member of the Council on Foreign Relations. Since July 2010, General McPeak has been Chairman of the American Battlefield Monuments Commission.

Sanford J. Hillsberg. Mr. Hillsberg joined our Board of Directors on September 3, 2013. Mr. Hillsberg has been an attorney with TroyGould PC since 1976 and is a member of the firm's Management Committee. Mr. Hillsberg has served as the Chairman of the Board of Directors of Galena Biopharma, Inc., a publicly-held biopharmaceutical company focused on developing oncology treatments, since 2007. Mr. Hillsberg was a founder and until December 2007, served as a director and Secretary of the Company Therapeutics, Ltd., a publicly-held clinical-stage biotechnology company focused on developing immune-based therapies to treat cancer, and its predecessor company since February 2004. Mr. Hillsberg served as a director and Secretary of Duska Therapeutics, Inc., a publicly-held biopharmaceutical company, and its predecessor company from 1999 until January 2006. He previously served as a director and Vice President of Medco Research, Inc., a then publicly-held pharmaceutical company. Mr. Hillsberg is a member of the Board of Governors of Cedars-Sinai Medical Center and has also previously served as a Commissioner of the Quality and Productivity Commission of the City of Los Angeles. Mr. Hillsberg holds a B.A. degree from the University of Pennsylvania and a J.D. degree from Harvard Law School.

Jay Venkatesan, M.D. Dr. Venkatesan joined our Board of Directors on September 3, 2013. Dr. Venkatesan currently is the Executive Vice President at Oncothyreon, Inc., a biotechnology company focused on oncology and rare diseases. He joined Oncothyreon following its acquisition of Alpine Biosciences in August 2014, where Dr. Venkatesan was Co-Founder and CEO. Prior to this, Dr. Venkatesan was the Managing Member and the Portfolio Manager of Ayer Capital Management LP, a position that he has held since founding that dedicated health care investment fund in 2008. Prior to founding Ayer Capital, Dr. Venkatesan was a Director at Brookside Capital Partners, the \$9.8 billion hedge fund group affiliated with Bain Capital. Prior to joining Brookside, Dr. Venkatesan was the founder and CEO of Varro Technologies, a knowledge management software company focused on the life sciences. Previously, he was involved in healthcare venture investing at Patricof & Co. Ventures and in consulting at McKinsey & Company. Dr. Venkatesan received his M.D. from the University of Pennsylvania School of Medicine and his MBA from the Wharton School of the University of Pennsylvania. He received his B.A., magna cum laude, from Williams College, where he was elected to Phi Beta Kappa.

Ryan Maynard. Mr. Maynard was appointed to our Board of Directors on February 16, 2015. Mr. Maynard currently is the Executive Vice President and Chief Financial Officer of Rigel Pharmaceuticals, Inc., a clinical-stage drug development public company. He joined Rigel in September 2001 as Corporate Controller and was appointed as an Assistant Secretary in October 2001. In June 2006 he became Vice President of Finance and Acting Chief Financial Officer and became our Vice President and Chief Financial Officer in January 2007. Prior to joining Rigel, Mr. Maynard was Corporate Controller and Director of Finance and Accounting for Personify, Inc., an e-commerce software company, from November 1999 to April 2001. From July 1998 to October 1999 he served as Controller of General Magic, Inc. and from July 1994 to June 1998 he held various positions at Siliconix, Inc., most recently as Senior Finance Manager. He previously worked at Ernst & Young, LLP. Mr. Maynard holds a B.S. in Commerce—Accounting from Santa Clara University.

## **Executive Officers**

**Elma Hawkins Ph.D. MBA.** Dr. Hawkins has served as our Chief Executive Officer since her appointment effective January 1, 2015. See, “Business Experience and Directorships,” above.

**Michael Handelman.** Mr. Handelman has served as our Chief Financial Officer and Secretary since February 2011. He also was on our Board of Directors from February 2011 until the Restructuring in May 2013. Mr. Handelman served as the Chief Financial Officer and as a financial management consultant of Oxis International, Inc., a public company engaged in the research, development and commercialization of nutraceutical products, from August 2009 until October 2011. From November 2004 to July 2009, Mr. Handelman served as Chief Financial Officer and Chief Operating Officer of TechnoConcepts, Inc., formerly a public company engaged in designing, developing, manufacturing and marketing wireless communications semiconductors, or microchips. Prior thereto, Mr. Handelman served from October 2002 to October 2004 as Chief Financial Officer of Interglobal Waste Management, Inc., a manufacturing company, and from July 1996 to July 1999 as Vice President and Chief Financial Officer of Janex International, Inc., a children’s toy manufacturer. Mr. Handelman was also the Chief Financial Officer from 1993 to 1996 of the Los Angeles Kings, a National Hockey League franchise. Mr. Handelman is a certified public accountant and holds a degree in accounting from the City University of New York.

**James Bender, Ph.D.** Dr. Bender joined us as our Vice President – Manufacturing on January 6, 2014. From September 2008 to December 2013 and has served as Vice President of Clinical Development and then as Vice President – Product Development and Manufacturing at the Company Therapeutics, Ltd., a publicly-held clinical-stage biotechnology company focused on developing immune-based therapies to treat cancer. From 2002 through 2008, Dr. Bender held various positions at IDM Pharma, most recently as director of product development where he led that company’s efforts relating to the clinical development of a cancer vaccine for the treatment of lung cancer. Prior to that, he held various positions at Nexell Therapeutics relating to the development of therapeutic stem cell and cancer vaccine products. Prior to that, Dr. Bender spent ten years with Baxter Healthcare Corporation, eight years with the University of New Mexico School of Medicine and five years with St. Joseph’s Hospital in Albuquerque, New Mexico. He has over 75 scientific publications, is an inventor of 11 U.S. patents and holds a Ph.D. degree in immunology from the University of New Mexico and an M.P.H. in laboratory management from the University of Michigan.

**Laszlo Radvanyi, Ph.D.** Dr. Radvanyi became our Chief Scientific Officer in June 2014. Dr. Radvanyi was a member of our Scientific & Medical Advisory Board from June 2011 until his appointment as our Chief Scientific Officer. Dr. Radvanyi currently is an Adjunct Professor at the Moffitt Cancer Center. From January 2005 through June 2104, Dr. Radvanyi had a dual appointment professorship in the Departments of Breast Medical Oncology and Melanoma Medical Oncology at the University of Texas, M.D. Anderson Cancer Center where he conducted clinical studies on tumor infiltrating lymphocytes therapy in metastatic melanoma. Prior thereto, Dr. Radvanyi served from October 2000 until January 2005 as a research scientist at the Immunology Group at Sanofi-Pasteur in Toronto. Dr. Radvanyi currently serves on the scientific advisory board of Aethlon Medical, Inc. Dr. Radvanyi received his Ph.D. in clinical biochemistry from the University of Toronto and completed post-doctoral fellowships at Scripps Research Institute and Harvard Medical School.

## **Relationships**

There are no family relationships among any of our current or new directors, executive officers or key employees.

### **Scientific & Medical Advisory Board**

To assist with the development and commercialization of our TIL-based therapy, we have recruited a team of scientists and clinicians experienced with the development and use of adoptive cell therapy using autologous tumor infiltrating lymphocytes for the treatment of cancer. Our Scientific & Medical Advisory Board advises regarding our scientific and regulatory strategy. The members include:

Cassian Yee, M.D., Fred Hutchinson Cancer Research Center. Dr. Yee currently is a Professor at both the Department of Melanoma Medical Oncology and the Department of Immunology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center.

Mario Sznol, M.D., Yale University School of Medicine. Dr. Mario Sznol is a Professor of Medicine and Clinical Research Program Leader for the Melanoma Program. Dr. Sznol was formerly with the National Cancer Institute. Dr. Sznol's expertise and experience is in cancer immunotherapy, drug development for cancer, and treatment of patients with melanoma and renal cell carcinoma. In addition, he is the Co-Director for the Yale SPORE in Skin Cancer. Dr. Sznol received his BA from Rice University, and his MD from the Baylor College of Medicine.

James Mulé, Ph.D., H. Lee Moffitt Cancer Center & Research Institute. Dr. James J. Mulé is Executive Vice President, Associate Center Director for Translational Research, the Michael McGillicuddy Endowed Chair for Melanoma Research and Treatment, and the Director of Cell-Based Therapies at H. Lee Moffitt Cancer Center & Research Institute. Dr. Mulé received his formal training at the Fred Hutchinson Cancer Research Center in Seattle, and at the Surgery Branch, Division of Cancer Treatment, National Cancer Institute, NIH, Bethesda, Md. He also was an adjunct faculty member in the Department of Surgery, Stanford University, the Director of the Tumor Immunology and Immunotherapy Clinical Research Program at the University of Michigan Comprehensive Cancer Center, and the Maude T. Lane Endowed Professor of Surgery, Department of Surgery. Dr. Mulé serves on the advisory boards of seven NCI-designated Cancer Centers and was a member of the NCI's Board of Scientific and Clinical Counselors.

Jeffrey Weber, M.D., Ph.D., H. Lee Moffitt Cancer Center & Research Institute. Dr. Weber is the director of the Donald A. Adam Comprehensive Melanoma Research Center at Moffitt Cancer Center. He is a professor and associate chair of the Department of Oncologic Sciences at the University of South Florida. Dr. Weber received his doctorate in Molecular Cell Biology from Rockefeller University and his medical degree from New York University Medical Center. Dr. Weber also trained at the National Cancer Institute.

Patrick Hwu, M.D., MD Anderson Cancer Center. Dr. Patrick Hwu was recruited to be MD Anderson Cancer Center's first Chairman of the Department of Melanoma Medical Oncology in 2003. Since that time, he has also served as Associate Director of the Center for Cancer Immunology Research and is the current Chair of MD Anderson Cancer Center's Promotion and Tenure Committee. Dr. Hwu is a member of the editorial board of the Journal of Immunotherapy.

David DiGiusto, Ph.D., City of Hope. Dr. DiGiusto cell biologist and immunologist. Dr. DiGiusto has over 17 years' experience developing cellular therapeutics for cancer and infectious disease. He serves in a number of positions with City of Hope, including: Director, Laboratory for Cellular Medicine; Research Professor, Department of Virology.

Daniel Powell, Ph.D., University of Pennsylvania School of Medicine. Dr. Powell holds the following positions at the University of Pennsylvania School of Medicine: Research Associate Professor of Pathology and Laboratory Medicine; Director, Cellular Therapy Tissue Facility; and, Department: Pathology and Laboratory Medicine.



## COMMITTEES OF THE BOARD OF DIRECTORS

Our Board has a standing Audit Committee, Nominating and Governance Committee, and Compensation Committee.

Audit Committee. The Audit Committee operates pursuant to a written charter. Among other things, the Audit Committee is responsible for:

- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- hiring our independent registered public accounting firm, and coordinating the oversight and review of the adequacy of our internal control over financial reporting with both management and the independent registered public accounting firm; and
- reviewing and, if appropriate, approving all transactions between our company or its subsidiaries and any related party.

As of the date of this Annual Report, Ryan Maynard, as Chairman, Jay Venkatesan, and General Merrill McPeak constitute all of the members of the Audit Committee. All of the members of the Audit Committee are non-employee directors and independent as defined under The Nasdaq Stock Market's listing standards. Mr. Maynard is a chief financial officer of a public company. Because of his knowledge of financial, audit and accounting matters, our Board has designated him as the "audit committee financial expert" of the Audit Committee.

The Audit Committee operates pursuant to a written charter, which is available on our website, [www.lbio.com](http://www.lbio.com).

Nominating and Governance Committee. The Nominating and Governance Committee recommends candidates to be nominated for election as directors at our annual meeting, consistent with criteria approved by the Board; develops and regularly reviews corporate governance principles and related policies for approval by the Board; oversees the organization of the Board to discharge the Board's duties and responsibilities properly and efficiently; and sees that proper attention is given and effective responses are made to stockholder concerns regarding corporate governance.

Usually, nominees for election to our Board are proposed by our existing directors. In identifying and evaluating individuals qualified to become Board members, our current directors will consider such factors as they deem appropriate to assist in developing a Board of Directors and committees thereof that are diverse in nature and comprised of experienced and seasoned advisors. Our Board of Directors has not adopted a formal policy with regard to the consideration of diversity when evaluating candidates for election to the Board. However, our Board believes that membership should reflect diversity in its broadest sense, but should not be chosen nor excluded based on race, color, gender, national origin or sexual orientation. In this context, the Board does consider a candidate's experience, education, industry knowledge and, history with the Company, and differences of viewpoint when evaluating his or her qualifications for election the Board. In evaluating such candidates, the Board seeks to achieve a balance of knowledge, experience and capability in its composition. In connection with this evaluation, the Board determines whether to interview the prospective nominee, and if warranted, one or more directors interview prospective nominees in person or by telephone.

In 2014, our Nominating and Governance Committee consisted of Merrill McPeak, as Chairman, and Sanford J. Hillsberg. In February 2015, Jay Venkatesan replaced Merrill McPeak as the Chairman of the Nominating and Governance Committee.

Compensation Committee. The Compensation Committee is responsible for the compensation of our executives and directors; reviews and approves any reports required by the SEC for inclusion in the annual report and proxy statement; provides general oversight of our compensation structure; and, if deemed necessary, retains and approves the terms of the retention of compensation consultants and other compensation experts. Other specific duties and responsibilities of the Compensation Committee include reviewing senior management selection and overseeing succession planning; reviewing and approving objectives relevant to executive officer compensation, evaluating performance and determining the compensation of executive officers in accordance with those objectives; approving severance arrangements and other applicable agreements for executive officers; overseeing our equity-based and incentive compensation; and establishing compensation policies and practices for service on the Board and its committees and for the Chairman of the Board.

The current members of the Compensation Committee are Sanford J. Hillsberg, as Chairman, and Jay Venkatesan.

## **Code of Ethics**

The Board of Directors has adopted a Code of Ethics and Business Conduct to provide guidance to our executive officers regarding standards for conduct of our business, which code has been delivered to all of our executive officers. The full text of our Code of Ethics is available on our website at [www.lionbio.com](http://www.lionbio.com). A copy of our Code of Ethics will be furnished without charge to any person upon written request. Requests should be sent to Secretary, Lion Biotechnologies, Inc., 21900 Burbank Blvd, Third Floor, Woodland Hills, California 91367.

## **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of our common stock, to file reports regarding ownership of, and transactions in, our securities with the Securities and Exchange Commission (the "SEC") and to provide us with copies of those filings. Based solely on our review of the copies received by us and on the written representations of certain reporting persons, we believe that the following Forms 3 and 4 for transaction that occurred in 2014 were filed later than is required under Section 16(a) of the Securities Exchange Act of 1934:

- The Form 4 required to be filed by James Bender, Vice President of Manufacturing, for securities he granted upon joining the Company on January 6, 2014 was filed late.
- The Form 3 and Form 4 required to be filed by Elma Hawkins, President and Chief Operating Officer, for securities issued to her upon joining the Company on August 21, 2014 were filed late.
- The Form 3 and Form 4 required to be filed by Radvanyi Laszlo, Chief Scientific Officer, for common stock he acquired upon joining the Company on June 23, 2014 were filed late.

## **Item 11. Executive Compensation**

### **Compensation Committee Interlocks and Insider Participation**

There are no "interlocks," as defined by the SEC, with respect to any member of the Compensation Committee during 2014.

### **Summary Compensation Table**

The following table shows the compensation paid or accrued during the last three fiscal years ended December 31, 2014 to (i) Manish Singh, Ph.D., the only individual who served as our principal executive officer during the year ended December 31, 2014, (ii) Michael Handelman, the only individual who served as our acting principal financial officer during the year ended December 31, 2014, and (iii) the other three persons who served as executive officers in 2014. The following executives are herein referred to as our "named executive officers." Manish Singh resigned as our Chief Executive Officer effective December 31, 2014, and Elma Hawkins has been our Chief Executive Officer since January 1, 2015.

### Summary Compensation Table

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)(3)	Option Awards (\$)(3)	All other Compen- sation (\$)	Total (\$)
Manish Singh, Ph.D. former Chief Executive Officer	2014	\$ 350,000	\$ 184,000	\$ -0-	\$ -0-	-0-	\$ 534,000
	2013	\$ 66,627(1)					66,627
-							
Elma Hawkins, Ph.D. President and Chief Operating Officer	2014	\$ 277,292(2)	\$ 59,583	\$ 1,120,000(2)	\$ 3,637,924(2)	-0-	\$ 5,094,799
James Bender, Ph.D. Vice President-Manufacturing(4)	2014	\$ 207,712	\$ 82,500	\$ 959,840	\$ 1,249,716	-0-	\$ 2,499,768
Laszlo Radvanyi, Ph.D.(5) Chief Scientific Officer	2014	\$ 130,769	\$ 56,458	\$ 1,171,800	\$ 1,369,068	-0-	\$ 2,728,095
Michael Handelman Chief Financial Officer	2014	\$ 180,000	\$ 45,000	\$ 641,250	\$ 887,507	-0-	\$ 1,753,757
	2013	\$ 180,000	-0-	-0-	\$ -0-	-0-	\$ 180,000
	2012	\$ 180,000	-0-	-0-	\$ -0-	-0-	\$ 180,000

- (1) Represents Dr. Singh's salary from the date of his appointment as our Chief Executive Officer on July 24, 2013 until December 31, 2013. Under his employment agreement, Dr. Singh's annual base salary was \$34,000 until we raised at least \$1,000,000 in additional financing, after which his salary would automatically increase to \$350,000. Since we raised over \$1,000,000 in a private placement on November 5, 2013, Dr. Singh's annual salary increased at that time to \$350,000.
- (2) Dr. Hawkins became our President and Chief Operating Officer on August 21, 2014. Prior to thereto, from February 2014 through August 21, 2014 she provided consulting services as our Head of Clinical Development. Compensation shown in this table includes compensation paid to Dr. Hawkins both as a consultant and as our President and Chief Operating Officer. The compensation she received as an officer consisted of \$137,222 of salary and options to purchase 400,000 shares of our common stock (having a grant date fair value of \$2,516,973). As consultant, her compensation consisted of \$159,693 of fees, options to purchase 200,000 shares (having a grant date fair value of \$1,120,951), and 200,000 shares of restricted stock (having a grant date fair value of \$1,120,000).
- (3) The amounts shown reflect the grant date fair value computed in accordance with FASB ASC 718 for the indicated year, adjusted to disregard the effects of any estimate of forfeitures related to service-based vesting. The assumptions we used in valuing options and restricted stock are described more fully in the footnotes to our financial statements incorporated in our Annual Report on Form 10-K for the year ended December 31, 2014.
- (4) Dr. Bender became our Vice President--Manufacturing on January 6, 2014.
- (5) Dr. Radvanyi became our Chief Scientific Officer in June 2014.

#### Employment Agreements

**Elma Hawkins, PhD, MBA.** Dr. Hawkins entered into an employment agreement with us on August 21, 2014 pursuant to which she agreed to serve as our President and Chief Operating Officer. From February 2014 until she agreed to become our President and Chief Operating Officer, Dr. Hawkins served as our head of clinical development under a consulting agreement. Under the new employment, we agreed to pay Dr. Hawkins an annual salary of \$325,000, the same amount that she was paid under the consulting agreement. As our President and Chief Operating Officer, Dr. Hawkins is also entitled to a year-end incentive bonus of up to 20% of her base salary. Effective as of August 21, 2014, we granted Dr. Hawkins a stock option to purchase 125,000 shares of our common stock (the "New Option") at an exercise price of \$6.70, which price is equal to the fair market value of our common stock on that date. Provided that she is still employed with us on the following dates, the New Option will vest in three installments as follows: (i) The right to purchase 41,667 shares shall vest on August 21, 2015; and the remaining shares shall vest quarterly over the next two years after August 21, 2015. Under February 2014 consulting agreement, Dr. Hawkins was granted a non-qualified stock option to purchase an aggregate of 200,000 shares of our common stock (the "Existing Option"), and 200,000 shares of restricted common stock. Accordingly, in addition to the 200,000 restricted shares, in the aggregate Dr. Hawkins currently has options for the purchase of 325,000 shares. The Existing Option and the 200,000 restricted shares remain in effect under the new employment agreement under the same terms under which they were granted in February 2014. Provided that Dr. Hawkins is still providing services to us on the following dates, the shares under the Existing Option that she received under the consulting agreement will vest in installments as follows: (i) The option to the purchase of 66,666 shares vested on February 21, 2015; and (ii) the remaining shares under the option shall vest in eight equal quarterly (three month) installments over the next two years after February 21, 2015. Provided that she is still providing services to us on the following dates, the 200,000 shares of restricted stock will vest in three installments as follows: (i) 40,000 shares vested on February 28, 2015; (ii) 60,000 shares shall vest on February 28, 2016, and (iii) 100,000 shares shall vest on February 28, 2017.

Effective December 12, 2014, Dr. Hawkins was appointed as our Chief Executive Officer, effective January 1, 2015. In connection with her appointment as Chief Executive Officer, the Company agreed to pay Dr. Hawkins an annual salary of \$350,000, which amount was automatically increased to \$400,000 when we raised more than \$25 million in a public offering later in December 2014. As the Company's President and Chief Executive Officer, Dr. Hawkins will also be entitled to a year-end incentive bonus of up to 40% of her base salary. Dr. Hawkins was also be granted a stock option to purchase 275,000 shares of common stock at an exercise price equal \$6.15 per share (the closing price of the common stock on December 12, 2014). Provided that she is still employed with the Company on the following dates, the option for these 275,000 shares will vest over three years as follows: (i) 91,667 shares will vest on January 1, 2016; and (ii) the remaining shares shall vest quarterly over the next two years after January 1, 2016.

Either party can terminate the employment agreement at any time; provided, however, that if we terminate Dr. Hawkins' employment agreement without cause (as defined in the employment agreement), all of her unvested stock options and unvested shares of restricted stock will become fully vested, and she shall have twelve months from the date of termination within which to exercise her vested options. In addition, Dr. Hawkins will be eligible to receive a severance payment equal to twelve months of her then base salary. If, within six months immediately preceding a Change in Control (as defined in his employment agreement) or within 12 months immediately following a Change of Control, Dr. Hawkins' employment is terminated by us for any reason other than cause, then Dr. Hawkins' unvested stock options and shares of restricted stock will immediately vest and she will be entitled to receive a severance payment equal to twelve months of her then base salary. Had the employment agreement been terminated by us without "cause" or following a change in control on December 31, 2014, Dr. Hawkins would have been entitled to receive a severance payment of \$350,000 and health insurance benefits of \$7,015 (representing the family health benefit payments for a twelve-month period).

Michael Handelman. On May 15, 2014 we entered into a new employment agreement with Michael Handelman pursuant to which Mr. Handelman will continue to serve as our Chief Financial Officer. Under his employment agreement, Mr. Handelman will continue to receive his current annual salary of \$180,000 and will be entitled to participate in any pension, retirement, disability, insurance, medical service, or other employee benefit plan that is generally available to all employees of the company.

Effective as of May 15, 2014, we granted Mr. Handelman (i) a five-year stock option to purchase an aggregate of 75,000 shares of the Company's common stock, and (ii) 75,000 shares of restricted common stock. The stock options have an exercise price of \$7.95 per share, the fair market value of the common stock on May 15, 2014. Provided that Mr. Handelman is still employed with the Company on the following dates, the foregoing stock options will vest as follows: Options for the purchase of 25,000 shares shall vest on May 15, 2015; and after May 15, 2015 the remaining shares shall vest in equal quarterly installments over the next two years. Furthermore, provided that Mr. Handelman is still employed with the Company on the following dates, the foregoing 75,000 shares of restricted stock will vest in three installments as follows: (i) 25,000 shares have vested; and (ii) 25,000 shares shall vest on May 15, 2016, and (iii) 25,000 shares shall vest on May 15, 2017.

Either party can terminate the employment agreement and Mr. Handelman's employment without cause at any time. Upon termination of the employment agreement, except as otherwise provided in the Agreement, the unvested options and the unvested shares of restricted stock will be forfeited and returned to the Company, however, if we terminate Mr. Handelman's employment without cause (as defined in the agreement) any of Mr. Handelman's unvested stock options and unvested shares of restricted stock will become fully vested, and he shall have twelve months from the date of termination within which to exercise his vested options. Furthermore, if we terminate the employment agreement without cause, Mr. Handelman will be eligible to receive a severance payment equivalent to six months of his then base salary.

James Bender. Dr. Bender, our Vice President--Manufacturing, entered into an employment agreement with us effective as of January 6, 2014. Under the employment, we paid Dr. Bender a \$30,000 signing bonus on January 6, 2014, and agreed to pay him an annual salary of \$210,000. Dr. Bender also is entitled to a year-end incentive bonus of up to 25% of his base salary. Effective as of January 6, 2014, we granted Dr. Bender (i) stock options to purchase an aggregate of 100,000 shares of our common stock, and (ii) 100,000 shares of restricted common stock. The stock options have an exercise price of \$9.60, the fair market value of the common stock on January 6, 2014. Provided that he is still employed with us on the following dates, the foregoing stock options will vest in three installments as follows: (i) Options for the purchase of 33,333 shares vested on January 6, 2015; and the remaining shares shall vest quarterly over the next two years after January 6, 2015. Provided that Dr. Bender is still employed with us on the following dates, the foregoing 100,000 restricted shares will similarly vest in three installments as follows: (i) 20,000 shares vested on September 30, 2014; (ii) 30,000 shares shall vest on September 30, 2015, and (iii) 50,000 shares shall vest on September 30, 2016. Either party can terminate the employment at any time; provided, however, that if we terminate the employment agreement without cause (as defined in the employment agreement), all of his unvested stock options and unvested shares of restricted stock will become fully vested, and he shall have twelve months from the date of termination within which to exercise his vested options. In addition, Dr. Bender will be eligible to receive a severance payment equivalent to six months of his then base salary. If, within six months immediately preceding a Change in Control (as defined in his employment agreement) or within 12 months immediately following a Change of Control, Dr. Bender's employment is terminated by us for any reason other than cause, then Dr. Bender's unvested stock options and shares of restricted stock will immediately vest and he will be entitled to receive a severance payment equal to six months of his then base salary. Had the Employment Agreement been terminated by us without "cause" or following a change in control on December 31, 2014, Dr. Bender would have been entitled to receive a severance payment of \$105,000 and health insurance benefits of \$12,196 (representing the family health benefit payments for a twelve-month period).

Laszlo Radvanyi. Dr. Radvanyi entered into an employment agreement with us, effective as of June 23, 2014, to serve as our Chief Scientific Officer. Under the employment, we paid Dr. Radvanyi a \$20,000 signing bonus, and agreed to pay him an annual salary of \$250,000. Dr. Radvanyi also is entitled to a year-end incentive bonus of up to 25% of his base salary. Effective as of June 23, 2014, we granted Dr. Radvanyi (i) stock options to purchase an aggregate of 180,000 shares of our common stock, and (ii) 180,000 shares of restricted common stock. The stock options have an exercise price of \$6.51, the fair market value of the common stock on June 23, 2014. Provided that he is still employed with us on the following dates, the foregoing stock options will vest in three installments as follows: (i) Options for the purchase of 60,000 shares shall vest on June 23, 2015; and the remaining shares shall vest quarterly over the next two years after June 23, 2015. Provided that Dr. Radvanyi is still employed with us on the following dates, the foregoing 180,000 restricted shares will similarly vest in three installments as follows: (i) 36,000 shares shall vest on April 30, 2015; (ii) 54,000 shares shall vest on April 30, 2016, and (iii) 90,000 shares shall vest on April 30, 2017. We also agreed to reimburse Dr. Radvanyi for certain relocation expenses in connection with relocation from Texas to our new research facility in Tampa, Florida. Either party can terminate the employment at any time; provided, however, that if we terminate the employment agreement without cause (as defined in the employment agreement), any of his unvested stock options and unvested shares of restricted stock will become fully vested, and he shall have twelve months from the date of termination within which to exercise his vested options. In addition, Dr. Radvanyi will be eligible to receive a severance payment equivalent to six months of his then base salary. If, within six months immediately preceding a Change in Control (as defined in his employment agreement) or within 12 months immediately following a Change of Control, Dr. Radvanyi's employment is terminated by us for any reason other than cause, then Dr. Radvanyi's unvested stock options and shares of restricted stock will immediately vest and he will be entitled to receive a severance payment equal to six months of his then base salary. Had the Employment Agreement been terminated by us without "cause" or following a change in control on December 31, 2014, Dr. Radvanyi would have been entitled to receive a severance payment of \$125,000 and health insurance benefits of \$10,997 (representing the family health benefit payments for a twelve-month period).

## 2010 Equity Incentive Plan

On March 29, 2010, our Board adopted the Genesis Biopharma, Inc. 2010 Equity Compensation Plan (the "2010 Plan") pursuant to which the Board reserved an aggregate of 35,000 shares of common stock for future issuance. The 2010 Plan provided for awards of incentive stock options, non-qualified stock options, rights to acquire restricted stock, rights to acquire unrestricted stock, and stock appreciation rights, or SARs, but since we did not obtain stockholder approval of the 2010 Plan within twelve (12) months after the date the Board adopted the 2010 Plan, incentive stock options could not be granted. As of October 2011, options for the issuance of all 35,000 shares had been granted, and no shares were available for additional grants under the 2010 Plan.

## 2011 Equity Incentive Plan

As of October 14, 2011, we adopted our 2011 Equity Incentive Plan (the "2011 Plan"). Employees, directors, consultants and advisors of the Company are eligible to participate in the 2011 Plan. The 2011 Plan initially had 180,000 shares of common stock reserved for issuance in the form of incentive stock options, non-qualified options, common stock, and grant appreciation rights. The 2011 Plan was not approved by our stockholders within the required one-year period following its adoption and, accordingly, no incentive stock options can be granted under that plan. In August 2013 our Board of Directors and a majority of our stockholders approved an amendment to increase the number of shares available under the 2011 Plan from 180,000 shares to 1,700,000 shares, and an amendment to increase the number options or other awards that can be granted to any one person during a twelve (12) month period from 50,000 shares to 300,000 shares. The foregoing amendment to the 2011 Plan became effective in September 2013. As of December 31, 2014, no shares were available for future grant under the 2011 Plan.

## 2014 Equity Incentive Plan

On September 19, 2014, our Board adopted the Lion Biotechnologies, Inc. 2014 Equity Incentive Plan (the "2014 Plan"). The 2014 Plan was approved by our stockholders in November 2014. The 2014 Plan initially authorized the issuance up to an aggregate of 2,350,000 shares of common stock of the Company. On April 10, 2015 our Board of Directors amended the 2014 Plan, subject to stockholder approval, to increase the total number of shares that can be issued under the 2014 Plan by 1,650,000 from 2,350,000 shares to 4,000,000 shares. The Company intends to submit the amendment to the 2014 Plan to increase the number of shares reserved under the 2014 Plan to the stockholders for their approval at the next annual meeting of stockholders currently anticipated to be held on June 12, 2015.

The following is a summary of the principal features of the 2014 Plan.

General. The 2014 Plan provides for awards of incentive stock options, non-statutory stock options, rights to acquire restricted stock, and stock appreciation rights, or SARs. Incentive stock options ("ISOs") granted under the 2014 Plan are intended to qualify as "incentive stock options" within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"). Non-statutory stock options (NQSOs) granted under the 2014 Plan are not intended to qualify as incentive stock options under the Code. See "Certain Federal Income Tax Consequences" below for a discussion of the principal federal income tax consequences of awards under the 2014 Plan. Subject to the provisions of the 2014 Plan relating to adjustments upon changes in our common stock, an aggregate of 2,350,000 shares of common stock have been reserved for issuance under the 2014 Plan. As of the date of this Annual Report, options for the purchase of a total of 686,627 shares have been granted under the 2014 Plan.

Purpose. Our board adopted the 2014 Plan to provide a means by which our employees, directors and consultants may be given an opportunity to benefit from increases in the value of our common stock, to assist in attracting and retaining the services of such persons, to bind the interests of eligible recipients more closely to our company's interests by offering them opportunities to acquire shares of our common stock and to afford such persons stock-based compensation opportunities that are competitive with those afforded by similar businesses.

Administration. Unless it delegates administration to a committee of the board, our board administers the 2014 Plan. Subject to the provisions of the 2014 Plan, our board has the power to determine in its discretion: (a) to grant options and SARs and grant or sell restricted stock; (b) to determine the fair market value of the shares of common stock subject to options or other awards; (c) to determine the exercise price of options granted, which shall be no less than the fair market value of any common stock on the date of grant, the economic terms of SARs granted, which shall provide for a benefit of the appreciation on common stock over not less than the value of our common stock on the date of grant, or the offering price of restricted stock; (d) to determine the persons to whom, and the time or times at which, options or SARs shall be granted or restricted stock granted or sold, and the number of shares subject to each option or SAR or the number of shares of restricted stock granted or sold; (e) to construe and interpret the terms and provisions of the 2014 Plan, of any applicable agreement and all options and SARs granted under the 2014 Plan, and of any restricted stock award under the 2014 Plan; (f) to prescribe, amend, and rescind rules and regulations relating to the 2014 Plan; (g) to determine the terms and provisions of each option and SAR granted and award of restricted stock (which need not be identical), including but not limited to, the time or times at which options and SARs shall be exercisable or the time at which the restrictions on restricted stock shall lapse; (h) with the consent of the grantee, to rescind any award or exercise of an option or SAR; (ix) to modify or amend the terms of any option, SAR or restricted stock (with the consent of the grantee or holder of the restricted stock if the modification or amendment is adverse to the grantee or holder); (i) to accelerate or defer (with the consent of the grantee) the exercise date of any option or SAR or the date on which the restrictions on restricted stock lapse; (j) to issue shares of restricted stock to an optionee in connection with the accelerated exercise of an option by such optionee; (k) to authorize any person to execute on behalf of our company any instrument evidencing the grant of an option, SAR or award of restricted stock; (l) to determine the duration and purposes of leaves of absence which may be granted to participants without constituting a termination of their employment for the purpose of the 2014 Plan; and (m) to make all other determinations deemed necessary or advisable for the administration of the 2014 Plan, any applicable agreement, option, SAR or award of restricted stock.

Eligibility. Incentive stock options may be granted under the 2014 Plan only to employees of our company and its affiliates. Employees, directors and consultants of our company and its affiliates are eligible to receive all other types of awards under the 2014 Plan.

Terms of Options and SARs. The exercise price of incentive stock options may not be less than the fair market value of our common stock subject to the option on the date of the grant and, in some cases, may not be less than 110% of such fair market value. The exercise price of nonstatutory options also may not be less than the fair market value of our common stock on the date of grant.

Options granted under the 2014 Plan may be exercisable in increments, or "vest," as determined by our board. Our board has the power to accelerate the time as of which an option may vest or be exercised, with the consent of the optionee. The maximum term of options and SARs under the 2014 Plan is ten years, except that in certain cases the maximum term is five years. Options and SARs awarded under the 2014 Plan generally will terminate 90 days after termination of the participant's service, subject to certain exceptions.

A recipient may not transfer an incentive stock option otherwise than by will or by the laws of descent and distribution. During the lifetime of the recipient, only the recipient may exercise an option or SAR. Our board may grant nonstatutory stock options and SARs that are transferable to the extent provided in the applicable written agreement.

Terms of Restricted Stock Awards. Our board may issue shares of restricted stock under the 2014 Plan as a grant or for such consideration, including services, and, subject to the Sarbanes-Oxley Act of 2002, promissory notes, as determined in its sole discretion.

Shares of restricted stock acquired under a restricted stock purchase or grant agreement may, but need not, be subject to forfeiture to us or other restrictions that will lapse in accordance with a vesting schedule to be determined by our board. In the event a recipient's employment or service with our company terminates, any or all of the shares of common stock held by such recipient that have not vested as of the date of termination under the terms of the restricted stock agreement may be forfeited to our company in accordance with such restricted stock agreement.

Rights to acquire shares of common stock under the restricted stock purchase or grant agreement shall be transferable by the recipient only upon such terms and conditions as are set forth in the restricted stock agreement, as our board shall determine in its discretion, so long as shares of common stock awarded under the restricted stock agreement remain subject to the terms of such agreement

Adjustment Provisions. If our common stock is changed by reason of a stock split, reverse stock split, stock dividend, recapitalization, combination or reclassification, then the number and class of shares of stock subject to each option and SAR outstanding under the 2014 Plan, and the exercise price of each outstanding option and the base value of SAR, will be automatically and proportionately adjusted, except that our company will not be required to issue fractional shares as a result of any such adjustments. Such adjustment in any outstanding option or SAR will be made without change in the total price applicable to the unexercised portion of the option or SAR, but with a corresponding adjustment in the price for each share covered by the unexercised portion of the option or SAR.

Effect of Certain Corporate Events. Except as otherwise provided in the applicable agreement, in the event of (i) a liquidation or dissolution of our company, (ii) a merger or consolidation of our company with or into another corporation or entity (other than a merger with a wholly-owned subsidiary), or (iii) a sale of all or substantially all of the assets of our company in a single transaction or a series of related transactions, all options and SARs will terminate upon consummation of the transaction unless our board determines that they will survive. If our board determines that outstanding options and SARs will survive, and if our company will not be the surviving entity in the transaction, our board will provide that the outstanding options and SARs will be assumed or an equivalent option or SAR substituted by an applicable successor entity or any affiliate of the successor entity. If outstanding options and SARs are to terminate upon consummation of the corporate transaction, any options or SARs outstanding immediately prior to the consummation of the corporate transaction will be deemed fully vested and exercisable immediately prior to the consummation of the corporate transaction (provided that the option or SAR has not expired by its terms and that the grantee takes all steps necessary to exercise the option or SAR prior to the corporate transaction as required by the agreement evidencing the option or SAR).

Duration, Amendment and Termination. Our board may suspend or terminate the 2014 Plan without stockholder approval or ratification, subject to certain restrictions, at any time or from time to time. Unless sooner terminated, the 2014 Plan will terminate ten years from the date of its adoption by our board, or on September 19, 2024.



Our Board may also amend the 2014 Plan at any time, and from time to time. However, except as relates to adjustments upon changes in common stock, no amendment will be effective unless approved by our stockholders to the extent stockholder approval is necessary to preserve incentive stock option treatment for federal income tax purposes. Our board may submit any other amendment to the 2014 Plan for stockholder approval in its discretion.

### **Certain Federal Income Tax Consequences**

**Non-qualified Stock Options.** There will be no federal income tax consequences to either the Company or the participant upon the grant of a non-discounted NQSO. However, the participant will realize ordinary income on the exercise of the NQSO in an amount equal to the excess of the fair market value of the common stock acquired upon the exercise of such option over the exercise price, and the Company will receive a corresponding deduction. The gain, if any, realized upon the subsequent disposition by the participant of the common stock will constitute short-term or long-term capital gain, depending on the participant's holding period.

**Incentive Stock Options.** There will be no regular federal income tax consequences to either the Company or the participant upon the grant or exercise of an ISO. If the participant does not dispose of the shares of common stock for two years after the date the option was granted and one year after the acquisition of such shares of common stock, the difference between the aggregate option price and the amount realized upon disposition of the shares of common stock will constitute long-term capital gain or loss, and the Company will not be entitled to a federal income tax deduction. If the shares of common stock are disposed of in a sale, exchange or other "disqualifying disposition" during those periods, the participant will realize taxable ordinary income in an amount equal to the excess of the fair market value of the common stock purchased at the time of exercise over the aggregate option price (adjusted for any loss of value at the time of disposition), and the Company will be entitled to a federal income tax deduction equal to such amount, subject to the limitations under Code Section 162(m).

While the exercise of an incentive stock option does not result in current taxable income, the excess of (1) the fair market value of the option shares at the time of exercise over (2) the exercise price, will be an item of adjustment for purposes of determining the participant's alternative minimum tax income.

**SARs.** A participant receiving an SAR will not recognize income, and the Company will not be allowed a tax deduction, at the time the award is granted. When a participant exercises the SAR, the amount of cash and the fair market value of any shares of common stock received will be ordinary income to the participant and will be allowed as a deduction for federal income tax purposes to the Company, subject to limitations under Code Section 162(m). In addition, the Board (or Committee), may at any time, in its discretion, declare any or all awards to be fully or partially exercisable and may discriminate among participants or among awards in exercising such discretion.

**Restricted Stock.** Unless a participant makes an election to accelerate recognition of the income to the date of grant, a participant receiving a restricted stock award will not recognize income, and the Company will not be allowed a tax deduction, at the time the award is granted. When the restrictions lapse, the participant will recognize ordinary income equal to the fair market value of the common stock, and the Company will be entitled to a corresponding tax deduction at that time, subject to the limitations under Code Section 162(m).

### **Outstanding Equity Awards**

The following table sets forth outstanding equity awards held by our named executive officers as of December 31, 2014 under our 2010 Plan, 2011 Plan and 2014 Plan:

## Outstanding Equity Awards At Year Ended December 30, 2014

Name	Option Awards						Stock Awards				
	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$)	
Manish Singh, former President and Chief Executive Officer	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-	
Elma Hawkins, current President and Chief Executive Officer(1)	2/21/14 8/21/14 12/12/14 <b>Total</b>	-0- -0- -0-	200,000 125,000 275,000 <b>600,000</b>	-0- -0- -0-	5.60 6.70 6.15	2/21/19 8/21/24 12/12/24	-0- -0- -0-	-0- -0- -0-	200,000 -0- <b>200,000</b>	1,574,000 -0- <b>1,574,000</b>	
James Bender, Vice President- Manufacturing(2)	1/6/14 12/5/14 <b>Total</b>	-0- -0-	100,000 46,667 <b>146,667</b>	-0- -0-	9.60 6.25	1/16/24 12/5/24	-0- -0-	-0- -0-	80,000 <b>80,000</b>	629,600 <b>629,600</b>	
Laszlo Radvanyi, Chief Scientific Officer(3)	6/23/14 12/5/14 <b>Total</b>	-0- -0-	180,000 32,407 <b>212,407</b>	-0- -0-	6.51 6.25	6/23/24 12/5/24	-0- -0-	-0- -0-	180,000 <b>180,000</b>	1,416,600 <b>1,416,600</b>	
Michael Handelman, Chief Financial Officer(4)	5/15/14 12/5/14 <b>Total</b>	-0- -0-	75,000 40,000 <b>115,000</b>	-0- -0-	8.55 6.25	5/15/24 12/5/24	-0- -0-	-0- -0-	50,000 <b>50,000</b>	393,500 <b>393,500</b>	

(1) Dr. Hawkins was appointed as our Chief Executive Officer effective January 1, 2015. From February 2014 through August 21, 2014 Dr. Hawkins provided consulting services as our Head of Clinical Development. Dr. Hawkins became our President and Chief Operating Officer on August 21, 2014. The stock options and shares of restricted stock reflected in the above table include options and restricted shares granted to Dr. Hawkins both as a consultant and as an executive officer of this Company. The stock options and restricted shares that she received as a consultant consisted of options to purchase 200,000 shares and 200,000 shares of restricted stock. (i) The stock option to purchase 200,000 shares has an exercise price of \$5.60 and will vest in installments as follows: The option to the purchase of 66,666 shares vested on February 21, 2015; and the remaining shares under the option shall vest in eight equal quarterly (three month) installments over the next two years after February 21, 2015. (ii) The stock option to purchase 125,000 shares at an exercise price of \$6.70 will vest in three installments as follows: The right to purchase 41,667 shares shall vest on August 21, 2015; and the remaining shares shall vest quarterly over the next two years after August 21, 2015. (iii) The stock option grant for 275,000 shares with an exercise price of \$6.15 vests as to 91,667 shares on January 1, 2016; the remaining options vest quarterly over the next two years after January 1, 2016.

(2) (i) The stock option grant for 100,000 shares at an exercise price of \$9.60 vests in three installments as follows: Options for the purchase of 33,333 shares vested on January 6, 2015; and the remaining shares shall vest quarterly over the next two years after January 6, 2015. (ii) The stock options for 46,667 shares with an exercise price of \$6.25 vest as to 33.33% of the shares on December 15, 2015, and the balance vests over two years in eight equal quarterly installments thereafter.

(3) (i) The stock option grant for 180,000 shares at an exercise price of \$6.51 vests in three installments as follows: Options for the purchase of 60,000 shares shall vest on June 23, 2015; and the remaining shares shall vest quarterly over the next two years after June 23, 2015. (ii) The stock options for 32,407 shares with an exercise price of \$6.25 vest as to 33.33% of the shares on December 15, 2015, and the balance vests over two years in eight equal quarterly installments thereafter.

(4) (i) The stock option for 75,000 shares with an exercise price of \$8.55 vests as to 25,000 shares on May 15, 2015; after May 15, 2015 the remaining shares shall vest in equal quarterly installments over the next two years. (ii) The stock options for 40,000 shares with an exercise price of \$6.25 vest as to 33.33% of the shares on December 15, 2015, and the balance vests over two years in eight equal quarterly installments thereafter.

## Option Exercises and Stock Vested

There were no exercises of stock options by any of our named executive officers during 2014.

## Director Compensation

The following table sets forth information concerning the compensation paid to all persons during 2014 who served as non-employee directors of this Company during 2014, for their services rendered as directors. Executive officers who serve on our Board of Directors are not compensated for their services as directors.

**Director Compensation Table**

<b>Name</b>	<b>Fees Earned or Paid in Cash (\$)</b>	<b>Stock Awards (\$)</b>	<b>Option Awards (\$)(1)</b>	<b>All Other Compensation (\$)</b>	<b>Total (\$)</b>
Merrill A. McPeak	\$ 63,000	--	310,579	--	373,269
Sanford J. Hillsberg	\$ 53,000	--	310,579	--	363,269
Jay Venkatesan	\$ 62,000	--	310,579	--	372,269

(1) Represents the grant date value computed in accordance with FASB ASC Topic 718.

Under our director compensation plan that was adopted on December 5, 2014, for services rendered in 2015, each director who is not an employee received an option to purchase up to 50,000 shares at an exercise price of \$6.25 (the closing price of our common stock on the date of grant). Options for 12,500 of these shares vest in the four quarterly periods following the date of grant. These options have a ten-year term and will be exercisable for two years following termination of service as a member of our Board of Directors, unless the Director is terminated for a cause, in which case the options are terminated. In addition to the foregoing grant of options, the directors will receive the following cash compensation for service on our Board of Directors and committees of our Board of Directors during 2015:

- an annual retainer fee of \$25,000 for each director, payable quarterly,
- an annual retainer fee of \$10,000 for the chairperson of each Committee of our Board of Directors, payable quarterly,
- a fee of \$2,500 per board meeting attended by the director in person,
- a fee of \$1,500 per board meeting attended by the director telephonically, and
- a fee of \$1,000 per committee meeting attended by the director.

We currently do not have a Chairperson of our Board of Directors. Merrill McPeak currently serves as our lead director and will receive an annual retainer in 2015 of \$10,000 (which is the same retainer paid to other chairpersons).

## Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth certain information regarding the beneficial ownership of our common stock and Series A Preferred as of April 15, 2015 by (i) each person who is known by us to own more than 5% of the outstanding common stock; (ii) each of our directors; (iii) each of the executive officers; and (iv) all of our current officers and directors as a group. As of April 15, 2015, a total of 44,762,594 shares of common stock were outstanding. The shares of Series A Preferred do not have voting rights and, therefore, are not included in the below table.

Name and Address of Beneficial Owner (1)	Common Stock	
	Number of Shares	Percent of Class (2)
Ayer Capital Management LP (3) 616 Corporate Way, Suite 2-4931 Valley Cottage, NY 10989	5,604,015	12.52%
Bristol Investment Fund Ltd. (4) Bristol Capital Advisors, LLC 10690 Wilshire Boulevard, Suite 1050 Los Angeles, CA 90024	3,868,074	8.64%
FMR LLC 245 Summer Street Boston, MA 02210 (5)	4,747,328	10.61%
Perceptive Life Sciences Master Fund Ltd. 499 Park Avenue, 25th Floor New York, NY 10022	4,470,784(6)	9.99%(6)
Joseph Edelman Perceptive Advisors LLC Perceptive Life Sciences Master Fund Ltd. 499 Park Avenue, 25th Floor New York, NY 10022(7)	4,470,784(6)	9.99%(6)
Jay Venkatesan	5,669,015(8)	12.65%
Michael Handelman	100,000(9)	*
Merrill A. McPeak	511,432(10)	1.14%
Sanford J. Hillsberg	334,000(11)	*
James G. Bender	144,853(12)	*
Laszlo Radvanyi	180,000(13)	*
Elma Hawkins	299,999(14)	*
Ryan D. Maynard	12,500(15)	*
All directors and executive officers as a group (8 persons)	7,251,799(16)	16.05%

\* Less than 1%.

- (1) Unless otherwise indicated, the address of each of the persons shown is c/o Lion Biotechnologies, Inc., 21900 Burbank Boulevard, 3<sup>rd</sup> Floor, Woodland Hills, California 91367.
- (2) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock subject to options, warrants and convertible securities currently exercisable or convertible, or exercisable or convertible within 60 days, are deemed outstanding, including for purposes of computing the percentage ownership of the person holding such option, warrant or convertible security, but not for purposes of computing the percentage of any other holder.
- (3) Based on a Schedule 13G filed with the SEC on June 3, 2013 by Ayer Capital Management, LP, ACM Capital Partners, LLC, Jay Venkatesan, Ayer Capital Partners Master Fund, L.P. and Ayer Capital Partners, LLC. Jay Venkatesan is the Managing Member of ACM Capital Partners, LLC and Ayer Capital Partners Master Fund, L.P.
- (4) Based on a Schedule 13G/A filed with the SEC on February 11, 2015, Bristol Investment Fund, Ltd. (“BIF”). Bristol Capital Advisors, LLC is the investment advisor to BIF. Paul Kessler is manager of Bristol Capital Advisors, LLC and as such has voting and dispositive power over the securities held by BIF. Mr. Kessler disclaims beneficial ownership of the shares owned by BIF.

- (5) Based on a Schedule 13G/A filed with the SEC on February 13, 2015 by FMR LLC. Edward C. Johnson 3d is a Director and the Chairman of FMR LLC and Abigail P. Johnson is a Director, the Vice Chairman and the President of FMR LLC. Members of the family of Edward C. Johnson 3d, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC.
- (6) Represents 3,214,549 outstanding shares, plus 1,256,235 shares of common stock that Perceptive Life Sciences Master Fund Ltd. could acquire on April 15, 2015 by either converting shares of Series A Preferred that it owns, or by exercising some of its warrants. Perceptive Life Sciences Master Fund currently owns 97,000 shares of common stock issuable upon the conversion of 194 shares of Series A Preferred, and warrants to purchase up to 2,805,000 shares of common stock. Under the terms of the Series A Preferred and the warrants, Perceptive Life Sciences Master Fund Ltd. is prohibited from converting shares of Series A Preferred or from exercising its warrants if such exercise would result in it owning beneficially more than 4.99% of the outstanding shares of our common stock as determined under Section 13(d) of the Securities Exchange Act of 1934 (as it is permitted to do, Perceptive Life Sciences Master Fund Ltd. has opted to increase the foregoing beneficial ownership limitation to 9.99%).
- (7) Based on a Schedule 13G/A filed with the SEC on February 17, 2015 by Perceptive Advisors LLC. According to the Schedule 13G, Perceptive Life Sciences Master Fund Ltd. an investment fund to which Perceptive Advisors LLC serves as the investment manager. Mr. Edelman is the managing member of Perceptive Advisors LLC. Mr. Edelman and Perceptive Advisors LLC are deemed to beneficially own the shares of Perceptive Life Sciences Master Fund Ltd.
- (8) Represents the 5,604,015 shares beneficially owned by Ayer Capital Management LP described in footnote (3) above, plus options to purchase 65,000 shares of common stock that are exercisable currently or within 60 days of April 15, 2015. Jay Venkatesan is the Managing Member of ACM Capital Partners, LLC and Ayer Capital Partners Master Fund, L.P.
- (9) Consists of 75,000 shares (of which 50,000 shares are restricted stock that are subject to forfeiture) and options to purchase 25,000 shares of common stock that are exercisable currently or within 60 days of April 15, 2015.
- (10) Represents 396,432 shares of common stock, 50,000 shares of common stock issuable upon exercise of a warrant, and options to purchase 65,000 shares of common stock that are exercisable currently or within 60 days of April 15, 2015.
- (11) Represents 269,000 shares of common stock and options to purchase 65,000 shares of common stock that are exercisable currently or within 60 days of April 15, 2015.
- (12) Represents 20,000 outstanding shares, 80,000 shares of restricted stock that are currently subject to forfeiture, and options to purchase 44,853 shares.
- (13) Represents 36,000 outstanding shares and 144,000 shares of restricted stock that are currently subject to forfeiture.
- (14) Represents 40,000 outstanding shares, 160,000 shares of restricted stock that are currently subject to forfeiture, and options to purchase 99,999 shares.
- (15) Represents options to purchase shares of common stock that are exercisable currently or within 60 days of April 15, 2015.
- (16) Includes options and warrants to purchase 427,352 shares of common stock that are exercisable currently or within 60 days of April 15, 2015.

#### **Equity Compensation Plan Information**

The following table summarizes, as of December 31, 2014, (i) the number of shares of our common stock that are issuable under our equity compensation plans upon the exercise of outstanding options, warrants and other rights, (ii) the weighted-average exercise price of such options, warrants and rights, and (iii) the number of securities remaining available for future issuance under our equity compensation plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights*	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by stockholders(1)	686,627(2)	\$ 6.30	1,381,373(3)
Equity compensation plans not approved by stockholders	1,221,250(2)	\$ 8.13	-0-
Total	1,907,877		1,381,373

\* Does not include warrants attached to units that were sold to investors in a private placement.

(1) Represents awards under the 2014 Plan. Neither the 2010 Plan nor the 2011 Plan were approved by the stockholders.

(2) Does not include shares of restricted stock that were issued under our equity compensation plans and that are currently outstanding. In the event that any such restricted shares are forfeited and returned to us, such forfeited shares will again be available for future issuance under the equity compensation plans. A total of 282,000 shares of restricted stock were granted and are outstanding under our equity compensation plans approved by stockholders, and a total of 500,500 shares of restricted stock were granted and are outstanding under our equity compensation plans that were not approved by stockholders.

(3) In April 2015, our Board of Directors amended the 2014 Plan to increase the number of shares that we are authorized to issue under the 2014 Plan from 2,365,000 to 4,000,000 shares of common stock. The foregoing increase in the number of shares available under the 2014 Plan has not yet been submitted to the stockholders for their approval. Accordingly, the shares reflected in this table are based on the 2,350,000 shares approved by our stockholders.

#### Item 13. Certain Relationships and Related Transactions, and Director Independence.

##### Certain Relationships and Related Transactions

On February 21, 2014, entered into an independent contractor services agreement (the “Consulting Agreement”) with Elma Hawkins Ph.D. pursuant to which Dr. Hawkins agreed to serve as our head of clinical development. Under the Consulting Agreement, Dr. Hawkins was granted a non-qualified stock option to purchase an aggregate of 200,000 shares of our common stock, and 200,000 shares of restricted common stock. In addition, between February 21, 2014 and August 21, 2014, Dr. Hawkins was paid \$159,693 of fees under the Consulting Agreement. On August 21, 2014, the Consulting Agreement was terminated and we entered into an employment agreement with Dr. Hawkins pursuant to which she agreed to serve as our President and Chief Operating Officer.

Sanford J. Hillsberg, one of our directors, is an attorney at TroyGould PC. TroyGould PC rendered legal services to our company in 2014 and has rendered legal services in 2015. We paid TroyGould PC \$393,230 in fees in 2014.

##### Director Independence

Our Board had determined that Sanford Hillsberg, Jay Venkatesen, Merrill McPeak and Ryan Maynard qualify as “independent directors” as under the Nasdaq Stock Market’s listing standards and the rules of the SEC, and have no material relationships with us (either directly or as a partner, shareholder or officer of any entity) that are inconsistent with a finding of their independence as members of our board of directors. Our board has determined that Messrs. Maynard, McPeak and Venkatesan also are “independent” for purposes of service as the members of our Audit Committee.

**Item 14. Principal Accounting Fees and Services****Summary of Principal Accounting Fees for Professional Services Rendered**

The following table presents the aggregate fees for professional audit services and other services rendered by Weinberg & Company, our independent registered public accountants for the fiscal years ended December 31, 2013 and December 31, 2014.

	<b>Year Ended December 31, 2013</b>	<b>Year Ended December 31, 2014</b>
Audit Fees	\$ 130,297	\$ 110,613
Audit-Related Fees	-	-
Tax Fees	-	7,350
All Other Fees	-	44,587
Total:	\$ 130,297	\$ 162,550

*Audit Fees* consist of fees billed for the annual audit of our financial statements and other audit services including the provision of consents and the review of documents filed with the SEC.

Our Audit Committee or our Board of Directors considered whether the provision of the services described above for the fiscal years ended December 31, 2013 and 2014, is compatible with maintaining the auditor's independence.

All audit and non-audit services that may be provided by our principal accountant to us require pre-approval by the Audit Committee of the Board of Directors. Further, our auditor shall not provide those services to us specifically prohibited by the SEC, including bookkeeping or other services related to the accounting records or financial statements of the audit client; financial information systems design and implementation; appraisal or valuation services, fairness opinion, or contribution-in-kind reports; actuarial services; internal audit outsourcing services; management functions; human resources; broker-dealer, investment adviser, or investment banking services; legal services and expert services unrelated to the audit; and any other service that the Public Company Accounting Oversight Board determines, by regulation, is impermissible.

**PART IV****Item 15. Exhibits, Financial Statements Schedules**

The following exhibits are filed with, or are incorporated by reference into, this Annual Report.

**EXHIBIT INDEX**

Exhibit	Description
1.1	Underwriting Agreement, dated as of December 17, 2014, between Lion Biotechnologies, Inc. and Jefferies LLC and Cowen and Company, LLC, as representatives of the underwriters (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on December 22, 2014)
1.2	Underwriting agreement, dated as of February 26, 2015, between Lion Biotechnologies, Inc. and Jefferies LLC, Cowen and Company, LLC and Piper Jaffray & Co., as the representatives of the underwriters (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on March 3, 2015)
10.46	Patent License Agreement, dated February 9, 2015, by and between the Company and the National Institutes of Health.*
10.47	Patent License Agreement, dated February 10, 2015, by and between the Company and the National Institutes of Health.*
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer

\* Certain portions of the Exhibit have been omitted based upon a request for confidential treatment filed by us with the Commission. The omitted portions of the Exhibit have been separately filed by us with the Commission.

**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.

**LION BIOTECHNOLOGIES, INC.**

Date: April 17, 2015

By: /s/ ELMA HAWKINS

Name: Elma Hawkins

Title: Chief Executive Officer



Text Marked By [\*\*\*] Has Been Omitted Pursuant To A Request For Confidential Treatment And Was Filed Separately With The Securities And Exchange Commission.

THE NATIONAL INSTITUTES OF HEALTH  
PATENT LICENSE AGREEMENT – *EXCLUSIVE*

COVER PAGE

For the **NIH** internal use only:

License Number: L-108-2015/0

License Application Number: A-079-2014

Serial Number(s) of Licensed Patent(s) or Patent Application(s):

U.S. Patent Application No. 61/771,247 filed March 1, 2013 [E-059-2013/0-US-01]

PCT Patent Application No. PCT/US2013/038799 filed April 30, 2013 [E-059-2013/0-US-01]

Licensee: Lion Biotechnologies, Inc.

Cooperative Research and Development Agreement (CRADA) Number: C-057-2011 (NCI 02734)

Public Benefit(s):

The public will benefit from the development of **Licensed Products** by the **Licensee** that are granted FDA approval. There is a long felt need for better treatments for metastatic melanoma. The development of novel TIL-based therapies will provide patients with new cancer treatment options in the realm of personalized medicine to support public health.

This Patent License Agreement, hereinafter referred to as the “**Agreement**”, consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D (Benchmarks and Performance), Appendix E (Commercial Development Plan), Appendix F (Example Royalty Report), and Appendix G (Royalty Payment Options). The Parties to this **Agreement** are:

- 1) The National Institutes of Health (“**NIH**”), an agency within the Department of Health and Human Services (“**HHS**”); and
- 2) The person, corporation, or institution identified above or on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as the “**Licensee**”.

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The **NIH** and the **Licensee** agree as follows:

1. BACKGROUND

- 1.1 In the course of conducting biomedical and behavioral research, the **NIH** or the **FDA** investigators made inventions that may have commercial applicability.
- 1.2 By assignment of rights from **NIH** or **FDA** employees and other inventors, **HHS**, on behalf of the **Government**, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by the **NIH** or the **FDA**.
- 1.3 The Secretary of **HHS** has delegated to the **NIH** the authority to enter into this **Agreement** for the licensing of rights to these inventions.
- 1.4 The **NIH** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.
- 1.5 The **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

- 2.1 “**Affiliate(s)**” means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with the **Licensee**. For this purpose, the term "control" shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.
- 2.2 “**Benchmarks**” mean the performance milestones that are set forth in Appendix D.
- 2.3 “**Commercial Development Plan**” means the written commercialization plan attached as Appendix E.
- 2.4 “**CRADA**” means a Cooperative Research and Development Agreement.
- 2.5 “**FDA**” means the Food and Drug Administration.
- 2.6 “**First Commercial Sale**” means the initial transfer by or on behalf of the **Licensee** or its sublicensees of the **Licensed Products** or the initial practice of a **Licensed Process** by or on behalf of the **Licensee** or its sublicensees in a country after obtaining regulatory approval by the U.S. Food and Drug Administration or any foreign equivalent necessary for the marketing and sale of such **Licensed Product** or practice of such **Licensed Process** in exchange for cash or some equivalent consideration to which value can be assigned for the purpose of determining **Net Sales**.
- 2.7 “**Government**” means the Government of the United States of America.
- 2.8 “**Licensed Fields of Use**” means the fields of use identified in Appendix B.

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2.9 “**Licensed Patent Rights**” shall mean:

- (a) Patent applications (including provisional patent applications and PCT patent applications) or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of these patents;
- (b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.9(a):
  - (i) continuations-in-part of 2.9(a);
  - (ii) all divisions and continuations of these continuations-in-part;
  - (iii) all patents issuing from these continuations-in-part, divisions, and continuations;
  - (iv) priority patent application(s) of 2.9(a); and
  - (v) any reissues, reexaminations, and extensions of these patents;
- (c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.9(a): all counterpart foreign and U.S. patent applications and patents to 2.9(a) and 2.9(b), including those listed in Appendix A; and
- (d) **Licensed Patent Rights** shall *not* include 2.9(b) or 2.9(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.9(a).

2.10 “**Licensed Processes**” means processes which, in the course of being practiced, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.11 “**Licensed Products**” means tangible materials which, in the course of manufacture, use, sale, or importation, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.12 “**Licensed Territory**” means the geographical area identified in Appendix B.

- 2.13 “**Net Sales**” means the total gross receipts received by **Licensee** for sales of **Licensed Products** or practice of **Licensed Processes** by or on behalf of the **Licensee** or its sublicensees, and from leasing, renting, or otherwise making the **Licensed Products** available to others for consideration without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by the **Licensee**, or sublicensees, and on its payroll, or for the cost of collections. “**Net Sales**” shall not include the supply of **Licensed Products** or use of **Licensed Processes**, for use in pre-clinical or clinical studies, or for process development, quality control or assurance, storage as safety stock, transfer as a charitable donation or any other transaction for which no gross revenue is received.
- 2.14 “**Practical Application**” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under these conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms not inconsistent with the terms applicable to similar products or processes and taking into account the efficacy and safety profile of the **Licensed Product** or the utility of the **Licensed Process** and other relevant commercial, scientific, technical and other factors.
- 2.15 “**Research License**” means a nontransferable, nonexclusive license to make and to use the **Licensed Products** or the **Licensed Processes** as defined by the **Licensed Patent Rights** for purposes of research only and not for purposes of commercial sale, manufacture or distribution or in lieu of purchase.
- 2.16 “**Genesis License**” means the **PHS Patent License Agreement -Nonexclusive (License No. L-129-2011/0)** between **PHS** and **Licensee**, as may be amended from time to time.

### 3. GRANT OF RIGHTS

- 3.1 The **NIH** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Fields of Use** and to practice and have practiced any **Licensed Process(es)** in the **Licensed Fields of Use**.
- 3.2 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the **NIH** other than the **Licensed Patent Rights** regardless of whether these patents are dominant or subordinate to the **Licensed Patent Rights**.

### 4. SUBLICENSING

- 4.1 Upon written approval, which shall include prior review of any sublicense agreement by the **NIH** and which shall not be unreasonably withheld or delayed, the **Licensee** may enter into sublicensing agreements under the **Licensed Patent Rights**.

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- 4.2 The **Licensee** agrees that any sublicenses shall provide that the obligations to the **NIH** of Paragraphs 5.1-5.4, 8.1, 10.1, 10.2, 12.5, and 13.8-13.10 of this **Agreement** shall be binding upon the sublicensee as if it were a party to this **Agreement**. The **Licensee** further agrees to attach copies of these Paragraphs to all sublicense agreements.
- 4.3 Any sublicenses granted by the **Licensee** shall provide for the termination of the sublicense, or the conversion to a license directly between the sublicensees and the **NIH**, at the option of the sublicensee, upon termination of this **Agreement** under Article 13. This conversion is subject to the **NIH** approval, which will not be unreasonably denied or delayed, and contingent upon acceptance by the sublicensee of the remaining provisions of this **Agreement**.
- 4.4 The **Licensee** agrees to forward to the **NIH** a complete copy of each fully executed sublicense agreement postmarked within thirty (30) days of the execution of the agreement. To the extent permitted by law, the **NIH** agrees to maintain each sublicense agreement in confidence.

5. STATUTORY AND NIH REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

- (a) the **NIH** reserves on behalf of the **Government** an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice of all inventions licensed under the **Licensed Patent Rights** throughout the world by or on behalf of the **Government** and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement to which the **Government** is a signatory. Prior to the **First Commercial Sale**, the **Licensee** agrees to provide the **NIH** with reasonable quantities of the **Licensed Products** or materials made through the **Licensed Processes** for **NIH** research use, including pre-clinical and clinical studies undertaken at the **NIH**; and
- (b) in the event that the **Licensed Patent Rights** are Subject Inventions made under **CRADA**, the **Licensee** grants to the **Government**, pursuant to 15 U.S.C. §3710a(b)(1)(A), a nonexclusive, nontransferable, irrevocable, paid-up license to practice the **Licensed Patent Rights** or have the **Licensed Patent Rights** practiced throughout the world by or on behalf of the **Government**. In the exercise of this license, the **Government** shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. §552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party. Prior to the **First Commercial Sale**, the **Licensee** agrees to provide the **NIH** with reasonable quantities of the **Licensed Products** or materials made through the **Licensed Processes** for **NIH** research use.
- 5.2 The **Licensee** agrees that products used or sold in the United States embodying the **Licensed Products** or produced through use of the **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from the **NIH**.
- 5.3 The **Licensee** acknowledges that the **NIH** may enter into future **CRADAs** under the Federal Technology Transfer Act of 1986 that relate to the subject matter of this **Agreement**. The **Licensee** agrees not to unreasonably deny requests for a **Research License** from future collaborators with the **NIH** when acquiring these rights is necessary in order to make a **CRADA** project feasible. The **Licensee** may request an opportunity to join as a party to the proposed **CRADA**.

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- 5.4 (a) in addition to the reserved license of Paragraph 5.1, the **NIH** reserves the right to grant **Research Licenses** directly or to require the **Licensee** to grant **Research Licenses** on reasonable terms. The purpose of these **Research Licenses** is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the **Licensed Patent Rights**, however, the **NIH** shall consult with the **Licensee** before granting to commercial entities a **Research License** or providing to them research samples of materials made through the **Licensed Processes**; and
- (b) in exceptional circumstances, and in the event that the **Licensed Patent Rights** are Subject Inventions made under a **CRADA**, the **Government**, pursuant to 15 U.S.C. §3710a(b)(1)(B), retains the right to require the **Licensee** to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the **Licensed Patent Rights** in the **Licensed Field of Use** on terms that are reasonable under the circumstances, or if the **Licensee** fails to grant this license, the **Government** retains the right to grant the license itself. The exercise of these rights by the **Government** shall only be in exceptional circumstances and only if the **Government** determines:
- (i) the action is necessary to meet health or safety needs that are not reasonably satisfied by the **Licensee**;
- (ii) the action is necessary to meet requirements for public use specified by Federal regulations, and these requirements are not reasonably satisfied by the **Licensee**; or
- (iii) the **Licensee** has failed to comply with an agreement containing provisions described in 15 U.S.C. §3710a(c)(4)(B); and
- (c) the determination made by the **Government** under this Paragraph 5.4 is subject to administrative appeal and judicial review under 35 U.S.C. §203(b).

## 6. ROYALTIES AND REIMBURSEMENT

- 6.1 The **Licensee** agrees to pay the **NIH** a noncreditable, nonrefundable license issue royalty as set forth in Appendix C.
- 6.2 The **Licensee** agrees to pay the **NIH** a nonrefundable minimum annual royalty as set forth in Appendix C.
- 6.3 The **Licensee** agrees to pay the **NIH** earned royalties as set forth in Appendix C.
- 6.4 The **Licensee** agrees to pay the **NIH** benchmark royalties as set forth in Appendix C.
- 6.5 The **Licensee** agrees to pay the **NIH** sublicensing royalties as set forth in Appendix C.
- 6.6 A patent or patent application licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments in any given country on the earliest of the dates that:

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- (a) the application has been abandoned and not continued;
  - (b) the patent expires or irrevocably lapses, or
  - (c) the patent has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.
- 6.7 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.
- 6.8 On sales of the **Licensed Products** by the **Licensee** to sublicensees or on sales made in other than an arms-length transaction, the value of the **Net Sales** attributed under this Article 6 to this transaction shall be that which would have been received in an arms-length transaction, based on sales of like quantity and quality products on or about the time of this transaction.
- 6.9 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **NIH** prior to the effective date of this **Agreement**, the **Licensee** shall pay the **NIH**, as an additional royalty, within sixty (60) days of the **NIH's** submission of a statement and request for payment to the **Licensee**, an amount equivalent to these unreimbursed expenses previously paid by the **NIH**.
- 6.10 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **NIH** on or after the effective date of this **Agreement**, the **NIH**, at its sole option, may require the **Licensee**:
- (a) to pay the **NIH** on an annual basis, within sixty (60) days of the **NIH's** submission of a statement and request for payment, a royalty amount equivalent to these unreimbursed expenses paid during the previous calendar year(s);
  - (b) to pay these unreimbursed expenses directly to the law firm employed by the **NIH** to handle these functions. However, in this event, the **NIH** and not the **Licensee** shall be the client of the law firm; or
  - (c) in limited circumstances, the **Licensee** may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the **Licensed Patent Rights**. In that event, the **Licensee** shall directly pay the attorneys or agents engaged to prepare, file, prosecute, or maintain these patent applications or patents and shall provide the **NIH** with copies of each invoice associated with these services as well as documentation that these invoices have been paid.
- 6.11 The **NIH** agrees, upon written request, to provide the **Licensee** with summaries of patent prosecution invoices for which the **NIH** has requested payment from the **Licensee** under Paragraphs 6.9 and 6.10. The **Licensee** agrees that all information provided by the **NIH** related to patent prosecution costs shall be treated as confidential commercial information and shall not be released to a third party (other than its **Affiliates**) except as required by law or a court of competent jurisdiction.

6.12 The **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any of the **Licensed Patent Rights** upon ninety (90) days written notice to the **NIH** and owe no payment obligation under Paragraph 6.10 for patent-related expenses incurred in that country after ninety (90) days of the effective date of the written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 Except as otherwise provided in this Article 7, the **NIH** agrees to take responsibility for, but to consult with, the **Licensee** in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and shall furnish copies of relevant patent-related documents to the **Licensee**.

7.2 Upon the **NIH's** written request, the **Licensee** shall assume the responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and shall, on an ongoing basis, promptly furnish copies of all patent-related documents to the **NIH**. In this event, the **Licensee** shall, subject to the prior approval of the **NIH**, select registered patent attorneys or patent agents to provide these services on behalf of the **Licensee** and the **NIH**. The **NIH** shall provide appropriate powers of attorney and other documents necessary to undertake this action to the patent attorneys or patent agents providing these services. The **Licensee** and its attorneys or agents shall consult with the **NIH** in all aspects of the preparation, filing, prosecution and maintenance of patent applications and patents included within the **Licensed Patent Rights** and shall provide the **NIH** sufficient opportunity to comment on any document that the **Licensee** intends to file or to cause to be filed with the relevant intellectual property or patent office.

7.3 At any time, after **Licensee** has assumed responsibility for the preparation, filing, prosecution, and maintenance of **Licensed Patent Rights** as provided in Section 7.2, the **NIH** may provide the **Licensee** with written notice that the **NIH** wishes to re-assume control of the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**. If the **NIH** elects to reassume these responsibilities, the **Licensee** agrees to cooperate fully with the **NIH**, its attorneys, and agents in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and to provide the **NIH** with complete copies of any and all documents or other materials in **Licensee's** possession or control that the **NIH** deems necessary to undertake such responsibilities. The **Licensee** shall be responsible for all costs associated with transferring patent prosecution responsibilities to an attorney or agent of the **NIH's** choice.

7.4 Each party shall promptly inform the other as to all material matters that come to its attention that may affect the preparation, filing, prosecution, or maintenance of the **Licensed Patent Rights** and permit each other to provide comments and suggestions with respect to the preparation, filing, prosecution, and maintenance of the **Licensed Patent Rights**, which comments and suggestions shall be considered by the other party.

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8. RECORD KEEPING

- 8.1 The **Licensee** agrees to keep accurate and correct records of the **Licensed Products** made, used, sold, or imported and the **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due the **NIH**. These records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours for inspection, at the expense of the **NIH**, by an accountant or other designated auditor selected by the **NIH** for the sole purpose of verifying reports and royalty payments hereunder. Licensee may require such auditor or accountant to enter into a confidentiality agreement with Licensee containing reasonable terms and conditions for the protection of Licensee's non-public and proprietary information. The accountant or auditor shall only disclose to the **NIH** information relating to the accuracy of reports and royalty payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then the **Licensee** shall reimburse the **NIH** for the cost of the inspection at the time the **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.8. All royalty payments required under this Paragraph shall be due within sixty (60) days of the date the **NIH** provides to the **Licensee** notice of the payment due.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

- 9.1 Prior to signing this **Agreement**, the **Licensee** has provided the **NIH** with the **Commercial Development Plan** in Appendix E, under which the **Licensee** intends to bring **Licensed Product(s)** or **Licensed Process(es)** within the subject matter of the **Licensed Patent Rights** to the point of **Practical Application**. This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** are determined as specified in Appendix D.
- 9.2 The **Licensee** shall provide written annual reports on its product development progress or efforts to commercialize under the **Commercial Development Plan** for each of the **Licensed Fields of Use** within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacturing, sublicensing, marketing, importing, and sales during the preceding calendar year, as well as, plans for the present calendar year. The **NIH** also encourages these reports to include information on any of the **Licensee's** public service activities that relate to the **Licensed Patent Rights**. If reported progress differs from that projected in the **Commercial Development Plan** and **Benchmarks**, the **Licensee** shall explain the reasons for these differences. In the annual report, the **Licensee** may propose amendments to the **Commercial Development Plan**, acceptance of which by the **NIH** may not be denied unreasonably. The **Licensee** agrees to provide any additional information reasonably required by the **NIH** to evaluate the **Licensee's** performance under this **Agreement**. The **Licensee** may amend the **Benchmarks** at any time upon written approval by the **NIH**. The **NIH** shall not unreasonably withhold approval of any request of the **Licensee** to extend the time periods of this schedule if the request is supported by a reasonable showing by the **Licensee** of diligence in its performance under the **Commercial Development Plan** and toward bringing the **Licensed Products** to the point of **Practical Application** as defined in 37 C.F.R. §404.3(d). The **Licensee** shall amend the **Commercial Development Plan** and **Benchmarks** at the request of the **NIH** to address any **Licensed Fields of Use** not specifically addressed in the plan originally submitted.
- 9.3 The **Licensee** shall report to the **NIH** the dates for achieving **Benchmarks** specified in Appendix D and the **First Commercial Sale** in each country in the **Licensed Territory** within thirty (30) days of such occurrences.

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- 9.4 Following the **First Commercial Sale**, the **Licensee** shall submit to the **NIH**, within sixty (60) days after each calendar half-year ending June 30 and December 31, a royalty report, as described in the example in Appendix F, setting forth for the preceding half-year period the amount of the **Licensed Products** sold or **Licensed Processes** practiced by or on behalf of the **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each royalty report, the **Licensee** shall submit payment of earned royalties due. If no earned royalties are due to the **NIH** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of the **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.13 to determine **Net Sales** made under Article 6 to determine royalties due. The royalty report shall also identify the site of manufacture for the **Licensed Product(s)** sold in the United States.
- 9.5 The **Licensee** agrees to forward semi-annually to the **NIH** a copy of these reports received by the **Licensee** from its sublicensees during the preceding half-year period as shall be pertinent to a royalty accounting to the **NIH** by the **Licensee** for activities under the sublicense.
- 9.6 Royalties due under Article 6 shall be paid in U.S. dollars and payment options are listed in Appendix G. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day preceding the day that the payment is due. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by the **Licensee**. The royalty report required by Paragraph 9.4 shall be mailed to the **NIH** at its address for **Agreement** Notices indicated on the Signature Page.
- 9.7 The **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay the tax and be responsible for all filings with appropriate agencies of foreign governments. As reasonably requested by **Licensee**, **NIH** shall cooperate with **Licensee** in applying for any valid exemption or obtaining any valid refund of such taxes paid by **Licensee**.
- 9.8 Additional royalties may be assessed by the **NIH** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by the **NIH** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent the **NIH** from exercising any other rights it may have as a consequence of the lateness of any payment.
- 9.9 All plans and reports required by this Article 9 and marked "confidential" by the **Licensee** shall, to the extent permitted by law, be treated by the **NIH** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by the **NIH** under the Freedom of Information Act (FOIA), 5 U.S.C. §552 shall be subject to the predisclosure notification requirements of 45 C.F.R. §5.65(d).

## 10. PERFORMANCE

- 10.1 The **Licensee** shall use its reasonable commercial efforts to bring the **Licensed Products** and the **Licensed Processes** to **Practical Application**. "Reasonable commercial efforts" for the purposes of this provision shall include reasonable adherence to the **Commercial Development Plan** in Appendix E and performance of the **Benchmarks** in Appendix D in each case as either may be amended from time to time. The efforts of a sublicensee or an **Affiliate** of **Licensee** shall be considered the efforts of the **Licensee**.

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- 10.2 Upon the **First Commercial Sale** in the United States, until the expiration or termination of this **Agreement**, the **Licensee** shall use its reasonable commercial efforts to make the **Licensed Products** and the **Licensed Processes** reasonably accessible to the United States public.
- 10.3 The **Licensee** agrees, after its **First Commercial Sale**, to make reasonable quantities of the **Licensed Products** or materials produced through the use of the **Licensed Processes** within the **Licensed Fields of Use** available to patient assistance programs.
- 10.4 The **Licensee** agrees, after its **First Commercial Sale** and as part of its marketing and product promotion, to develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians detailing the **Licensed Products** or medical aspects of the prophylactic and therapeutic uses of the **Licensed Products**.
- 10.5 The **Licensee** agrees to supply, to the Mailing Address for **Agreement** Notices indicated on the Signature Page, the Office of Technology Transfer, **NIH** with inert samples of the **Licensed Products** or the **Licensed Processes** or their packaging for educational and display purposes only.

## 11. INFRINGEMENT AND PATENT ENFORCEMENT

- 11.1 The **NIH** and the **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights**, as well as, any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either party becomes aware.
- 11.2 Pursuant to this **Agreement** and the provisions of 35 U.S.C. Chapter 29, the **Licensee** may:
  - (a) bring suit in its own name, at its own expense, and on its own behalf for infringement of presumably valid claims in the **Licensed Patent Rights**;
  - (b) in any suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; or
  - (c) settle any claim or suit for infringement of the **Licensed Patent Rights** provided, however, that the **NIH** and appropriate **Government** authorities shall have the first right to take such actions; and
  - (d) if the **Licensee** desires to initiate a suit for patent infringement, the **Licensee** shall notify the **NIH** in writing. If the **NIH** does not notify the **Licensee** of its intent to pursue legal action within ninety (90) days, the **Licensee** shall be free to initiate suit. The **NIH** shall have a continuing right to intervene in the suit. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any suit for patent infringement. The **Licensee** may request the **Government** to initiate or join in any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit, the **Licensee** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of the motion or other action, including all costs incurred by the **Government** in opposing the motion or other action. In all cases, the **Licensee** agrees to keep the **NIH** reasonably apprised of the status and progress of any litigation. Before the **Licensee** commences an infringement action, the **Licensee** shall notify the **NIH** and give careful consideration to the views of the **NIH** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

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- 11.3 In the event that a declaratory judgment action alleging invalidity or non-infringement of any of the **Licensed Patent Rights** shall be brought against the **Licensee** or raised by way of counterclaim or affirmative defense in an infringement suit brought by the **Licensee** under Paragraph 11.2, pursuant to this **Agreement** and the provisions of 35 U.S.C. Part 29 or other statutes, the **Licensee** may:
- (a) defend the suit in its own name, at its own expense, and on its own behalf for presumably valid claims in the **Licensed Patent Rights**;
  - (b) in any suit, ultimately to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; and
  - (c) settle any claim or suit for declaratory judgment involving the **Licensed Patent Rights**-provided, however, that the **NIH** and appropriate **Government** authorities shall have the first right to take these actions and shall have a continuing right to intervene in the suit; and
  - (d) if the **NIH** does not notify the **Licensee** of its intent to respond to the legal action within a reasonable time, the **Licensee** shall be free to do so. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any declaratory judgment action. The **Licensee** may request the **Government** to initiate or to join any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit by motion or any other action of the **Licensee**, the **Licensee** shall reimburse the **Government** for any costs, expenses, or fees, which the **Government** incurs as a result of the motion or other action. If the **Licensee** elects not to defend against the declaratory judgment action, the **NIH**, at its option, may do so at its own expense. In all cases, the **Licensee** agrees to keep the **NIH** reasonably apprised of the status and progress of any litigation. Before the **Licensee** commences an infringement action, the **Licensee** shall notify the **NIH** and give careful consideration to the views of the **NIH** and to any potential effects of the litigation on the public health in deciding whether to bring suit.
- 11.4 In any action under Paragraphs 11.2 or 11.3 the expenses including costs, fees, attorney fees, and disbursements, shall be paid by the **Licensee**. The value of any recovery made by the **Licensee** through court judgment or settlement actually collected shall first be applied by **Licensee** to reimburse it for all of its costs and expenses (including attorneys' fees, expert witness fees, and any reimbursement payments made to **NIH** or the **Government**) and the balance shall be treated as **Net Sales** and subject to earned royalties as provided in Appendix C when and as collected.
- 11.5 The **NIH** shall cooperate fully with the **Licensee** in connection with any action under Paragraphs 11.2 or 11.3. The **NIH** agrees promptly to provide access to all necessary documents and to render reasonable assistance in response to a request by the **Licensee**.

## 12. NEGATION OF WARRANTIES AND INDEMNIFICATION

- 12.1 The **NIH** offers no warranties other than those specified in Article 1.

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- 12.2 The **NIH** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.
- 12.3 **THE NIH MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE LICENSED PATENT RIGHTS OR TANGIBLE MATERIALS RELATED THERETO.**
- 12.4 The **NIH** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.
- 12.5 The **Licensee** shall indemnify and hold the **NIH**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:
- (a) the use by or on behalf of the **Licensee**, its sublicensees, directors, employees, or third parties of any **Licensed Patent Rights**; or
  - (b) the design, manufacture, distribution, or use of any **Licensed Products, Licensed Processes** or materials by the **Licensee**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**.
- 12.6 The **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

13. **TERM, TERMINATION, AND MODIFICATION OF RIGHTS**

- 13.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 14.16 are not fulfilled, and shall extend to the expiration of the last to expire of the **Licensed Patent Rights** unless sooner terminated as provided in this Article 13.
- 13.2 In the event that the **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 13.5, and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, or if not reasonably capable of remedy within such period, **Licensee** has not taken substantial steps to remedy the alleged default within such ninety (90) day period, the **NIH** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.
- 13.3 In the event that the **Licensee (i)** becomes insolvent, (ii) files a petition in bankruptcy, or has such a petition filed against it and, in either case, such petition is not dismissed within sixty (60) days, the **Licensee** shall immediately notify the **NIH** in writing.
- 13.4 The **Licensee** shall have a unilateral right to terminate this **Agreement** or any licenses in any country or territory by giving the **NIH** sixty (60) days written notice to that effect.
- 13.5 The **NIH** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if the **NIH** determines that the **Licensee**:

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- (a) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to the **NIH's** satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve the **Practical Application** of the **Licensed Products** or the **Licensed Processes**;
  - (b) has not achieved and is not reasonably likely to achieve the **Benchmarks** as may be modified under Paragraph 9.2;
  - (c) has willfully made a material false statement of, or willfully omitted a material fact in the license application or in any report required by this **Agreement**;
  - (d) has committed a material breach of a covenant or agreement contained in this **Agreement**;
  - (e) is not keeping the **Licensed Products** or the **Licensed Processes** within the scope of the **Licensed Fields of Use** reasonably accessible to the public after commercial use commences;
  - (f) cannot reasonably satisfy unmet health and safety needs; or
  - (g) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2 unless waived.
- 13.6 In making the determination referenced in Paragraph 13.5, the **NIH** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by the **Licensee** under Paragraph 9.2. Prior to invoking termination or modification of this **Agreement** under Paragraph 13.5, the **NIH** shall give written notice to the **Licensee** providing the **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, the **NIH's** concerns as to the items referenced in 13.5(a)-13.5(g). If the **Licensee** fails to alleviate the **NIH's** reasonable concerns as to the items referenced in 13.5(a)-13.5(g) or fails to initiate corrective action to the **NIH's** reasonable satisfaction, the **NIH** may terminate this **Agreement**.
- 13.7 When the public health and safety so require, and after written notice to the **Licensee** providing the **Licensee** a sixty (60) day opportunity to respond, the **NIH** shall have the right to require the **Licensee** to grant sublicenses to responsible applicants, on commercially reasonable terms, in any **Licensed Fields of Use** under the **Licensed Patent Rights**, unless the **Licensee** can reasonably demonstrate that the granting of the sublicense would not materially increase the availability to the public of the subject matter of the **Licensed Patent Rights**. The **NIH** shall not require the granting of a sublicense unless the responsible applicant has first negotiated in good faith with the **Licensee** for a sublicense on commercially reasonable terms and conditions.
- 13.8 The **NIH** reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this **Agreement** if it is determined that this action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the **Licensee**.

- 13.9 Within thirty (30) days of receipt of written notice of the **NIH's** unilateral decision to modify or terminate this **Agreement**, the **Licensee** may, consistent with the provisions of **37 C.F.R. §404.11**, appeal the decision by written submission to the designated **NIH** official. The decision of the designated **NIH** official shall be the final agency decision. The **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.
- 13.10 Within ninety (90) days of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by the **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expenses, due to the **NIH** shall become immediately due and payable upon termination or expiration. If terminated under this Article 13, sublicensees may elect to convert their sublicenses to direct licenses with the **NIH** pursuant to Paragraph 4.3. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, the **Licensee** shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to the **NIH** or provide the **NIH** with certification of the destruction thereof. The **Licensee** may not be granted additional **NIH** licenses if the final reporting requirement is not fulfilled.

14. GENERAL PROVISIONS

- 14.1 Neither party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of either party to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by that party or excuse a similar subsequent failure to perform any of these terms or conditions by the that party.
- 14.2 This **Agreement** constitutes the entire agreement between the parties relating to the subject matter of the **Licensed Patent Rights**, the **Licensed Products** and the **Licensed Processes**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.
- 14.3 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, this determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.
- 14.4 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.
- 14.5 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.
- 14.6 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to another address as may be designated in writing by the other party. **Agreement** notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

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- 14.7 This **Agreement** shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) except to the **Licensee's Affiliate(s)** without the prior written consent of the **NIH**. The parties agree that the identity of the parties is material to the formation of this **Agreement** and that the obligations under this **Agreement** are nondelegable. In the event that the **NIH** approves a proposed assignment, the **Licensee** shall pay the **NIH**, as an additional royalty, one percent (1%) of the fair market value of any consideration received for any assignment of this **Agreement** within sixty (60) days of the assignment.
- 14.8 The **Licensee** agrees in its use of any **NIH**-supplied biological materials that are supplied under this Agreement to comply with all applicable statutes, regulations, and guidelines, including **NIH** and **HHS** regulations and guidelines. The **Licensee** agrees not to use such biological materials for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. The **Licensee** agrees not to use such biological materials for research involving human subjects or clinical trials outside of the United States without notifying the **NIH**, in writing, of the research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the **NIH** of research involving such biological materials in human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of the research or trials.
- 14.9 The **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of these items may require a license from the appropriate agency of the U.S. **Government** or written assurances by the **Licensee** that it shall not export these items to certain foreign countries without prior approval of this agency. The **NIH** neither represents that a license is or is not required or that, if required, it shall be issued.
- 14.10 The **Licensee** agrees to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All the **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in a manner to preserve the **NIH's** patent rights in those countries.
- 14.11 By entering into this **Agreement**, the **NIH** does not directly or indirectly endorse any product or service provided, or to be provided, by the **Licensee** whether directly or indirectly related to this **Agreement**. The **Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government**, the **NIH**, any other **Government** organizational unit, or any **Government** employee. Additionally, the **Licensee** shall not use the names of the **NIH**, the **FDA** or the **HHS** or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written approval of the **NIH**.
- 14.12 The parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. The **Licensee** agrees first to appeal any unsettled claims or controversies to the designated **NIH** official, or designee, whose decision shall be considered the final agency decision. Thereafter, the **Licensee** may exercise any administrative or judicial remedies that may be available.



- 14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 C.F.R. Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.
- 14.14 Any formal recordation of this **Agreement** required by the laws of any **Licensed Territory** as a prerequisite to enforceability of the **Agreement** in the courts of any foreign jurisdiction or for other reasons shall be carried out by the **Licensee** at its expense, and appropriately verified proof of recordation shall be promptly furnished to the **NIH**.
- 14.15 Paragraphs 4.3, 8.1, 9.5-9.8, 9.9 12.1-12.5, 13.9, 13.10, 14.12 and 14.15 of this **Agreement** shall survive termination of this **Agreement**.
- 14.16 The terms and conditions of this **Agreement** shall, at the **NIH's** sole option, be considered by the **NIH** to be withdrawn from the **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by the **NIH** within sixty (60) days from the date of the **NIH's** signature found at the Signature Page.

**SIGNATURES BEGIN ON NEXT PAGE**

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NIH PATENT LICENSE AGREEMENT – *EXCLUSIVE*

SIGNATURE PAGE

For the **NIH**:

/s/ Richard U. Rodriguez  
Richard U. Rodriguez  
Director, Division of Technology Development and Transfer  
Office of Technology Transfer  
National Institutes of Health

2/9/2015  
Date

Mailing Address or E-mail Address for **Agreement** notices and reports:

Chief, Monitoring & Enforcement Branch  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard, Suite 325  
Rockville, Maryland 20852-3804 U.S.A.

E-mail: LicenseNotices\_Reports@mail.nih.gov

For the **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Licensee** made or referred to in this document are truthful and accurate.):

by:

/s/ Elma Hawkins  
Signature of Authorized Official

2/10/2015  
Date

Elma Hawkins, Ph.D.  
Printed Name

President and CEO  
Title

I. Official and Mailing Address for **Agreement** notices:

Peter Ho, Ph.D.  
Director, Business Development  
21900 Burbank Blvd., 3<sup>rd</sup> Floor  
Woodland Hills, CA 91367  
Phone: 818-992-3127  
Fax: 818-475-5194  
Email: peter.ho@lionbio.com

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II. Official and Mailing Address for Financial notices (the **Licensee's** contact person for royalty payments)

Peter Ho, Ph.D.  
Director, Business Development  
21900 Burbank Blvd., 3<sup>rd</sup> Floor  
Woodland Hills, CA 91367  
Phone: 818-992-3127  
Fax: 818-475-5194  
Email: peter.ho@lionbio.com

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

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**APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)**

**Patent(s) or Patent Application(s):**

- I. U.S. Patent Application No. 61/771,247 filed March 1, 2013 [E-059-2013/0-US-01]
- II. PCT Patent Application No. PCT/US2013/038799 filed April 30, 2013 [E-059-2013/0-PCT-02]

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## APPENDIX B – LICENSED FIELDS OF USE AND TERRITORY

### I. **Licensed Fields of Use:**

The use of the **Licensed Patent Rights** to develop and manufacture autologous tumor infiltrating lymphocyte adoptive cell therapy products for the treatment of metastatic melanoma.

Tumor infiltrating lymphocytes (TIL) are a subset of T lymphocytes (T cells) that migrate and are located within a tumor site. TIL isolated from these tumor sites exhibit natural anti-tumor activity without genetic modifications. For the avoidance of doubt, cell therapy products involving genetically modified tumor infiltrating lymphocytes are excluded from **Licensed Fields of Use**.

### II. **Licensed Territory:** Worldwide

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## APPENDIX C – ROYALTIES

### **Royalties:**

- I. The **Licensee** agrees to pay to the **NIH** a noncreditable, nonrefundable license issue royalty in the amount of Fifty Thousand dollars (\$50,000) within sixty (60) days from the effective date of this **Agreement**.
- II. The **Licensee** agrees to pay to the **NIH** a nonrefundable minimum annual royalty in the amount of [**\* \* \***] as follows:
  - (a) The first minimum annual royalty is due within sixty (60) days of the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1; and
  - (b) Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year.
  - (c) In the case of each of (a) and (b) above, such payments shall be due so long a **Licensee** has not terminated this Agreement pursuant to Paragraph 13.4.
- III. The **Licensee** agrees to pay the **NIH** earned royalties of [**\* \* \***] on **Net Sales** by or on behalf of **Licensee** or its sublicensees. **Licensee** shall be entitled to a credit of [**\* \* \***] against the earned royalty rate for each percent point in excess of [**\* \* \***] that **Licensee** must pay to an unaffiliated licensor(s) for the manufacture and sale of **Licensed Product(s)** and **Licensed Process(es)**. Said credit however, shall not reduce the earned royalty rate due to **NIH** for **Licensed Product(s)** and **Licensed Process(es)** below [**\* \* \***].

Notwithstanding anything in this **Agreement** to the contrary, the earned royalties set forth in this Section III do not apply to, and are not otherwise due or payable with respect to, any **Licensed Products** or **Licensed Processes** that also fall within the scope of one or more claims of the patents licensed to the **Licensee** by the **NIH** under the **Genesis License**. In the event that any products developed and sold or processes practiced by or on behalf of the **Licensee** or any of its sublicensees under this **Agreement** both qualify as a **Licensed Product** or **Licensed Process** under this **Agreement** and fall within the scope of one or more claims of the patents licensed to the **Licensee** under the **Genesis License**, then the **Licensee** will not be obligated to pay any of the earned royalties set forth in this Section III with respect to such **Licensed Products** or **Licensed Processes** and the only earned royalties payable by **Licensee** to the **NIH** with respect to such **Licensed Products** and **Processes** (if any) will be due and payable in accordance with and pursuant to the terms of the **Genesis License**.
- IV. The **Licensee** agrees to pay the **NIH Benchmark** royalties within sixty (60) days of achieving each **Benchmark**:
  - (a) [**\* \* \***] for successful completion of the first Phase 2 clinical study. For purposes of this Agreement “successful completion” shall mean a clinical trial that yields data that is statistically significant and otherwise sufficient to permit Licensee to file a New Drug Application (NDA).
  - (b) [**\* \* \***] for successful completion of the first Phase 3 clinical study.
  - (c) [**\* \* \***] upon the first FDA approval or foreign equivalent for a Licensed Product or Licensed Process.

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(d) [\*\*\*] for the First Commercial Sale of a Licensed Product or Licensed Process in the United States.

(e) [\*\*\*] for the First Commercial Sale of a Licensed Product or Licensed Process in any foreign country for either of Licensed Field of Use.

Notwithstanding anything in this **Agreement** to the contrary, the **NIH Benchmark** royalties set forth in this Section IV do not apply to, and are not otherwise due or payable with respect to, any **Licensed Products** that also fall within the scope of one or more claims of the patents licensed to the **Licensee** by the **NIH** under the **Genesis License**. In the event that any products developed and sold by or on behalf of the **Licensee** or any of its sublicensees under this **Agreement** both qualify as **Licensed Products** under this **Agreement** and fall within the scope of one or more claims of the patents licensed to the **Licensee** under the **Genesis License**, the **Licensee** will not be obligated to pay any of the **NIH Benchmark** royalties set forth in this Section IV with respect to such **Licensed Products** and the only **NIH Benchmark** royalties payable by the **Licensee** to the **NIH** with respect to such **Licensed Products** (if any) will be due and payable in accordance with and pursuant to the terms of the **Genesis License**.

V. The **Licensee** agrees to pay the **NIH**:

(a) additional sublicensing royalties of [\*\*\*] on the fair market value of any consideration received for granting each sublicense within sixty (60) days of the execution of each sublicense if any such sublicense is executed prior to FDA approval or foreign equivalent for a Licensed Product or Licensed Process within each Licensed Field of Use from Appendix B; and

(b) additional sublicensing royalties of [\*\*\*] on the fair market value of any consideration received for granting each sublicense within sixty (60) days of the execution of each sublicense if any such sublicense is executed following FDA approval or foreign equivalent for a Licensed Product or Licensed Process within each Licensed Field of Use from Appendix B.

(c) Notwithstanding anything in this **Agreement** to the contrary, any such consideration will not include the following:

- (1) Bona fide support for research and development activities corresponding directly to the development of **Licensed Product(s)** and/or **Licensed Process(es)**, which do not exceed Licensee's fully-burdened cost for undertaking such research and development, and limited to support which is received after the effective date of this **Agreement** specifically excluding any support which is used by Licensee to offset research and development expenses which are incurred prior to the effective date of this **Agreement**;
- (2) Proceeds derived from debt financing received after the effective date of this **Agreement**, to the extent that such financing is at market rates;
- (3) As earned royalties on Net Sales or sales by sublicensee(s).

Notwithstanding anything in this **Agreement** to the contrary, in the event that the **Licensee** grants any third party a sublicense both under Article 4 of this **Agreement** and under the license rights granted to it in the **Background License**, then the **Licensee** will not be obligated to pay to the **NIH** any portion of any **Non-Royalty Sublicense Income** received by it for granting such sublicense pursuant to this Section V and the **Licensee** will only be obligated to pay to the **NIH** the percentage of any such sublicensing royalties set forth in Appendix C to the **Background License**, in accordance with the terms of the **Background License**.

**APPENDIX D – BENCHMARKS AND PERFORMANCE**

The **Licensee** agrees to the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days of achieving a **Benchmark**, shall notify the **NIH** that the **Benchmark** has been achieved.

	<u>Benchmark</u>	<u>Deadline</u>
I.	[* * *]	[* * *]
II.	[* * *]	[* * *]
III.	[* * *]	[* * *]
IV.	[* * *]	[* * *]
V.	[* * *]	[* * *]
VI.	[* * *]	[* * *]

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**APPENDIX E – COMMERCIAL DEVELOPMENT PLAN**

**Licensee** intends to use the licensed technology to develop and commercialize a product (based an enriched population of T cells from tumors or enriched TILs) to treat melanoma.

**[ \* \* \* ]**

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**APPENDIX F – EXAMPLE ROYALTY REPORT**

**Required royalty report information includes:**

- OTT license reference number (L-XXX-200X/0)
- Reporting period
- Catalog number and units sold of each Licensed Product (domestic and foreign)
- Gross Sales per catalog number per country
- Total Gross Sales
- Itemized deductions from Gross Sales
- Total Net Sales
- Earned Royalty Rate and associated calculations
- Gross Earned Royalty
- Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
- Net Earned Royalty due

**Example**

Catalog Number	Product Name	Country	Units Sold	Gross Sales (US\$)
1	A	US	250	62,500
1	A	UK	32	16,500
1	A	France	25	15,625
2	B	US	0	0
3	C	US	57	57,125
4	D	US	12	1,500

Total Gross Sales	153,250
Less Deductions:	
Freight	3,000
Returns	7,000
Total Net Sales	143,250
Royalty Rate	8%
Royalty Due	11,460
Less Creditable Payments	10,000
<b>Net Royalty Due</b>	<b>1,460</b>

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## APPENDIX G – ROYALTY PAYMENT OPTIONS

The OTT License Number MUST appear on payments, reports and correspondence.

### Automated Clearing House (ACH) for payments through U.S. banks only

The NIH encourages its licensees to submit electronic funds transfer payments through the Automated Clearing House (ACH). Submit your ACH payment through the U.S. Treasury web site located at: <https://www.pay.gov>. Locate the "NIH Agency Form" through the Pay.gov "Agency List".

### Electronic Funds Wire Transfers

The following account information is provided for wire payments. In order to process payment via Electronic Funds Wire Transfer sender MUST supply the following information within the transmission:

Drawn on a **U.S. bank account** via FEDWIRE should be sent directly to the following account:

Beneficiary Account:	Federal Reserve Bank of New York or TREAS NYC
Bank:	Federal Reserve Bank of New York
ABA#	021030004
Account Number:	75080031
Bank Address:	33 Liberty Street, New York, NY 10045
Payment Details:	License Number (L-XXX-XXXX) Name of the Licensee

Drawn on a **foreign bank account** should be sent directly to the following account. Payment must be sent in **U.S. Dollars (USD)** using the following instructions:

Beneficiary Account:	Federal Reserve Bank of New York/ITS or FRBNY/ITS
Bank:	Citibank N.A. (New York)
SWIFT Code:	CITIUS33
Account Number:	36838868
Bank Address:	388 Greenwich Street, New York, NY 10013
Payment Details (Line 70):	<b>NIH</b> 75080031 License Number (L-XXX-XXXX) Name of the Licensee
Detail of Charges (line 71a):	Charge Our

### Checks

All checks should be made payable to "NIH Patent Licensing"

Checks drawn on a **U.S. bank account** and sent by US Postal Service should be sent directly to the following address:

National Institutes of Health (NIH)  
P.O. Box 979071  
St. Louis, MO 63197-9000

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Checks drawn on a U.S. bank account and sent by **overnight or courier** should be sent to the following address:

US Bank  
Government Lockbox SL-MO-C2GL  
1005 Convention Plaza  
St. Louis, MO 63101  
Phone: 314-418-4087

Checks drawn on a **foreign bank account** should be sent directly to the following address:

National Institutes of Health (NIH)  
Office of Technology Transfer  
Royalties Administration Unit  
6011 Executive Boulevard  
Suite 325, MSC 7660  
Rockville, Maryland 20852

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Text Marked By [ \* \* \* ] Has Been Omitted Pursuant To A Request For Confidential Treatment And Was Filed Separately With The Securities And Exchange Commission.

**THE NATIONAL INSTITUTES OF HEALTH**  
**PATENT LICENSE AGREEMENT – EXCLUSIVE**

COVER PAGE

For the **NIH** internal use only:

License Number: L-107-2015/0

License Application Number: A-286-2014

Serial Number(s) of Licensed Patent(s) or Patent Application(s):

**Group A**

- I. U.S. Provisional Patent Application No. 61/237,889, filed August 26, 2009 entitled “Adoptive cell therapy with young T cells” (HHS Ref No. E-273-2009/0-US-01);
- II. U.S. Patent No. 8,383,099 issued February 26, 2013 entitled “Adoptive cell therapy with young T cells” (HHS Ref No. E-273-2009/0-US-02);
- III. U.S. Patent Application No. 13/742,541 filed January 16, 2013 entitled “Adoptive cell therapy with young T cells” (HHS Ref No. E-273-2009/0-US-03);
- IV. U.S. Provisional Patent Application No. 61/466,200 filed March 22, 2011 entitled “Methods of growing tumor infiltrating lymphocytes in gas-permeable containers” (HHS Ref No. E-114-2011/0-US-01);
- V. PCT Application No. PCT/US2012/029744 filed March 20, 2012 entitled “Methods of growing tumor infiltrating lymphocytes in gas-permeable containers” (HHS Ref No. E-114-2011/0-PCT-02);
- VI. U.S. Patent Application No. 13/424,646 filed May 20, 2012 entitled “Methods of growing tumor infiltrating lymphocytes in gas-permeable containers” (HHS Ref No. E-114-2011/0-US-03);

**Group B**

- I. U.S. Provisional Patent Application No. 60/408,681, filed September 6, 2002 entitled “Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy” (HHS Ref No. E-275-2002/0-US-01);

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- II. PCT Application No. PCT/US2012/029744 filed September 5, 2003 entitled “Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy” (HHS Ref No. E-275-2002/1-PCT-01);
- III. U.S. Patent No. 8,034,334 issued October 11, 2011 entitled “Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy” (HHS Ref No. E-275-2002/1-US-02);
- IV. European Patent Application No. 03794636.5 filed April 4, 2005 entitled “Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy” (HHS Ref No. E-275-2002/1-EP-03);
- V. Canadian Patent No. 2,497,552 issued May 27, 2014 entitled “Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy” (HHS Ref No. E-275-2002/1-CA-04);
- VI. Australian Patent No. 2003265948 issued September 3, 2009 entitled “Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy” (HHS Ref No. E-275-2002/1-AU-05);
- VII. U.S. Patent No. 8,287,857 issued October 16, 2012 entitled “Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy” (HHS Ref No. E-275-2002/1-US-06);

Licensee: Lion Biotechnologies, Inc.

Cooperative Research and Development Agreement (CRADA) Number: C-057-2011 (NCI 02734)

Public Benefit(s):

The public will benefit from the development of **Licensed Products** by the **Licensee** that are granted FDA approval. There is a long felt need for better treatments for metastatic melanoma. The development of novel TIL-based therapies will provide patients with new cancer treatment options in the realm of personalized medicine to support public health.

This Patent License Agreement, hereinafter referred to as the “**Agreement**”, consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D (Benchmarks and Performance), Appendix E (Commercial Development Plan), Appendix F (Example Royalty Report), and Appendix G (Royalty Payment Options). The Parties to this **Agreement** are:

- 1) The National Institutes of Health (“**NIH**”), an agency within the Department of Health and Human Services (“**HHS**”); and
- 2) The person, corporation, or institution identified above or on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as the “**Licensee**”.

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The **NIH** and the **Licensee** agree as follows:

1. BACKGROUND

- 1.1 In the course of conducting biomedical and behavioral research, the **NIH** or the **FDA** investigators made inventions that may have commercial applicability.
- 1.2 By assignment of rights from **NIH** or **FDA** employees and other inventors, **HHS**, on behalf of the **Government**, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by the **NIH** or the **FDA**.
- 1.3 The Secretary of **HHS** has delegated to the **NIH** the authority to enter into this **Agreement** for the licensing of rights to these inventions.
- 1.4 The **NIH** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.
- 1.5 The **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

- 2.1 “**Affiliate(s)**” means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with the **Licensee**. For this purpose, the term "control" shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.
- 2.2 “**Benchmarks**” mean the performance milestones that are set forth in Appendix D.
- 2.3 “**Commercial Development Plan**” means the written commercialization plan attached as Appendix E.
- 2.4 “**CRADA**” means a Cooperative Research and Development Agreement.
- 2.5 “**FDA**” means the Food and Drug Administration.
- 2.6 “**First Commercial Sale**” means the initial transfer by or on behalf of the **Licensee** or its sublicensees of the **Licensed Products** or the initial practice of a **Licensed Process** by or on behalf of the **Licensee** or its sublicensees in a country after obtaining regulatory approval by the U.S. Food and Drug Administration or any foreign equivalent necessary for the marketing and sale of such **Licensed Product** or practice of such **Licensed Process** in exchange for cash or some equivalent consideration to which value can be assigned for the purpose of determining **Net Sales**.
- 2.7 “**Government**” means the Government of the United States of America.
- 2.8 “**Licensed Fields of Use**” means the fields of use identified in Appendix B.

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2.9 “**Licensed Patent Rights**” shall mean:

- (a) Patent applications (including provisional patent applications and PCT patent applications) or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of these patents;
- (b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.9(a):
  - (i) continuations-in-part of 2.9(a);
  - (ii) all divisions and continuations of these continuations-in-part;
  - (iii) all patents issuing from these continuations-in-part, divisions, and continuations;
  - (iv) priority patent application(s) of 2.9(a); and
  - (v) any reissues, reexaminations, and extensions of these patents;
- (c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.9(a): all counterpart foreign and U.S. patent applications and patents to 2.9(a) and 2.9(b), including those listed in Appendix A; and
- (d) **Licensed Patent Rights** shall *not* include 2.9(b) or 2.9(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.9(a).

2.10 “**Licensed Processes**” means processes which, in the course of being practiced, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.11 “**Licensed Products**” means tangible materials which, in the course of manufacture, use, sale, or importation, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.12 “**Licensed Territory**” means the geographical area identified in Appendix B.



- 2.13 “**Net Sales**” means the total gross receipts received by **Licensee** for sales of **Licensed Products** or practice of **Licensed Processes** by or on behalf of the **Licensee** or its sublicensees, and from leasing, renting, or otherwise making the **Licensed Products** available to others for consideration without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by the **Licensee**, or sublicensees, and on its payroll, or for the cost of collections. “**Net Sales**” shall not include the supply of **Licensed Products** or use of **Licensed Processes**, for use in pre-clinical or clinical studies, or for process development, quality control or assurance, storage as safety stock, transfer as a charitable donation or any other transaction for which no gross revenue is received.
- 2.14 “**Practical Application**” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under these conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms not inconsistent with the terms applicable to similar products or processes and taking into account the efficacy and safety profile of the **Licensed Product** or the utility of the **Licensed Process** and other relevant commercial, scientific, technical and other factors.
- 2.15 “**Research License**” means a nontransferable, nonexclusive license to make and to use the **Licensed Products** or the **Licensed Processes** as defined by the **Licensed Patent Rights** for purposes of research only and not for purposes of commercial sale, manufacture or distribution or in lieu of purchase.
- 2.16 “**Commercially Reasonable Efforts**” means, with respect to the efforts to be expended by **Licensee** with respect to any objective, the reasonable, diligent, good faith efforts to accomplish such objective as **Licensee** would normally use to accomplish a similar objective under similar circumstances. It is understood and agreed that with respect to the research, development and sale of **Licensed Products** or **Licensed Process(es)** by **Licensee**, such efforts shall be substantially equivalent to those efforts and resources commonly used by **Licensee** for products owned by it or to which it has rights, which product is at a similar stage in its development or product life cycle. **Commercially Reasonable Efforts** shall be determined on a market-by-market basis, and it is anticipated that the level of effort will be different for different markets, and will change over time, reflecting changes in the status of the **Licensed Products** or **Licensed Process(es)** and the market(s) involved.

### 3. GRANT OF RIGHTS

- 3.1 The **NIH** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license to Group A of the **Licensed Patent Rights** and a non-exclusive license to Group B of the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Fields of Use** and to practice and have practiced any **Licensed Process(es)** in such **Licensed Fields of Use**.

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- 3.2 The **NIH** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a non-exclusive license to Groups A and B of the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Fields of Use** (b-d) in Appendix B and to practice and have practiced any **Licensed Process(es)** in such **Licensed Fields of Use**.
- 3.3 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the **NIH** other than the **Licensed Patent Rights** regardless of whether these patents are dominant or subordinate to the **Licensed Patent Rights**.

#### 4. SUBLICENSING

- 4.1 Upon written approval, which shall include prior review of any sublicense agreement by the **NIH** and which shall not be unreasonably withheld or delayed, the **Licensee** may enter into sublicensing agreements under the **Licensed Patent Rights**.
- 4.2 The **Licensee** agrees that any sublicenses shall provide that the obligations to the **NIH** of Paragraphs 5.1-5.4, 8.1, 10.1, 10.2, 12.5, and 13.8-13.10 of this **Agreement** shall be binding upon the sublicensee as if it were a party to this **Agreement**. The **Licensee** further agrees to attach copies of these Paragraphs to all sublicense agreements.
- 4.3 Any sublicenses granted by the **Licensee** shall provide for the termination of the sublicense, or the conversion to a license directly between the sublicensees and the **NIH**, at the option of the sublicensee, upon termination of this **Agreement** under Article 13. This conversion is subject to the **NIH** approval, which will not be unreasonably denied or delayed, and contingent upon acceptance by the sublicensee of the remaining provisions of this **Agreement**.
- 4.4 The **Licensee** agrees to forward to the **NIH** a complete copy of each fully executed sublicense agreement postmarked within thirty (30) days of the execution of the agreement. To the extent permitted by law, the **NIH** agrees to maintain each sublicense agreement in confidence.

#### 5. STATUTORY AND NIH REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

- 5.1 (a) the **NIH** reserves on behalf of the **Government** an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice of all inventions licensed under the **Licensed Patent Rights** throughout the world by or on behalf of the **Government** and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement to which the **Government** is a signatory. Prior to the **First Commercial Sale**, the **Licensee** agrees to provide the **NIH** with reasonable quantities of the **Licensed Products** or materials made through the **Licensed Processes** for **NIH** research use. Given the nature of the envisioned **Licensed Products** as personalized autologous cell therapy products, if any **Licensed Products** and/or materials made through the **Licensed Processes** are not available in reasonable quantities for **NIH** research use, they shall not be subject to the foregoing obligation; and

(b) in the event that the **Licensed Patent Rights** are Subject Inventions made under **CRADA**, the **Licensee** grants to the **Government**, pursuant to 15 U.S.C. §3710a(b)(1)(A), a nonexclusive, nontransferable, irrevocable, paid-up license to practice the **Licensed Patent Rights** or have the **Licensed Patent Rights** practiced throughout the world by or on behalf of the **Government**. In the exercise of this license, the **Government** shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. §552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party. Prior to the **First Commercial Sale**, the **Licensee** agrees to provide the **NIH** with reasonable quantities of the **Licensed Products** or materials made through the **Licensed Processes** for **NIH** research use. Given the nature of the envisioned **Licensed Products** as personalized autologous cell therapy products, if any **Licensed Products** and/or materials made through the **Licensed Processes** are not available in reasonable quantities for **NIH** research use, they shall not be subject to the foregoing obligation.

5.2 The **Licensee** agrees that products used or sold in the United States embodying the **Licensed Products** or produced through use of the **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from the **NIH**.

5.3 The **Licensee** acknowledges that the **NIH** may enter into future **CRADAs** under the Federal Technology Transfer Act of 1986 that relate to the subject matter of this **Agreement**. The **Licensee** agrees not to unreasonably deny requests for a **Research License** from future collaborators with the **NIH** when acquiring these rights is necessary in order to make a **CRADA** project feasible. The **Licensee** may request an opportunity to join as a party to the proposed **CRADA**.

5.4 (a) in addition to the reserved license of Paragraph 5.1, the **NIH** reserves the right to grant **Research Licenses** directly or to require the **Licensee** to grant **Research Licenses** on reasonable terms. The purpose of these **Research Licenses** is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the **Licensed Patent Rights**, however, the **NIH** shall consult with the **Licensee** before granting to commercial entities a **Research License** or providing to them research samples of materials made through the **Licensed Processes**; and

(b) in exceptional circumstances, and in the event that the **Licensed Patent Rights** are Subject Inventions made under a **CRADA**, the **Government**, pursuant to 15 U.S.C. §3710a(b)(1)(B), retains the right to require the **Licensee** to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the **Licensed Patent Rights** in the **Licensed Field of Use** on terms that are reasonable under the circumstances, or if the **Licensee** fails to grant this license, the **Government** retains the right to grant the license itself. The exercise of these rights by the **Government** shall only be in exceptional circumstances and only if the **Government** determines:

(i) the action is necessary to meet health or safety needs that are not reasonably satisfied by the **Licensee**;

- (ii) the action is necessary to meet requirements for public use specified by Federal regulations, and these requirements are not reasonably satisfied by the **Licensee**; or
  - (iii) the **Licensee** has failed to comply with an agreement containing provisions described in 15 U.S.C. §3710a(c)(4)(B); and
- (c) the determination made by the **Government** under this Paragraph 5.4 is subject to administrative appeal and judicial review under 35 U.S.C. §203(b).

6. **ROYALTIES AND REIMBURSEMENT**

- 6.1 The **Licensee** agrees to pay the **NIH** a noncreditable, nonrefundable license issue royalty as set forth in Appendix C.
- 6.2 The **Licensee** agrees to pay the **NIH** a nonrefundable minimum annual royalty as set forth in Appendix C.
- 6.3 The **Licensee** agrees to pay the **NIH** earned royalties as set forth in Appendix C.
- 6.4 The **Licensee** agrees to pay the **NIH** benchmark royalties as set forth in Appendix C.
- 6.5 The **Licensee** agrees to pay the **NIH** sublicensing royalties as set forth in Appendix C.
- 6.6 A patent or patent application licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments in any given country on the earliest of the dates that:
- (a) the application has been abandoned and not continued;
  - (b) the patent expires or irrevocably lapses, or
  - (c) the patent has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.
- 6.7 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.
- 6.8 On sales of the **Licensed Products** by the **Licensee** to sublicensees or on sales made in other than an arms-length transaction, the value of the **Net Sales** attributed under this Article 6 to this transaction shall be that which would have been received in an arms-length transaction, based on sales of like quantity and quality products on or about the time of this transaction.
- 6.9 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents to the extent included within the **Licensed Patent Rights** and paid by the **NIH** prior to the effective date of this **Agreement**, the **Licensee** shall pay the **NIH**, as an additional royalty, within sixty (60) days of the **NIH's** submission of a statement and request for payment to the **Licensee**, an amount equivalent to these unreimbursed expenses previously paid by the **NIH**.

- 6.10 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents to the extent included within the **Licensed Patent Rights** and paid by the **NIH** on or after the effective date of this **Agreement**, the **NIH**, at its sole option, may require the **Licensee**:
- (a) to pay the **NIH** on an annual basis, within sixty (60) days of the **NIH's** submission of a statement and request for payment, a royalty amount equivalent to these unreimbursed expenses paid during the previous calendar year(s) provided, however, that if the **NIH** grants a commercialization license under the **Licensed Patent Rights** to one or more third parties, then the **Licensee** shall pay the **NIH** a pro-rated portion of such unreimbursed expenses calculated by dividing the total patent costs paid during the previous calendar year(s) by the number of commercialization licensees of record whose licenses have a **Licensed Field of Use** which includes the development of therapeutic or diagnostic products and falls within the scope of the **Licensed Patent Rights** as of the date of this statement. For avoidance of doubt, if the **Licensee** is the only commercialization licensee of record whose license has a **Licensed Field of Use** which includes the development of therapeutic or diagnostic products and falls within the scope of the **Licensed Patent Rights** as of the date of this statement, the **Licensee** shall pay **NIH** a royalty amount equivalent to one hundred percent (100%) of these unreimbursed expenses paid during the previous calendar year(s);
  - (b) to pay these unreimbursed expenses directly to the law firm employed by the **NIH** to handle these functions. However, in this event, the **NIH** and not the **Licensee** shall be the client of the law firm; or
  - (c) in limited circumstances, the **Licensee** may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the **Licensed Patent Rights**. In that event, the **Licensee** shall directly pay the attorneys or agents engaged to prepare, file, prosecute, or maintain these patent applications or patents and shall provide the **NIH** with copies of each invoice associated with these services as well as documentation that these invoices have been paid.
- 6.11 The **NIH** agrees, upon written request, to provide the **Licensee** with summaries of patent prosecution invoices for which the **NIH** has requested payment from the **Licensee** under Paragraphs 6.9 and 6.10. The **Licensee** agrees that all information provided by the **NIH** related to patent prosecution costs shall be treated as confidential commercial information and shall not be released to a third party (other than its **Affiliates**) except as required by law or a court of competent jurisdiction.
- 6.12 The **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any of the **Licensed Patent Rights** upon ninety (90) days written notice to the **NIH** and owe no payment obligation under Paragraph 6.10 for patent-related expenses incurred in that country after ninety (90) days of the effective date of the written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

- 7.1 Except as otherwise provided in this Article 7, the **NIH** agrees to take responsibility for, but to consult with, the **Licensee** in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and shall furnish copies of relevant patent-related documents to the **Licensee**.
- 7.2 Upon the **NIH's** written request, the **Licensee** shall assume the responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and shall, on an ongoing basis, promptly furnish copies of all patent-related documents to the **NIH**. In this event, the **Licensee** shall, subject to the prior approval of the **NIH**, select registered patent attorneys or patent agents to provide these services on behalf of the **Licensee** and the **NIH**. The **NIH** shall provide appropriate powers of attorney and other documents necessary to undertake this action to the patent attorneys or patent agents providing these services. The **Licensee** and its attorneys or agents shall consult with the **NIH** in all aspects of the preparation, filing, prosecution and maintenance of patent applications and patents included within the **Licensed Patent Rights** and shall provide the **NIH** sufficient opportunity to comment on any document that the **Licensee** intends to file or to cause to be filed with the relevant intellectual property or patent office.
- 7.3 At any time, after **Licensee** has assumed responsibility for the preparation, filing, prosecution, and maintenance of **Licensed Patent Rights** as provided in Section 7.2, the **NIH** may provide the **Licensee** with written notice that the **NIH** wishes to re-assume control of the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**. If the **NIH** elects to reassume these responsibilities, the **Licensee** agrees to cooperate fully with the **NIH**, its attorneys, and agents in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and to provide the **NIH** with complete copies of any and all documents or other materials in **Licensee's** possession or control that the **NIH** deems necessary to undertake such responsibilities. The **Licensee** shall be responsible for all costs associated with transferring patent prosecution responsibilities to an attorney or agent of the **NIH's** choice.
- 7.4 Each party shall promptly inform the other as to all material matters that come to its attention that may affect the preparation, filing, prosecution, or maintenance of the **Licensed Patent Rights** and permit each other to provide comments and suggestions with respect to the preparation, filing, prosecution, and maintenance of the **Licensed Patent Rights**, which comments and suggestions shall be considered by the other party.

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8. RECORD KEEPING

- 8.1 The **Licensee** agrees to keep accurate and correct records of the **Licensed Products** made, used, sold, or imported and the **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due the **NIH**. These records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours for inspection, at the expense of the **NIH**, by an accountant or other designated auditor selected by the **NIH** for the sole purpose of verifying reports and royalty payments hereunder. Licensee may require such auditor or accountant to enter into a confidentiality agreement with Licensee containing reasonable terms and conditions for the protection of Licensee's non-public and proprietary information. The accountant or auditor shall only disclose to the **NIH** information relating to the accuracy of reports and royalty payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then the **Licensee** shall reimburse the **NIH** for the cost of the inspection at the time the **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.8. All royalty payments required under this Paragraph shall be due within sixty (60) days of the date the **NIH** provides to the **Licensee** notice of the payment due.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

- 9.1 Prior to signing this **Agreement**, the **Licensee** has provided the **NIH** with the **Commercial Development Plan** in Appendix E, under which the **Licensee** intends to use **Commercially Reasonable Efforts** to bring **Licensed Product(s)** or **Licensed Process(es)** within the subject matter of the **Licensed Patent Rights** to the point of **Practical Application**. This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** are determined as specified in Appendix D.
- 9.2 The **Licensee** shall provide written annual reports on its product development progress or efforts to commercialize under the **Commercial Development Plan** for each of the **Licensed Fields of Use** within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacturing, sublicensing, marketing, importing, and sales during the preceding calendar year, as well as, plans for the present calendar year. The **NIH** also encourages these reports to include information on any of the **Licensee's** public service activities that relate to the **Licensed Patent Rights**. If reported progress differs from that projected in the **Commercial Development Plan** and **Benchmarks**, the **Licensee** shall explain the reasons for these differences. In the annual report, the **Licensee** may propose amendments to the **Commercial Development Plan**, acceptance of which by the **NIH** may not be denied unreasonably. The **Licensee** agrees to provide any additional information reasonably required by the **NIH** to evaluate the **Licensee's** performance under this **Agreement**. The **Licensee** may amend the **Benchmarks** at any time upon written approval by the **NIH**. The **NIH** shall not unreasonably withhold approval of any request of the **Licensee** to extend the time periods of this schedule if the request is supported by a reasonable showing by the **Licensee** of diligence in its performance under the **Commercial Development Plan** and toward bringing the **Licensed Products** to the point of **Practical Application** as defined in 37 C.F.R. §404.3(d). The **Licensee** shall amend the **Commercial Development Plan** and **Benchmarks** at the request of the **NIH** to address any **Licensed Fields of Use** not specifically addressed in the plan originally submitted.
- 9.3 The **Licensee** shall report to the **NIH** the dates for achieving **Benchmarks** specified in Appendix D and the **First Commercial Sale** in each country in the **Licensed Territory** within thirty (30) days of such occurrences.

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- 9.4 Following the **First Commercial Sale**, the **Licensee** shall submit to the **NIH**, within sixty (60) days after each calendar half-year ending June 30 and December 31, a royalty report, as described in the example in Appendix F, setting forth for the preceding half-year period the amount of the **Licensed Products** sold or **Licensed Processes** practiced by or on behalf of the **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each royalty report, the **Licensee** shall submit payment of earned royalties due. If no earned royalties are due to the **NIH** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of the **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.13 to determine **Net Sales** made under Article 6 to determine royalties due. The royalty report shall also identify the site of manufacture for the **Licensed Product(s)** sold in the United States.
- 9.5 The **Licensee** agrees to forward semi-annually to the **NIH** a copy of these reports received by the **Licensee** from its sublicensees during the preceding half-year period as shall be pertinent to a royalty accounting to the **NIH** by the **Licensee** for activities under the sublicense.
- 9.6 Royalties due under Article 6 shall be paid in U.S. dollars and payment options are listed in Appendix G. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day preceding the day that the payment is due. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by the **Licensee**. The royalty report required by Paragraph 9.4 shall be mailed to the **NIH** at its address for **Agreement** Notices indicated on the Signature Page.
- 9.7 The **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay the tax and be responsible for all filings with appropriate agencies of foreign governments. As reasonably requested by **Licensee**, **NIH** shall cooperate with **Licensee** in applying for any valid exemption or obtaining any valid refund of such taxes paid by **Licensee**.
- 9.8 Additional royalties may be assessed by the **NIH** on any payment that is more than ninety (90) days overdue at the rate of **[\* \* \*]** per month. This **[\* \* \*]** per month rate may be applied retroactively from the original due date until the date of receipt by the **NIH** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent the **NIH** from exercising any other rights it may have as a consequence of the lateness of any payment.
- 9.9 All plans and reports required by this Article 9 and marked "confidential" by the **Licensee** shall, to the extent permitted by law, be treated by the **NIH** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by the **NIH** under the Freedom of Information Act (FOIA), 5 U.S.C. §552 shall be subject to the predisclosure notification requirements of 45 C.F.R. §5.65(d).

## 10. PERFORMANCE

- 10.1 The **Licensee** shall use its **Commercially Reasonable Efforts** to bring the **Licensed Products** and the **Licensed Processes** to **Practical Application**. "Reasonable commercial efforts" for the purposes of this provision shall include reasonable adherence to the **Commercial Development Plan** in Appendix E and performance of the **Benchmarks** in Appendix D in each case as either may be amended from time to time. The efforts of a sublicensee or an **Affiliate** of **Licensee** shall be considered the efforts of the **Licensee**.

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- 10.2 Upon the **First Commercial Sale** in the United States, until the expiration or termination of this **Agreement**, the **Licensee** shall use its **Commercially Reasonable Efforts** to make the **Licensed Products** and the **Licensed Processes** reasonably accessible to the United States public.
- 10.3 The **Licensee** agrees, after its **First Commercial Sale**, to make reasonable quantities of the **Licensed Products** or materials produced through the use of the **Licensed Processes** within the **Licensed Fields of Use** available to patient assistance programs.
- 10.4 The **Licensee** agrees, after its **First Commercial Sale** and as part of its marketing and product promotion, to develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians detailing the **Licensed Products** or medical aspects of the prophylactic and therapeutic uses of the **Licensed Products**.
- 10.5 The **Licensee** agrees to supply, to the Mailing Address for **Agreement** Notices indicated on the Signature Page, the Office of Technology Transfer, **NIH** with inert samples of the **Licensed Products** or the **Licensed Processes** or their packaging for educational and display purposes only.

## 11. INFRINGEMENT AND PATENT ENFORCEMENT

- 11.1 The **NIH** and the **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights**, as well as, any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either party becomes aware.
- 11.2 Pursuant to this **Agreement** and the provisions of 35 U.S.C. Chapter 29, the **Licensee** may:
  - (a) bring suit in its own name, at its own expense, and on its own behalf for infringement of presumably valid claims in the **Licensed Patent Rights**;
  - (b) in any suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; or
  - (c) settle any claim or suit for infringement of the **Licensed Patent Rights** provided, however, that the **NIH** and appropriate **Government** authorities shall have the first right to take such actions; and
  - (d) if the **Licensee** desires to initiate a suit for patent infringement, the **Licensee** shall notify the **NIH** in writing. If the **NIH** does not notify the **Licensee** of its intent to pursue legal action within ninety (90) days, the **Licensee** shall be free to initiate suit. The **NIH** shall have a continuing right to intervene in the suit. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any suit for patent infringement. The **Licensee** may request the **Government** to initiate or join in any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit, the **Licensee** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of the motion or other action, including all costs incurred by the **Government** in opposing the motion or other action. In all cases, the **Licensee** agrees to keep the **NIH** reasonably apprised of the status and progress of any litigation. Before the **Licensee** commences an infringement action, the **Licensee** shall notify the **NIH** and give careful consideration to the views of the **NIH** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

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- 11.3 In the event that a declaratory judgment action alleging invalidity or non-infringement of any of the **Licensed Patent Rights** shall be brought against the **Licensee** or raised by way of counterclaim or affirmative defense in an infringement suit brought by the **Licensee** under Paragraph 11.2, pursuant to this **Agreement** and the provisions of 35 U.S.C. Part 29 or other statutes, the **Licensee** may:
- (a) defend the suit in its own name, at its own expense, and on its own behalf for presumably valid claims in the **Licensed Patent Rights**;
  - (b) in any suit, ultimately to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; and
  - (c) settle any claim or suit for declaratory judgment involving the **Licensed Patent Rights**-provided, however, that the **NIH** and appropriate **Government** authorities shall have the first right to take these actions and shall have a continuing right to intervene in the suit; and
  - (d) if the **NIH** does not notify the **Licensee** of its intent to respond to the legal action within a reasonable time, the **Licensee** shall be free to do so. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any declaratory judgment action. The **Licensee** may request the **Government** to initiate or to join any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit by motion or any other action of the **Licensee**, the **Licensee** shall reimburse the **Government** for any costs, expenses, or fees, which the **Government** incurs as a result of the motion or other action. If the **Licensee** elects not to defend against the declaratory judgment action, the **NIH**, at its option, may do so at its own expense. In all cases, the **Licensee** agrees to keep the **NIH** reasonably apprised of the status and progress of any litigation. Before the **Licensee** commences an infringement action, the **Licensee** shall notify the **NIH** and give careful consideration to the views of the **NIH** and to any potential effects of the litigation on the public health in deciding whether to bring suit.
- 11.4 In any action under Paragraphs 11.2 or 11.3 the expenses including costs, fees, attorney fees, and disbursements, shall be paid by the **Licensee**. The value of any recovery made by the **Licensee** through court judgment or settlement actually collected shall first be applied by **Licensee** to reimburse it for all of its costs and expenses (including attorneys' fees, expert witness fees, and any reimbursement payments made to **NIH** or the **Government**) and the balance shall be treated as **Net Sales** and subject to earned royalties as provided in Appendix C when and as collected.
- 11.5 The **NIH** shall cooperate fully with the **Licensee** in connection with any action under Paragraphs 11.2 or 11.3. The **NIH** agrees promptly to provide access to all necessary documents and to render reasonable assistance in response to a request by the **Licensee**.

## 12. NEGATION OF WARRANTIES AND INDEMNIFICATION

- 12.1 The **NIH** offers no warranties other than those specified in Article 1.

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- 12.2 The **NIH** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.
- 12.3 **THE NIH MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE LICENSED PATENT RIGHTS OR TANGIBLE MATERIALS RELATED THERETO.**
- 12.4 The **NIH** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.
- 12.5 The **Licensee** shall indemnify and hold the **NIH**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:
- (a) the use by or on behalf of the **Licensee**, its sublicensees, directors, employees, or third parties of any **Licensed Patent Rights**; or
  - (b) the design, manufacture, distribution, or use of any **Licensed Products, Licensed Processes** or materials by the **Licensee**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**.
- 12.6 The **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

13. **TERM, TERMINATION, AND MODIFICATION OF RIGHTS**

- 13.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 14.16 are not fulfilled, and shall extend to the expiration of the last to expire of the **Licensed Patent Rights** unless sooner terminated as provided in this Article 13.
- 13.2 In the event that the **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 13.5, and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, or if not reasonably capable of remedy within such period, **Licensee** has not taken substantial steps to remedy the alleged default within such ninety (90) day period, the **NIH** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.
- 13.3 In the event that the **Licensee (i)** becomes insolvent, (ii) files a petition in bankruptcy, or has such a petition filed against it and, in either case, such petition is not dismissed within sixty (60) days, the **Licensee** shall immediately notify the **NIH** in writing.
- 13.4 The **Licensee** shall have a unilateral right to terminate this **Agreement** or any licenses in any country or territory by giving the **NIH** sixty (60) days written notice to that effect.
- 13.5 The **NIH** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if the **NIH** determines that the **Licensee**:

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- (a) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to the **NIH's** satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve the **Practical Application** of the **Licensed Products** or the **Licensed Processes**;
  - (b) has not achieved and is not reasonably likely to achieve the **Benchmarks** as may be modified under Paragraph 9.2;
  - (c) has willfully made a material false statement of, or willfully omitted a material fact in the license application or in any report required by this **Agreement**;
  - (d) has committed a material breach of a covenant or agreement contained in this **Agreement**;
  - (e) is not keeping the **Licensed Products** or the **Licensed Processes** within the scope of the **Licensed Fields of Use** reasonably accessible to the public after commercial use commences;
  - (f) cannot reasonably satisfy unmet health and safety needs; or
  - (g) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2 unless waived.
- 13.6 In making the determination referenced in Paragraph 13.5, the **NIH** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by the **Licensee** under Paragraph 9.2. Prior to invoking termination or modification of this **Agreement** under Paragraph 13.5, the **NIH** shall give written notice to the **Licensee** providing the **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, the **NIH's** concerns as to the items referenced in 13.5(a)-13.5(g). If the **Licensee** fails to alleviate the **NIH's** reasonable concerns as to the items referenced in 13.5(a)-13.5(g) or fails to initiate corrective action to the **NIH's** reasonable satisfaction, the **NIH** may terminate this **Agreement**.
- 13.7 When the public health and safety so require, and after written notice to the **Licensee** providing the **Licensee** a sixty (60) day opportunity to respond, the **NIH** shall have the right to require the **Licensee** to grant sublicenses to responsible applicants, on commercially reasonable terms, in any **Licensed Fields of Use** under the **Licensed Patent Rights**, unless the **Licensee** can reasonably demonstrate that the granting of the sublicense would not materially increase the availability to the public of the subject matter of the **Licensed Patent Rights**. The **NIH** shall not require the granting of a sublicense unless the responsible applicant has first negotiated in good faith with the **Licensee** for a sublicense on commercially reasonable terms and conditions.
- 13.8 The **NIH** reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this **Agreement** if it is determined that this action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the **Licensee**.

- 13.9 Within thirty (30) days of receipt of written notice of the **NIH's** unilateral decision to modify or terminate this **Agreement**, the **Licensee** may, consistent with the provisions of **37 C.F.R. §404.11**, appeal the decision by written submission to the designated **NIH** official. The decision of the designated **NIH** official shall be the final agency decision. The **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.
- 13.10 Within ninety (90) days of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by the **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expenses, due to the **NIH** shall become immediately due and payable upon termination or expiration. If terminated under this Article 13, sublicensees may elect to convert their sublicenses to direct licenses with the **NIH** pursuant to Paragraph 4.3. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, the **Licensee** shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to the **NIH** or provide the **NIH** with certification of the destruction thereof. The **Licensee** may not be granted additional **NIH** licenses if the final reporting requirement is not fulfilled.

14. GENERAL PROVISIONS

- 14.1 Neither party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of either party to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by that party or excuse a similar subsequent failure to perform any of these terms or conditions by the that party.
- 14.2 This **Agreement** constitutes the entire agreement between the parties relating to the subject matter of the **Licensed Patent Rights**, the **Licensed Products** and the **Licensed Processes**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.
- 14.3 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, this determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.
- 14.4 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.
- 14.5 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.
- 14.6 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to another address as may be designated in writing by the other party. **Agreement** notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

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- 14.7 This **Agreement** shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) except to the **Licensee's Affiliate(s)** without the prior written consent of the **NIH**. The parties agree that the identity of the parties is material to the formation of this **Agreement** and that the obligations under this **Agreement** are nondelegable. In the event that the **NIH** approves a proposed assignment, the **Licensee** shall pay the **NIH**, as an additional royalty, one percent (1%) of the fair market value of any consideration received for any assignment of this **Agreement** within sixty (60) days of the assignment.
- 14.8 The **Licensee** agrees in its use of any **NIH**-supplied biological materials that are supplied under this Agreement to comply with all applicable statutes, regulations, and guidelines, including **NIH** and **HHS** regulations and guidelines. The **Licensee** agrees not to use such biological materials for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. The **Licensee** agrees not to use such biological materials for research involving human subjects or clinical trials outside of the United States without notifying the **NIH**, in writing, of the research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the **NIH** of research involving such biological materials in human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of the research or trials.
- 14.9 The **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of these items may require a license from the appropriate agency of the U.S. **Government** or written assurances by the **Licensee** that it shall not export these items to certain foreign countries without prior approval of this agency. The **NIH** neither represents that a license is or is not required or that, if required, it shall be issued.
- 14.10 The **Licensee** agrees to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All the **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in a manner to preserve the **NIH's** patent rights in those countries.
- 14.11 By entering into this **Agreement**, the **NIH** does not directly or indirectly endorse any product or service provided, or to be provided, by the **Licensee** whether directly or indirectly related to this **Agreement**. The **Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government**, the **NIH**, any other **Government** organizational unit, or any **Government** employee. Additionally, the **Licensee** shall not use the names of the **NIH**, the **FDA** or the **HHS** or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written approval of the **NIH**.
- 14.12 The parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. The **Licensee** agrees first to appeal any unsettled claims or controversies to the designated **NIH** official, or designee, whose decision shall be considered the final agency decision. Thereafter, the **Licensee** may exercise any administrative or judicial remedies that may be available.

- 14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 C.F.R. Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.
- 14.14 Any formal recordation of this **Agreement** required by the laws of any **Licensed Territory** as a prerequisite to enforceability of the **Agreement** in the courts of any foreign jurisdiction or for other reasons shall be carried out by the **Licensee** at its expense, and appropriately verified proof of recordation shall be promptly furnished to the **NIH**.
- 14.15 Paragraphs 4.3, 8.1, 9.5-9.8, 9.9 12.1-12.5, 13.9, 13.10, 14.12 and 14.15 of this **Agreement** shall survive termination of this **Agreement**.
- 14.16 The terms and conditions of this **Agreement** shall, at the **NIH's** sole option, be considered by the **NIH** to be withdrawn from the **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by the **NIH** within sixty (60) days from the date of the **NIH's** signature found at the Signature Page.

**SIGNATURES BEGIN ON NEXT PAGE**

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NIH PATENT LICENSE AGREEMENT – *EXCLUSIVE*

SIGNATURE PAGE

For the **NIH**:

/s/ Richard U. Rodriguez  
Richard U. Rodriguez  
Director, Division of Technology Development and Transfer  
Office of Technology Transfer  
National Institutes of Health

02/09/15  
Date

Mailing Address or E-mail Address for **Agreement** notices and reports:

Chief, Monitoring & Enforcement Branch  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard, Suite 325  
Rockville, Maryland 20852-3804 U.S.A.

E-mail: LicenseNotices\_Reports@mail.nih.gov

For the **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Licensee** made or referred to in this document are truthful and accurate.):

by:

/s/ Elma Hawkins  
Signature of Authorized Official

02/09/15  
Date

Elma Hawkins, Ph.D.  
Printed Name

President and CEO  
Title

I. Official and Mailing Address for **Agreement** notices:

Peter Ho, Ph.D.  
Director, Business Development  
21900 Burbank Blvd., 3<sup>rd</sup> Floor  
Woodland Hills, CA 91367  
Phone: 818-992-3127  
Fax: 818-475-5194  
Email: peter.ho@lionbio.com

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II. Official and Mailing Address for Financial notices (the **Licensee's** contact person for royalty payments)

Peter Ho, Ph.D.  
Director, Business Development  
21900 Burbank Blvd., 3<sup>rd</sup> Floor  
Woodland Hills, CA 91367  
Phone: 818-992-3127  
Fax: 818-475-5194  
Email: peter.ho@lionbio.com

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

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**APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)**

**Patent(s) or Patent Application(s):**

**Group A**

- I. U.S. Provisional Patent Application No. 61/237,889, filed August 26, 2009 entitled “Adoptive cell therapy with young T cells” (HHS Ref No. E-273-2009/0-US-01);
- II. U.S. Patent No. 8,383,099 issued February 26, 2013 entitled “Adoptive cell therapy with young T cells” (HHS Ref No. E-273-2009/0-US-02);
- III. U.S. Patent Application No. 13/742,541 filed January 16, 2013 entitled “Adoptive cell therapy with young T cells” (HHS Ref No. E-273-2009/0-US-03);
- IV. U.S. Provisional Patent Application No. 61/466,200 filed March 22, 2011 entitled “Methods of growing tumor infiltrating lymphocytes in gas-permeable containers” (HHS Ref No. E-114-2011/0-US-01);
- V. PCT Application No. PCT/US2012/029744 filed March 20, 2012 entitled “Methods of growing tumor infiltrating lymphocytes in gas-permeable containers” (HHS Ref No. E-114-2011/0-PCT-02);
- VI. U.S. Patent Application No. 13/424,646 filed May 20, 2012 entitled “Methods of growing tumor infiltrating lymphocytes in gas-permeable containers” (HHS Ref No. E-114-2011/0-US-03);

**Group B**

- I. U.S. Provisional Patent Application No. 60/408,681, filed September 6, 2002 entitled “Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy” (HHS Ref No. E-275-2002/0-US-01);
- II. PCT Application No. PCT/US2012/029744 filed September 5, 2003 entitled “Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy” (HHS Ref No. E-275-2002/1-PCT-01);
- III. U.S. Patent No. 8,034,334 issued October 11, 2011 entitled “Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy” (HHS Ref No. E-275-2002/1-US-02);
- IV. European Patent Application No. 03794636.5 filed April 4, 2005 entitled “Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy” (HHS Ref No. E-275-2002/1-EP-03);
- V. Canadian Patent No. 2,497,552 issued May 27, 2014 entitled “Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy” (HHS Ref No. E-275-2002/1-CA-04);

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- VI. Australian Patent No. 2003265948 issued September 3, 2009 entitled “Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy” (HHS Ref No. E-275-2002/1-AU-05);
- VII. U.S. Patent No. 8,287,857 issued October 16, 2012 entitled “Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy” (HHS Ref No. E-275-2002/1-US-06);

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## APPENDIX B – LICENSED FIELDS OF USE AND TERRITORY

### I. **Licensed Fields of Use:**

- (a) The use of the **Licensed Patent Rights** to develop, manufacture, and sale autologous tumor infiltrating lymphocyte adoptive cell therapy products for the treatment of metastatic melanoma.

Tumor infiltrating lymphocytes (TIL) are a subset of T lymphocytes (T cells) that migrate and are located within a tumor site. TIL isolated from these tumor sites exhibit natural anti-tumor activity without genetic modifications. For the avoidance of doubt, cell therapy products involving genetically modified TIL or TIL isolated by cancer-specific mutations are excluded from the **Licensed Fields of Use**, unless the cell therapy products are a combination of TIL therapy with the **Licensee's** proprietary technologies or the **Licensee's** in-licensed technologies.

### II. **Licensed Territory:** Worldwide

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## APPENDIX C – ROYALTIES

### **Royalties:**

- I. The **Licensee** agrees to pay to the **NIH** a noncreditable, nonrefundable license issue royalty in the amount of Three Hundred and Fifty Thousand dollars (\$350,00) within sixty (60) days from the effective date of this **Agreement**.
- II. The **Licensee** agrees to pay to the **NIH** a nonrefundable minimum annual royalty in the amount of [\*\*\*] as follows:
  - (a) The first minimum annual royalty is due within sixty (60) days of the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1; and
  - (b) Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year.
  - (c) In the case of each of (a) and (b) above, such payments shall be due so long as **Licensee** has not terminated this Agreement pursuant to Paragraph 13.4.
- III. The **Licensee** agrees to pay the **NIH** earned royalties of [\*\*\*] on **Net Sales** by or on behalf of **Licensee** or its sublicensees. **Licensee** shall be entitled to a credit of [\*\*\*] against the earned royalty rate for each percent point in excess of [\*\*\*] that **Licensee** must pay to an unaffiliated licensor(s) for the manufacture and sale of **Licensed Product(s)** and **Licensed Process(es)**. Said credit however, shall not reduce the earned royalty rate due to **NIH** for **Licensed Product(s)** and **Licensed Process(es)** below [\*\*\*].
- IV. The **Licensee** agrees to pay the **NIH Benchmark** royalties within sixty (60) days of achieving each **Benchmark** by **Licensee** or its sublicensees for each **Licensed Product**:
  - (a) [\*\*\*] for successful completion of the first **Licensee**-sponsored Phase 2 clinical study.
  - (b) [\*\*\*] for successful completion of the first **Licensee**-sponsored Phase 3 clinical study.
  - (c) [\*\*\*] upon the first FDA approval or foreign equivalent for a **Licensed Product** or **Licensed Process**.
  - (d) [\*\*\*] for the First Commercial Sale of a **Licensed Product** or **Licensed Process** in the United States.
  - (e) [\*\*\*] for the First Commercial Sale of a Licensed Product or Licensed Process in any foreign country for either of Licensed Field of Use.

For purposes of this **Agreement**, “successful completion of a **Licensee**-sponsored Phase 2 Clinical Study” shall mean, with respect to a specified construct, formulation and dose of a specified **Licensed Product** in a specified cancer indication, the statistical demonstration in a pivotal Phase 2 Clinical Study of safety and efficacy, sufficient to support a Phase 3 clinical trial submission by the **Licensee** for such specified construct, formulation and dose of such specified **Licensed Product** for the treatment of such specified cancer indication.

For purposes of this **Agreement**, “successful completion of a **Licensee**-sponsored Phase 3 Clinical Study” shall mean, with respect to a specified construct, formulation and dose of a specified **Licensed Product** in a specified cancer indication, the statistical demonstration in a pivotal Phase 3 Clinical Study of safety and efficacy, sufficient to support a BLA submission by the **Licensee** for such specified construct, formulation and dose of such specified **Licensed Product** for the treatment of such specified cancer indication.

V. The **Licensee** agrees to pay the **NIH**:

(a) additional sublicensing royalties of **[\* \* \*]** on the fair market value of any consideration received for granting each sublicense within sixty (60) days of the execution of each sublicense if any such sublicense is executed prior to FDA approval or foreign equivalent for a Licensed Product or Licensed Process within each Licensed Field of Use from Appendix B; and

(b) additional sublicensing royalties of **[\* \* \*]** on the fair market value of any consideration received for granting each sublicense within sixty (60) days of the execution of each sublicense if any such sublicense is executed following FDA approval or foreign equivalent for a Licensed Product or Licensed Process within each Licensed Field of Use from Appendix B.

(c) Notwithstanding anything in this Agreement to the contrary, any such consideration will not include the following:

- (1) Bona fide support research and development activities corresponding directly to the development of **Licensed Product(s)** and/or **Licensed Process(es)**, which do not exceed Licensee's fully-burdened cost for undertaking such research and development, and limited to support which is received after the effective date of this Agreement specifically excluding any support which is used by Licensee to offset research and development expenses which are incurred prior to the effective date of this Agreement;
- (2) Proceeds derived from debt financing received after the effective date of this Agreement, to the extent that such financing is at market rates;
- (3) Consideration received after the effective date of this Agreement for the purchase of an equity interest in Licensee to the extent that the price per share paid for such equity does not exceed by more than twenty-five percent (25%) the average closing price of such equity on the stock exchange for the thirty (30) consecutive business days immediately preceding the date on which said stock is transferred, or if such equity is not so traded, then the fair market value of such equity as reasonably agreed to by the parties or as determined in the same financing round involving non-sublicensee investors;
- (4) As earned royalties on Net Sales or sales by sublicensee(s); and
- (5) Any non-monetary consideration which is specifically in the form of license(s) received in exchange for the grant of a sublicense, if such license(s) are necessary or useful for the development of Licensed Product(s) and/or Licensed Process(es).

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**APPENDIX D – BENCHMARKS AND PERFORMANCE**

The **Licensee** agrees to the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days of achieving a **Benchmark**, shall notify the **NIH** that the **Benchmark** has been achieved.

	<u>Benchmark</u>	<u>Deadline</u>
I.	[* * *]	[* * *]
II.	[* * *]	[* * *]
III.	[* * *]	[* * *]
IV.	[* * *]	[* * *]
V.	[* * *]	[* * *]

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**APPENDIX E – COMMERCIAL DEVELOPMENT PLAN**

**Licensee** intends to use the licensed technology to develop and commercialize a product based on T cells derived from tumors or tumor-infiltrating lymphocytes (TILs) to treat patients with melanoma, HPV cancers, bladder cancer, breast cancer, lung cancer, and other solid tumors.

In August 2011, **Licensee** entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) to develop and evaluate improved adoptive cell transfer (ACT) based immunotherapies using TILs to treat patients with metastatic melanoma utilizing the business development expertise and resources of **Licensee** (C-057-2011, NCI 02734). The CRADA includes the development of improved methods for the generation and selection of TIL, standard operating procedures (SOPs) for large-scale TIL growth, selection and testing to support the FDA approval of an ACT/TIL therapy approach. It further includes clinical trials designed and implemented to evaluate the clinical effectiveness of ACT/TIL therapy resulting from large-scale techniques in patients with metastatic melanoma based on the proprietary NCI Surgery Branch technology and approaches developed as part of the CRADA. In January 2015, **Licensee** and the NCI amended the CRADA to add HPV cancers (such as cervical, anal, and head and neck cancers), bladder cancer, breast cancer, and lung cancer.

The overall strategy for commercial development and program prioritization for an ACT/TIL product for the treatment of metastatic melanoma is summarized below:

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**APPENDIX F – EXAMPLE ROYALTY REPORT**

**Required royalty report information includes:**

- OTT license reference number (L-XXX-200X/0)
- Reporting period
- Catalog number and units sold of each Licensed Product (domestic and foreign)
- Gross Sales per catalog number per country
- Total Gross Sales
- Itemized deductions from Gross Sales
- Total Net Sales
- Earned Royalty Rate and associated calculations
- Gross Earned Royalty
- Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
- Net Earned Royalty due

**Example**

Catalog Number	Product Name	Country	Units Sold	Gross Sales (US\$)
1	A	US	250	62,500
1	A	UK	32	16,500
1	A	France	25	15,625
2	B	US	0	0
3	C	US	57	57,125
4	D	US	12	1,500

Total Gross Sales	153,250
Less Deductions:	
Freight	3,000
Returns	7,000
Total Net Sales	143,250
Royalty Rate	8%
Royalty Due	11,460
Less Creditable Payments	10,000
<b>Net Royalty Due</b>	<b>1,460</b>

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## APPENDIX G – ROYALTY PAYMENT OPTIONS

The OTT License Number MUST appear on payments, reports and correspondence.

### Automated Clearing House (ACH) for payments through U.S. banks only

The NIH encourages its licensees to submit electronic funds transfer payments through the Automated Clearing House (ACH). Submit your ACH payment through the U.S. Treasury web site located at: <https://www.pay.gov>. Locate the "NIH Agency Form" through the Pay.gov "Agency List".

### Electronic Funds Wire Transfers

The following account information is provided for wire payments. In order to process payment via Electronic Funds Wire Transfer sender MUST supply the following information within the transmission:

Drawn on a **U.S. bank account** via FEDWIRE should be sent directly to the following account:

Beneficiary Account:	Federal Reserve Bank of New York or TREAS NYC
Bank:	Federal Reserve Bank of New York
ABA#	021030004
Account Number:	75080031
Bank Address:	33 Liberty Street, New York, NY 10045
Payment Details:	License Number (L-XXX-XXXX) Name of the Licensee

Drawn on a **foreign bank account** should be sent directly to the following account. Payment must be sent in **U.S. Dollars (USD)** using the following instructions:

Beneficiary Account:	Federal Reserve Bank of New York/ITS or FRBNY/ITS
Bank:	Citibank N.A. (New York)
SWIFT Code:	CITIUS33
Account Number:	36838868
Bank Address:	388 Greenwich Street, New York, NY 10013
Payment Details (Line 70):	NIH 75080031 License Number (L-XXX-XXXX) Name of the Licensee
Detail of Charges (line 71a):	Charge Our

### Checks

All checks should be made payable to "NIH Patent Licensing"

Checks drawn on a **U.S. bank account** and sent by US Postal Service should be sent directly to the following address:

National Institutes of Health (NIH)  
P.O. Box 979071  
St. Louis, MO 63197-9000

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Checks drawn on a U.S. bank account and sent by **overnight or courier** should be sent to the following address:

US Bank  
Government Lockbox SL-MO-C2GL  
1005 Convention Plaza  
St. Louis, MO 63101  
Phone: 314-418-4087

Checks drawn on a **foreign bank account** should be sent directly to the following address:

National Institutes of Health (NIH)  
Office of Technology Transfer  
Royalties Administration Unit  
6011 Executive Boulevard  
Suite 325, MSC 7660  
Rockville, Maryland 20852

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**CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, Elma Hawkins, certify that:

1. I have reviewed this Annual Report on Form 10-K/A of Lion Biotechnologies, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 17, 2015

/s/ Elma Hawkins  
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Elma Hawkins  
Chief Executive Officer  
(Principal Executive Officer)

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**CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, Michael Handelman, certify that:

1. I have reviewed this Annual Report on Form 10-K/A of Lion Biotechnologies, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 17, 2015

/s/ Michael Handelman  
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Michael Handelman  
Chief Financial Officer  
(Principal Financial Officer)

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