

Prelude
THERAPEUTICS

(New)

STAR Campus II
550 S. College Avenue, Suite 110
Newark, DE 19713

December 23, 2016

Br. 2

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Mr. Blake Welling
Chief, CIRDA
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

07-35398-01
03039018
03620

REC'D 12/28/16 PM 07:00

Subject: Expedited Action Requested
Application for Material License
Prelude Therapeutics Incorporated
Newark, Delaware

Dear Mr. Welling:

Enclosed please find the Materials License application for the Prelude Therapeutics Incorporated (Prelude) facility in Newark, Delaware.

We have enclosed the completed NRC Form 313 as well as the required supporting documentation and license fee as instructed by Ms. Kelly Riner of the NRC Accounts Receivable Branch.

Prelude is a startup company focused on developing new drugs for cancer targeting novel mechanisms. We raised limited seed capital in August of 2016 to establish our laboratories and hire key scientists. We have successfully done both and are ready to test the compounds we created. To evaluate our molecules, we need the capability to utilize 3H-based enzyme assay in our laboratory. Results from this assay will form the basis for the value creation at Prelude and will allow us to generate additional funds needed to support our company. Acquiring the capability to use radioisotopes in our laboratory in an expeditious manner is a business-critical need.

Should you have any questions regarding this application or should there be anything we can do to speed this process, please contact our consultant Ms. Jessica Leonard of IES Engineers at jleonard@iesengineers.com or me.

Thank you in advance for assistance with this application.

Sincerely,

Kris Vaddi, DVM, Ph.D.
CEO & Founder

cc: M. Wang, Prelude
J. Leonard, IES

592649

NMSS/RGN1 MATERIALS-002

NRC FORM 313 (06-2016) 10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 06/30/2019 Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to infocollections.Resource@nrc.gov , and to the Desk Officer, Office of Information and Regulatory Affairs, NE08-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.
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INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: MATERIALS SAFETY LICENSING BRANCH DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001 ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS: IF YOU ARE LOCATED IN: ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO: LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 2100 RENAISSANCE BOULEVARD, SUITE 100 KING OF PRUSSIA, PA 19406-2713	IF YOU ARE LOCATED IN: ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO: MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 Lisle, IL 60532-4352 ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO: NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 1600 E. LAMAR BOULEVARD ARLINGTON, TX 76011-4511
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PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item) <input checked="" type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____ <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____	2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code) Min Wang, Ph.D. Prelude Therapeutic Incorporated 550 S. College Ave, Suite 110 Newark, DE 19713								
3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED Prelude Therapeutics 550 S. College Ave., Suite 120 Newark, DE 19713	4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION Min Wing, Ph.D. <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%;">BUSINESS TELEPHONE NUMBER</td> <td style="width:50%;">BUSINESS CELLULAR TELEPHONE NUMBER</td> </tr> <tr> <td style="text-align: center;">3022733364</td> <td style="text-align: center;">5614102029</td> </tr> <tr> <td colspan="2">BUSINESS EMAIL ADDRESS</td> </tr> <tr> <td colspan="2" style="text-align: center;">mwang@preludetx.com</td> </tr> </table>	BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER	3022733364	5614102029	BUSINESS EMAIL ADDRESS		mwang@preludetx.com	
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mwang@preludetx.com									

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.	7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.
10. RADIATION SAFETY PROGRAM.	9. FACILITIES AND EQUIPMENT.
12. LICENSE FEES (Fees required only for new applications, with few exceptions*) (See 10 CFR 170 and Section 170.31) *Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.	11. WASTE MANAGEMENT.

	FEE CATEGORY	3M	AMOUNT ENCLOSED \$	4,800
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13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE Kris Vaddh, CEO	SIGNATURE 	DATE 12-23-16
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FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

NRC Form 313 (06/2016)
Application for Materials License
Prelude Therapeutics

ITEM 1

THIS IS AN APPLICATION FOR

A. New License

ITEM 2

NAME AND ADDRESS OF APPLICANT (INCLUDE ZIP CODE)

Prelude Therapeutics Incorporated
550 South College Ave, Suite 110
Newark, DE 19713

ITEM 3

ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

550 South College Ave, Suite 110
Newark, DE 19713

ITEM 4

NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Min Wang, Ph.D.

BUSINESS TELEPHONE NUMBER

302-273-3364

BUSINESS CELLULAR TELEPHONE NUMBER

561-410-2029

BUSINESS EMAIL ADDRESS

mwang@preludetx.com

ITEM 5

RADIOACTIVE MATERIAL

a. Element and Mass Number	b. Chemical and/or physical form	c. Maximum amount to be possessed at any one time
Hydrogen 3	Non-volatile	50 mCi

Financial Assurance is not required because the applicable quantity is 20 times less than that stated in Appendix B 10 CFR Part 30.

ITEM 6

PURPOSE(S) FOR WHICH LICENSE MATERIAL WILL BE USED

Prelude Therapeutics (Prelude) is a startup company focused on developing new drugs for cancer targeting novel mechanisms. Radioactive materials will be used for research and development as defined in Section 30.4 of 10 CFR Part 30¹, as incorporated into Pennsylvania Code, and in accordance with the amounts, forms, and purposes described above. At this time live animal studies are not planned.

¹Research and development means: (1) Theoretical analysis, exploration, or experimentation; or (2) the

extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. "Research and development" as used in this part and parts 31 through 35 does not include the internal or external administration of byproduct material, or the radiation therefrom, to human beings.

ITEM 7
INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR
TRAINING EXPERIENCE

Radiation Safety Officer

Dr. Min Wang

Dr. Wang has been appointed Radiation Safety Officer (RSO) and is responsible for ensuring the safe use of radiation as described in Appendix I of "Consolidated Guidance About Materials Licenses Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope" (NUREG-SR1556, Vol. 7).

Dr. Wang has 10 years of experience performing biochemical experiments involving radioactive isotopes. He was trained and authorized to do radiological research at the University of New Mexico, the Scripps Research Institute, and the University of Massachusetts, Medical School.

Dr. Wang's training and experience are included in Attachment A.

ITEM 8
TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Individuals whose assigned duties involve exposure to radiation and/or radioactive material and in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1mSv (100 mrem) will receive instruction commensurate with their duties and responsibilities as required by 10 CFR 19.12 as incorporated into PA Code. In addition to training at the time of initial assignment, these individuals will also receive annual refresher training from the RSO or a qualified consultant.

Other individuals, such as ancillary staff, will receive instruction commensurate with their duties and responsibilities to insure compliance with applicable regulations and license conditions.

Training may be in the form of a lecture, demonstrations, and/or videotapes, and will emphasize practical subjects important to the safe use of licensed material.

Topics to be covered may include:

A. The Radiation Safety Officer, Authorized Users and Supervised Users

- B. Ordering, receiving, transfer and storage of radioisotopes
- C. Designated Areas
- D. Applicable regulations and license conditions
- E. Potential hazards associated with radioactive material in each work area
- F. Appropriate radiation safety procedures and proper personal protective equipment
- G. Licensee's in-house work rules
- H. Each individual's obligation to report unsafe conditions to the RSO
- I. Appropriate response to spills, emergencies or other unsafe conditions
- J. Worker's right to be informed of occupational radiation exposure and bioassay results, if applicable.
- K. Locations where the licensee has posted or made available: notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions.
- L. Waste disposal procedures
- M. Other topics as applicable

ITEM 9
FACILITIES AND EQUIPMENT

A. Facilities

The Prelude facility is a portion of a multi-tenant structure. At the Prelude address it is single story. The facility consists of modern labs with durable, easily cleaned floors and work surfaces, and proper ventilation. The standard assortment of incubators, centrifuges, and freezers used in a modern laboratory are also available. Prelude will limit the use of radioactive materials to licensed areas. (See Attachment C² for a copy of the facility floor plan with requested RAM use areas designated by cross hatching and dots.)

The facility requires key card access to enter and guests are escorted. This makes it easy to limit accessibility. Licensed material will be received, used, and stored only within the approved areas. In addition, although licensed materials will be secure through the above facility access requirements, stored licensed material may be secured by additional means (for example a lock box, in a locked cabinet, or in a locked freezer) when authorized personnel are not present.

² For security reasons, Prelude requests that the floor plan in Attachment C not be made available to the public, but rather treated as privileged and confidential.

B. Equipment

The following radiation detection equipment (or equivalent) will be available:

- A MicroBeta 2 Microplate Counter by Perkin Elmer

Prelude will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG – 1556, Vol. 7, “Program-Specific Guidance About Academic, Research and Development, and Other Laboratory Licenses of Limited Scope,” dated December 1999. Prelude reserves the right to upgrade survey instruments as necessary.

ITEM 10 RADIATION SAFETY PROGRAM

A. Program Commitment

Prelude will implement a radiation protection program commensurate with the scope and extent of our licensed activities and sufficient to ensure compliance with applicable NRC regulations. In accordance with 10 CFR Part 20.1101, Prelude will review this radiation protection program content and its implementation annually.

B. ALARA Commitment

Prelude will use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

C. Material Receipt and Accountability

1. Procedures for Ordering and Receiving Radioactive Material

The RSO or his/her designee will approve or place all orders for radioactive material to ensure that the requested materials, quantities, and manufacturer/client are authorized by the Material License and that the Prelude possession limits are not exceeded.

Receipt of licensed materials will take place only at the specified company loading dock, which is part of the restricted laboratory area. The RSO or his designee will be notified of the arrival of a radioactive package. Radioactive material deliveries will not be accepted after hours. Storage will take place in authorized areas only and may be in lockable boxes, freezers, etc. Use of licensed materials will take place only in Authorized areas as described in Item 9, Facilities and Equipment.

Packages will be opened in accordance with 10 CFR 20.1906. Prelude will implement procedures for the safe opening of packages containing licensed material similar to those outlined in Appendix N to NUREG – 1556, Vol. 7, “Program-Specific Guidance About Academic, Research and Development, and Other Laboratory Licenses of Limited Scope,” dated December 1999.

2. Radioactive Material Inventory

Prelude will maintain an inventory of RAM onsite in the form of an excel workbook with areas for entry of receipt and disposal of all isotopes and a feature that provides an ongoing tally of the quantity of each isotope onsite. (Prelude reserves the right to revise this inventory plan should a better, regulatory compliant, alternative present itself.) The inventory will be updated regularly (at a frequency not to exceed 6 months) to allow determination of the total activity on hand and ensure license limits are not exceeded. RAM use and Decay in Storage records will be separate from this inventory and maintained in the lab or by the RSO.

E. Records of the Radiation Protection Program

The Radiation Safety Officer will maintain the records of the Radiation Protection Program as required by 10 CFR 20 subpart L and also any records as required by 10 CFR 19 and 30.

F. Radioactive Spills and Emergencies

Prelude will implement procedures for safe use of radioactive materials, including security of materials and emergencies similar to those outlined in Appendix P to NUREG – 1556, Vol. 7, “Program-Specific Guidance About Academic, Research and Development, and Other Laboratory Licenses of Limited Scope,” dated December 1999.

Prelude reserves the right to modify these procedures if: 1) the changes are reviewed and approved by the RSO in writing; 2) affected Prelude staff is provided training in the revised procedures prior to implementation; 3) the changes are in compliance with the NRC regulations and the Prelude license; and 4) the changes do not degrade the effectiveness of the program.

G. Survey Program

Prelude will establish a survey program as follows:

- 1) All areas where radioactive material is used or stored will be surveyed pursuant to 10 CFR 20.1501.
- 2) When radioactive material is in use onsite, the RSO or his/her designee will survey all areas where radioactive material is used or stored at least monthly.

- 3) If radioactive material use is suspended for a length of time greater than a month and the previous month survey shows no "hot spots" monthly surveys will be suspended until radioactive material use begins again.
- 4) The trigger/action levels for decontamination will be the same as those outlined in Table Q.2 in Appendix Q to NUREG 1556 Vol. 7. Levels exceeding the trigger levels will be decontaminated. The RSO will be notified if decontamination fails to reduce the levels below the trigger levels.
- 5) Individual users will be encouraged to survey themselves, their lab coats and the facilities they were using whenever they finish a procedure using any level of radioactivity. Records of these surveys are not required.

ITEM 11
WASTE MANAGEMENT

Personnel will be instructed to segregate waste, as necessary, at the time it is generated and to place it into appropriately labeled containers. Personnel will be reminded that non-radioactive waste such as leftover reagents, boxes, and packaging material should not be mixed with radioactive waste. Waste will be appropriately shielded.

Lab procedures will be reviewed periodically to ensure radioactive waste is not created unnecessarily. All new procedures will be reviewed to ensure that waste is handled in a manner consistent with established procedures.

Prelude may perform waste Decay-in-Storage onsite for isotopes with half-lives less than 120 days in accordance with NRC regulations and NUREG 1556 Vol. 7.

Prelude may perform disposal of liquids into sanitary sewerage in accordance with NRC regulations and the procedures published in Appendix T to NUREG 1556-Volume 7.

Solid radioactive waste will be transferred to an authorized recipient in accordance with 10 CFR 20.2006.

ITEM 12
LICENSE FEES

FEE CATEGORY: 3M

AMOUNT ENCLOSED: \$4,800*

Certification of Small Entity Status form provided in Attachment C.

NRC Form 313 (06/2016)
Application for Materials License
Prelude Therapeutics

ATTACHMENT A

RSO EXPERIENCE

MIN WANG, Ph.D.

Email: mwang@preludetx.com edu Tel: 561-410-2029

Education:

[REDACTED] Ph.D. in Chemistry, University of New Mexico, Albuquerque, NM, US
[REDACTED] M.S. degree in Physical Chemistry, Sichuan University, China
[REDACTED] B.S. degree in Chemistry, Sichuan University, China

Work with Radionuclides

1. University of New Mexico 2006-2011
2. The Scripps Research Institute 2012-2014
3. University of Massachusetts, Medical School, 2014-2016

Radiation Safety Training Course

2006 and 2010 in University of New Mexico, Albuquerque, NM;
2012 in The Scripps Research Institute, Jupiter, FL;
2014 in University of Massachusetts, Medical School, Worcester, MA;

Training Pertinent to Radiation Safety

Type of Training Lecture/	Where Trained	Duration of Training Clocked Hours
Radiation Physics	#'s 1, 2 and 3 above	6 hrs/over 30 hrs
Radiation Protection	#'s 1, 2 and 3 above	6 hrs/over 30 hrs
Radioactivity Measurement	#'s 1, 2 and 3 above	6 hrs/over 30 hrs
Radiation Biology	#'s 1 2 and 3 above	6 hrs/over 30 hrs
Radiopharmaceutical Chemistry	#'s 1, 2 and 3 above	6 hrs/over 30 hrs

Experience with Radiation

Isotope	mCi used at one time	Location	Clock Hours	Type
¹⁴ C	0.005	# 1 above	over 100	Enzymatic assay

14C	0.001	# 2 above	over 500	Enzymatic assay
14C	0.004	# 3 above	over 500	Enzymatic assay

Research Experience

2014-2016 Postdoc\Dept. of Biochemistry & Molecular Pharmacology, University of Massachusetts, Medical School, Worcester, MA.

2012-2014 Research Associate\Dept. of Chemistry, the Scripps Research Institute, Jupiter, FL
: Advisor: Dr. Paul R Thompson

Enzyme structure-function analysis, catalytic mechanism study and inhibitor development

- Clone and purified wild type and mutants of human PRMT5 and PRMT5-MEP50 complex from sf9 cell. Designed an optimized insect cell expression protocol lead to significant increase in protein yield and purity.
- Developed enzymatic assay, *in vitro* inhibition assay and covalent inhibitor inactivation assay by using ¹⁴C-labeled AdoMet.
- Assigned the kinetic mechanism of PRMT5 by determination of the product inhibition and dead-end inhibition pattern using ¹⁴C-labeled AdoMet gel based assay, lead a publication on Biochemistry.
- Pioneer work on the substrate processivity and interaction between PRMT5 and MEP50, identified the key residues that regulate the formation of mono- or dimethylated products, illustrate the substrate binding mechanism, identified the methylation site in histone H4 for the first time by using intact peptide mapping mass spectrometry method, lead a publication on Biochemistry.
- Investigated redox regulation of PRMT1 activity *in vivo* and *in vitro*, Identified non-catalytic cysteines, which are responsible for decreased activity of PRMT1 by combining gel-based activity assay, florescence labeling, intact peptide mapping mass spectrometry and streptavidin pull down assay. My work argued the unilateral view that the accumulation of ADMA under oxidation stress is caused by increased PRMT1 activity, a manuscript is under preparation.
- Designed and synthesized peptide substrates, probe and inhibitors for PRMT5, identified several leading peptides as novel models for PRMT5.
- Initiated PRMT1 and PRMT5 inhibitor study, identified active site cysteines in PRMT1 and PRMT5-MEP50 complex as potential covalent inhibitor targets, designed and synthesized a covalent inhibitor, result in nM inhibition as a potential anticancer drug candidate.

2006-2011 Research Associate, University of New Mexico, Albuquerque, NM

Advisor: Dr. Debra Dunaway-Mariano.

Enzyme Function Initiative (EFI) project

- Clone and purified over 100 proteins from *E. coli*., and screen the phosphatase activity for enzyme function initiative (EFI) project, distinguished several new HAD family phosphatases in *E. coli*.

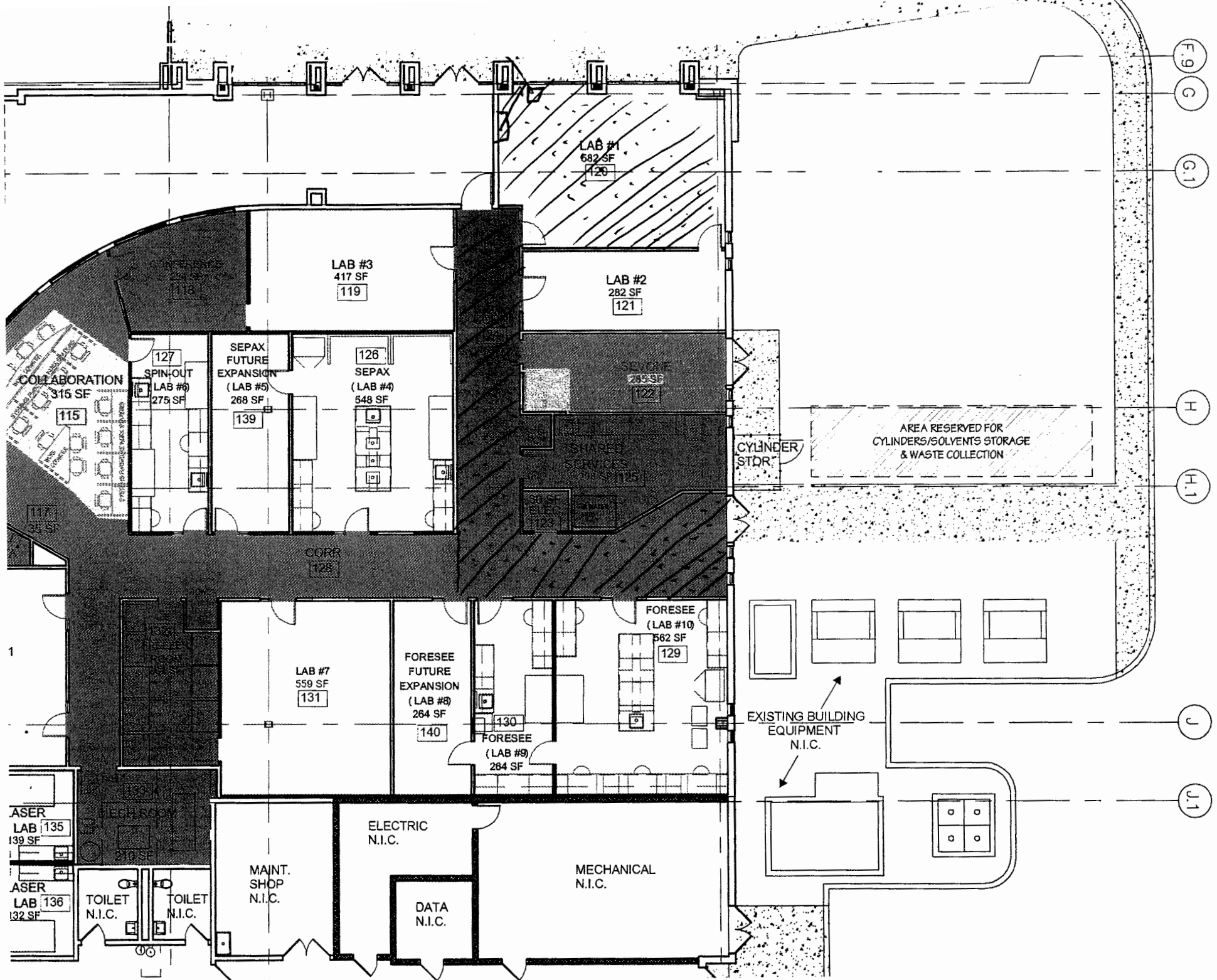
- Discovered a novel thioesterase in menaquinone biosynthetic pathway for the first time; profiled the complete menaquinone pathway in bacteria, lead a publication on FBSE Letter
- Designed and developed ^{14}C -labeled coenzyme A, UV spectrometry and HPLC based enzyme assays, allowing conveniently and precisely examining enzyme activity, kinetic parameters and enzyme inhibitor pattern and inhibition constants, lead a publication on FEBS letter.
- Designed and synthesized bunch of intermediates in menaquinone biosynthetic pathway by combing chemical and enzymatic synthesis techniques; discovered a new thioesterase in the pathway and identified functions of two neighbor genes.
- Identified three protein's function in fatty acid β -oxidation pathway in *Pseudomonas aeruginosa* and their physiological substrates.
- Participate in the NIH first glue grant on enzyme function initiative project and work on the protein purification, activity screen and characterization of HAD phosphatase functions from *E. coli*. Clone and purified over hundred putative HAD phosphatases, screened their phosphatase activity and determined their steady state kinetic data by using PNPP, EnzChek phosphatase assay, and discontinuous Malachite green assay, lead to a publication on PNAS

Selected Publications

- 1) **Min Wang**, Heather Rust, Jacob Fuhrmann, Paul Thompson, Protein Arginine Methyltransferase 1 Activity is Redox Regulated, manuscript in preparation;
- 2) Hao C. Nguyen, **Min Wang**, Andrew Salsburga, Bryan Knuckley, Development of a plate-based screening assay to investigate the substrate specificity of the PRMT family of enzymes, (2015) *ACS Combinatorial Science*, 17: 500-505
- 3) Hua Huang, Chetanya Pandya, Chunliang Liu, Nawar Al-Obaidi, **Min Wang**, Li Zheng, Sarah Teows Keating, Miyuki Aono, James Love, Brandon Evans, Ronald Seidel, Brandan S Hillerich, Scott J Garforth, Steven C Almo, Patrick S. Mariano, Debra Dunaway-Mariano, Karen N. Allen, Jeremiah D. Farelli, Panoramic view of a superfamily of phosphatases through sbustrate profiling, (2015) *Proc. Natl Acad. Sci. USA*, 112: E1974-E1983
- 4) **Min Wang**, Jakob Fulman, Paul R Thompson, PRMT5 Catalyzes Substrate Dimethylation in a distributive fashion, (2014) *Biochemistry*. 53 (50): 7884-7892
- 5) **Min Wang**, Rui-Ming Xu, and Paul R. Thompson, Substrate specificity, processivity, and kinetic mechanism of protein arginine methyltransferase 5 (2013) *Biochemistry*. 52(32): 5430-5440.
- 6) **Min Wang**, Feng Song, Rui Wu, Karen N. Allen, Patrick S. Mariano, Debra Dunaway-Mariano, Co-evolution of HAD phosphatase and hotdog-fold thioesterase domain function in the menaquinone-pathway fusion proteins BF1314 and PG1653 (2013) *FEBS Lett*. 587 (17): 2851-2859.

NRC Form 313 (06/2016)
Application for Materials License
Prelude Therapeutics

ATTACHMENT B
FACILITY DIAGRAM





ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Kris Vaddi, DVM, Ph.D.
CEO & Founder
Prelude Therapeutic Incorporated
550 S. College Avenue, Suite 110
Newark, DE 19713

Date

December 28, 2016

License Number(s)

07-35398-01

Mail Control Number(s)

592649

Licensing and/or Technical Reviewer or Branch

Commercial, Industrial, R&D, and Academic Branch

This is to acknowledge receipt of your: ☒ Letter and/or ☒ Application Dated: 12/23/2016

The initial processing, which included an administrative review, has been performed.

☐ Amendment ☐ Termination ☒ New License ☐ Renewal

☒ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
Follow the instructions on the form for submission.

☐ The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, (610) 337-5239