



FOCUSED ON:

2 CLINICAL ONCOLOGY CANDIDATES

2023 ANNUAL REPORT



FOCUSED ON:

EFFORTS TO DELIVER BENEFITS TO PATIENTS

2023 ANNUAL REPORT

FOCUSED ON:

DATA DRIVEN DECISIONS

FOCUSED ON:

CREATING VALUE

FOCUSED ON:

OUR LEADERSHIP



"It's rewarding to have the opportunity to lead the company as we advance novel therapies that can benefit patients with cancer. We are now just months away from reporting first in human data combining voruciclib, our CDK9 inhibitor, with Venclexta® and ME-344, our mitochondrial inhibitor, combined with Avastin®."

David M. Urso, JD
President and CEO

DEAR SHAREHOLDERS

What is most rewarding about working in the biopharmaceutical industry is the opportunity to develop therapies that can benefit patients. Our business at MEI Pharma is to develop cancer therapies that address meaningful unmet medical needs, that if successful, would present valuable commercial opportunities and in turn create significant value for our stockholders.

I assumed the role of MEI's President and CEO in June 2023, inspired to lead the Company's two clinical stage oncology drug development programs, voruciclib and ME-344. At the time, a proposed acquisition of Infinity Pharmaceuticals was pending to augment the pipeline with a later-stage clinical asset in an area of significant company expertise. While we believed the potential upside of the Infinity merger was compelling for stockholders, the transaction, ultimately, was not approved by a narrow margin. We value the views of our stockholders, and since the termination of the merger we've turned our focus fully toward advancing our two promising clinical-stage programs - which are both now a year more advanced - as a standalone company.

We expect to report clinical data during the first half of 2024 that will help inform the potential of each program to benefit patients and to create value for our stockholders. We are just months away from reporting the first human data for voruciclib, a CDK9 inhibitor, combined with Venclexta® (venetoclax) in patients with relapsed/refractory AML, and for ME-344, a mitochondrial inhibitor, combined with Avastin® (bevacizumab) in patients with previously treated metastatic colorectal cancer. We expect to report data from the dose escalation portion of the Phase 1 clinical trial evaluating voruciclib plus Venclexta in early calendar 2024, and data from Cohort 1 of the Phase 1b clinical trial evaluating ME-344 plus Avastin in the first half of 2024.

The programs represent differentiated and novel drug combinations with the potential to overcome resistance mechanisms to two standard-of-care therapies: the BCL2 inhibitor Venclexta in the case of voruciclib and the VEGF inhibitor Avastin in the case of ME-344. We chose these combination approaches based on strong scientific hypotheses to address known resistance mechanisms of each standard-of-care therapy, clear medical need and the consequent significant commercial opportunities associated with each program.

HIGHLIGHTS

Clinical data from the Phase 1 clinical trial evaluating voruciclib plus Venclexta® is expected in early CY2024.

Clinical data from the Phase 1b clinical trial evaluating ME-344 plus Avastin® is expected in the first half of CY2024.

Our excitement about these programs is reinforced by promising nonclinical and clinical data, including early data from our ongoing voruciclib Phase 1 study evaluating voruciclib as a single agent and in combination with Venclexta – which is a standard-of-care in acute myeloid leukemia and used in other hematologic malignancies as well. The supporting data for our other candidate, ME-344, includes results from a 42-patient, controlled window-of-opportunity clinical study evaluating the combination of ME-344 with Avastin in HER2 negative breast cancer patients in which we observed decreases in the proliferation biomarker Ki67. We are collaborating with some of the leading oncologists in the country in both of our clinical studies, and they share our enthusiasm for these programs.

Looking ahead, the opportunities for each program are potentially significant. Venclexta use across acute myeloid leukemia, chronic lymphocytic leukemia and double-hit diffuse large B-cell lymphoma generated approximately \$2.0 billion in 2022 worldwide sales. Venclexta sales are continuing to grow and are expected to generate \$3.4 billion in revenue by 2028. Avastin and bevacizumab biosimilars are used to treat a variety of cancers, including colorectal cancer and ovarian cancer. Worldwide in 2022, Avastin and bevacizumab biosimilars sales reached \$2.0 billion and are expected to grow to \$3.3 billion by 2028.

With the progression of our development pipeline, and capital to support our near-term development plans, we believe that MEI is well-positioned to continue pursuing improved therapeutic options to cancer patients and create value for our stockholders.

In closing, I want to thank our employees for their hard work and dedication. It is their expertise and commitment to science that enable us to move forward with the important work we do every day to improve outcomes for patients.

Thank you for your investment in MEI and your continued support.

Sincerely,

David Urso
President and CEO



FOCUSED ON:
EXPERTISE

MANAGEMENT



David M. Urso, JD
President And CEO

Mr. Urso was appointed President and Chief Executive Officer in June 2023, at which time he was also appointed to the MEI board. He joined MEI Pharma in April 2014 with nearly two decades of experience in the life science industry as a senior vice president and general counsel. In July 2018, he was appointed MEI's chief operating officer. Previously, he was chief operating officer and general counsel at Tioga Pharmaceuticals, a privately held drug development company he co-founded in 2005 as a principal at Forward Ventures, where he was responsible for identifying and developing life science venture capital investments. Before joining Forward Ventures in 2002, David was director of corporate development and legal affairs at DNA Sciences. Previously, he worked as an attorney in the corporate securities and licensing groups at Wilson Sonsini Goodrich & Rosati LLP and Cooley Godward LLP, after beginning his career as a bench scientist at SmithKline Beecham and the University of Pennsylvania Medical School. Mr. Urso received a J.D. from Harvard Law School and a bachelor's degree in Molecular Biology and Philosophy from Reed College.

Justin (Jay) File
Chief Financial Officer

Mr. File was appointed Chief Financial Officer in August 2023 with 30 years of experience in accounting and finance, working in both public and private companies. He has a diverse range of experience, having worked in various industries, including the life sciences industry for the past 16 years. From 2015 to 2023, Mr. File was the Chief Financial Officer of Evofem Biosciences, Inc., a women's health company that developed and commercialized Phexxi®, a nonhormonal contraceptive for women. While at Evofem he helped bring the company public through a reverse merger and was responsible for overseeing corporate finance and accounting, information technology and investor relations. Previously, Mr. File provided executive financial and accounting oversight consulting services to biotechnology companies, and before that led accounting operations and reporting at Sequenom, Inc., a molecular diagnostic company. He additionally served as Treasurer of Sequenom's diagnostic subsidiary. Before joining industry, Mr. File worked for approximately ten years in public accounting, primarily with Arthur Andersen LLP. Mr. File graduated from Central Washington University with a Bachelor of Science in Accounting and Business Administration. He is a Certified Public Accountant (inactive).

Anne Frese

Chief People Officer

Ms. Frese joined MEI Pharma as Chief People Officer in June 2022. She has over 30 years of experience from a variety of industries including biotech, consulting, hospitality and engineering. Throughout her career, she has been a builder of organizations and talent, matching people and culture to ensure innovation and growth. Previously, Ms. Frese served as Chief Human Resources Officer at Vyripharm Enterprises and Vice President of Human Resources at both Artiva Therapeutics and Bellicum Pharmaceuticals, Inc. She received a bachelor's degree in Labor Relations and Economics from the McGill University.

Richard Ghalie, MD

Chief Medical Officer

Dr. Ghalie was appointed Chief Medical Officer as of May 3, 2021. He joined MEI as Senior Vice President, Clinical Development in March 2016. He is a hematologist and oncologist with more than 25 years of drug development experience at public and private companies. Dr. Ghalie has held several executive positions in the pharmaceutical industry, including serving as Chief Medical Officer at Denovo BioPharma, HemaQuest Pharmaceuticals, Novalar Pharmaceuticals and Favrilite, and previously as Vice President at Ligand Pharmaceuticals and NeoRx. He was the medical lead of teams that successfully filed NDAs and MAAs resulting in the approval of four new indications. Previously, he served as Medical Director of the Bone Marrow Transplant Center of Rush University Medical Center. Dr. Ghalie holds a medical degree from the French School of Medicine in Lebanon, a MS from the University Paris XI and a MBA from the University of Washington in Seattle. He has authored or co-authored more than 125 manuscripts, book chapters and scientific publications.

Yomara Gomez-Naiden

Senior Vice President, Operations And Quality

Ms. Gomez-Naiden joined MEI Pharma as Senior Vice President, Quality in January 2022. She has over 25 years of experience in both biotechnology and pharmaceutical industries, and her expertise spans in quality assurance operations, quality systems, integrations, regulatory compliance, and quality management. She has also contributed to the successful approval of drugs and biologics in multiple therapeutic areas. Previously, Ms. Gomez-Naiden served as Vice President of Corporate Quality at AGC Biologics where she led the establishment of the company's first Global Quality Management System and Corporate Quality Program. Prior to that, Ms. Gomez-Naiden held positions of increasing responsibilities at Acerta Pharma, GE Life Sciences, Merck, Schering-Plough, PF Laboratories, and Warner Lambert (now Pfizer). She received a bachelor's degree in Chemistry from the University of Puerto Rico and an MBA in Pharmaceutical Chemistry from Fairleigh Dickinson University.

Nicole Chyoko Iida

Vice President, Legal Affairs

Ms. Iida joined MEI Pharma as Associate General Counsel, Contracts and Operations in October 2018. She has over 20 years of in-house experience in the pharmaceutical industry. Most recently, she was head of a large contracts group at ACADIA Pharmaceuticals which supported the contract needs of the entire company, which included commercial, clin ops, medical affairs and CMC. Prior to that, Ms. Iida spent over a decade at Arena Pharmaceuticals, holding positions of increasing responsibilities, including lead counsel supporting several clinical studies. She began her career as a patent attorney in a small IP boutique firm in San Diego. Ms. Iida received a Juris Doctor and Masters in Intellectual Property from the University of New Hampshire Franklin Pierce School of Law and a bachelor's degree in Biomedical Engineering from the University of Southern California. She is admitted to practice in the State Bar of California and the Hawaii State Bar Association (inactive), and is registered to practice before the United States Patent and Trademark Office.

Eugene Park

Vice President, Marketing

Mr. Park joined MEI Pharma in July 2021 with over 14 years of commercial experience in oncology within the biopharma industry, most recently as Vice President, Marketing at Coherus BioSciences. He has spent the last several years serving as the head of marketing for several small biotechnology companies, including Immunomedics and Halozyme Therapeutics, where he led efforts to build out the marketing organization and capabilities in preparation for the commercial launch of novel oncology therapeutics. Previously, Mr. Park spent 10 years in big pharma, moving through various sales and marketing roles and leading multiple US launches at Pfizer Oncology and Novartis Oncology. His experience spans a broad range of tumor types and includes building brands for small molecule, biologic, and biosimilar assets. Mr. Park holds a BS in Biology from the Massachusetts Institute of Technology and an MBA from Columbia Business School.

Caroline Ruiz

Vice President, Clinical Operations

Ms. Ruiz was appointed Vice President, Clinical Operations in January 2022. She joined MEI as Executive Director of Clinical Operations in July 2020. She has over 20 years of experience in drug development across multiple indications, including oncology, the central nervous system, and immunology. She has held various senior positions in Clinical Management and Clinical Operations, managing regional business units, large portfolios (40+ studies), and global teams. Previously, she was Senior Director, Neurodegenerative Disease Portfolio Head, at IQVIA. She received a bachelor's degree in Biology from University of California, San Diego.

Jason Sausser

Vice President, Information Technology

Mr. Sausser joined MEI Pharma as Vice President, Information Technology in March 2022. He brings over 25 years of information technology experience in a variety of Life Sciences and Health Care industries. Mr. Sausser previously held positions as Head of IT for Omniome, Inc. supporting R&D and business efforts to develop new sequencing technologies and Sequenom, Inc. (now LabCorp) supporting Sequencing research and laboratory operations. He is an Adjunct Faculty member at Point Loma Nazarene University in the Computer and Mathematics Department. Mr. Sausser received a B.S. degree in Business from the University of Redlands and a M.S. in Information Systems from San Diego State University.

David A. Walsey, J.D., LL.M

Senior Vice President, Corporate Affairs

Mr. Walsey joined MEI Pharma as Vice President of Investor Relations and Corporate Communications in February 2018. He was appointed Senior Vice President, Corporate Affairs in May 2021. Mr. Walsey has over 20 years of experience leading communications initiatives for public biotech companies. He has led investor relations and corporate communications programs at Alder Biopharmaceuticals, Optimer Pharmaceuticals, Sarepta Therapeutics (f/k/a AVI BioPharma), Arena Pharmaceuticals and Maxim Pharmaceuticals. He also has agency experience developing communications strategy and programs for biotechnology clients, having held senior positions at W20, Ruth Group and Noonan Russo. He began his career as an attorney in private practice in New York City. Mr. Walsey holds an LL.M. in Taxation from the New York University School of Law, a J.D. from Brooklyn Law School, and a B.A. from Franklin and Marshall College.

Charles V. Baltic III, JD

Non-Executive Chair

Mr. Baltic has served as a Director of MEI Pharma since October 2011. He served as Chair of the Nominating and Governance Committee from 2012 until he was appointed Chair of the Board in January 2023. Mr. Baltic also serves as a Director and Chairman of the Board of AssayQuant Technologies, Inc., a private, commercial-stage company focused on kinase-based assay technology licensed from the Massachusetts Institute of Technology. Mr. Baltic was affiliated with Needham & Company, LLC as Managing Director and Co-Head of Healthcare Banking from 2009 - 2019 and as Senior Advisor from 2019 - 2022. Mr. Baltic served as acting CEO of Amyndas Pharmaceuticals, a private biotechnology company focused on immunology and innate immunity complement therapeutics based on technology licensed from the University of Pennsylvania from March 2021 to October 2021. Mr. Baltic served as Executive Vice President and COO of SIDIS Corp. from 2019 - 2021, overseeing the sale of the Propel Labs flow cytometry business to Thermo Fisher Scientific in February 2021. Mr. Baltic was a Managing Director and head of the biotechnology practice at CRT Capital Group from 2006 - 2008. From 2001 - 2006, he served as a Managing Director in Healthcare Investment Banking at Wachovia Securities. Prior to Wachovia, he was with Healthcare Investment Banking at Cowen from 1996 - 2001. Prior to his investment banking career in 1996, Mr. Baltic practiced corporate and securities law with the firm of Dewy Ballantine. Mr. Baltic previously served as a Director of SIDIS Corp. from 2015 - 2019. Mr. Baltic served as a Director of the trade association Life Science Washington from 2013 - 2018. He served as a Director of MedVantage Inc., a private health informatics company acquired by IMS Health (now IQVIA Holdings) in 2011. Mr. Baltic served on the U.S. Securities and Exchange Commission's Advisory Committee on Small and Emerging Growth Companies from 2013 - 2015. He served as a founding Trustee of Hope Funds for Cancer Research from 2007 - 2017. Mr. Baltic earned B.A. (honors) and J.D. degrees from Georgetown University and a M.B.A. degree in finance from the Wharton School of the University of Pennsylvania.

Taheer Dattoo

Non-Executive Director

Mr. Dattoo has been a director since October 2023. He has served in various roles of increasing seniority at Anson Funds, a hedge fund with a global investment portfolio, since 2016, including most recently as Principal and Portfolio Manager since January 2023, as well as Portfolio Manager from January 2019 to December 2022 and as an Analyst, from 2016 to December 2019. While employed at Anson Funds, Mr. Dattoo has primarily focused on North American small-cap equities, special situations and thematic investing. Prior to joining Anson, Mr. Dattoo served as an investment banker for BMO Capital Markets, the capital markets subsidiary of Bank of Montreal (NYSE/TSX: BMO), an international financial services company, from 2013 to 2015. Mr. Dattoo earned a B.A. in economics and finance from McGill University. We believe that Mr. Dattoo's extensive experience identifying, funding and engaging in business development activities qualifies him to serve on the Board.

Frederick W. Driscoll

Non-Executive Director

Mr. Driscoll was appointed as a director in February 2018. He currently serves on the board of directors of Cue Biopharma, Collettar Biosciences, Inc. and NantKwest, Inc. and SmartPharm Therapeutics. He served as the chief financial officer of Flexion Therapeutics, Inc. from 2013 to 2017. Prior to joining Flexion, he was the chief financial officer at Novavax, Inc. from 2009 to 2013. From 2008 to 2009, Mr. Driscoll served as the chief executive officer at Genelabs Technologies, Inc. and from 2007 to 2008 he served as the company's chief financial officer. He was also the chief executive officer of OXiGENE, Inc. from 2000 to 2006. Mr. Driscoll also served as the chairman of the board and audit committee chair at OXiGENE and as a member of the audit committee for Cynapsus Therapeutics, Inc. Mr. Driscoll earned a bachelor's degree in accounting and finance from Bentley University.

James Flynn

Non-Executive Director

Mr. Flynn has been a director since October 2023. He is currently a Managing Member and Portfolio Manager of Nerium Capital LLC, an investment adviser he founded in 2021. Nerium Capital LLC is the General Partner of Nerium Partners LP, a healthcare focused investment partnership. Mr. Flynn also currently serves as a Board Member for Axiom Health, a provider of software and big-data solutions to the healthcare industry, since 2022, and has been an advisor to the company since 2020. From 2017 to 2018, Mr. Flynn worked as a therapeutics analyst at Aptigon Capital (a Citadel Company), an investment firm. Prior to that, from 2003 to 2017, Mr. Flynn served in various roles at Amici Capital, LLC, an investment firm, including healthcare portfolio manager (2008 to 2017). From 2002 to 2003, Mr. Flynn worked in the credit research/high yield group at Putnam Investments, an investment firm. Mr. Flynn earned a S.B. degree in Management Science with a concentration in Finance and a minor in Economic Science from the Massachusetts Institute of Technology (MIT). Mr. Flynn is a Chartered Financial Analyst (CFA) charterholder. We believe that Mr. Flynn's relevant industry expertise and extensive experience identifying, funding and engaging in business development activities qualifies him to serve on the Board.

Nick Glover, PhD

Non-Executive Director

Dr. Glover was appointed as a director in June 2013. He served as President and Chief Executive Officer of Sierra Oncology (NASDAQ: SRRA), a drug development company focused on advancing targeted therapeutics for the treatment of patients with cancer, from July 2014 through May 2020. Prior to joining Sierra, he served as President and Chief Executive Officer of YM BioSciences, an oncology drug development company, from November 2010 until its acquisition by Gilead Sciences for \$510 million in February 2013. Previously, Dr. Glover was President and Chief Executive Officer of Viventia Biotech, a biopharmaceutical company involved in the discovery and development of monoclonal antibody-based technologies for the treatment of cancer, which he joined after serving as an investment manager for MDS Capital, a life sciences venture capital firm. Dr. Glover holds a B.Sc. (Hons) in Chemistry from the University of East Anglia, U.K., a M.Sc. in Chemistry from the University of British Columbia, Canada, and a Ph.D. in Chemistry from Simon Fraser University, Canada.

Thomas C. Reynolds, MD, PhD

Non-Executive Director

Dr. Reynolds was appointed as a director in February 2013. He is President of Two Paddles Consulting LLC since December 2013, providing consulting services to biotechnology companies. Dr. Reynolds currently serves as an independent director of Trillium Therapeutics Inc. (NASDAQ: TRIL, TSX: TR), an immuno-oncology company, since March 2014. Previously, he served as Chief Medical Officer of Seattle Genetics from March 2007 until his retirement in February 2013. While at Seattle Genetics, he was responsible for building and leading an integrated clinical development, regulatory and medical affairs organization, highlighted by the development and approval of ADCETRIS®. From 2002 to 2007, Dr. Reynolds served at ZymoGenetics (acquired by Bristol-Myers Squibb in 2010), most recently as Vice President, Medical Affairs, where he oversaw the clinical development and regulatory filing of RECOTHROM®. Previously, he was Vice President, Clinical Affairs at Targeted Genetics, and before that was at Somatix Therapy (acquired by Cell Genesys in 1997). Dr. Reynolds received his M.D. and Ph.D. in Biophysics from Stanford University and a B.A. in Chemistry from Dartmouth College.

David M. Urso

President and CEO

Mr. Urso was appointed President and Chief Executive Officer in June 2023, at which time he was also appointed to the MEI board. He joined MEI Pharma in April 2014 with nearly two decades of experience in the life science industry as a senior vice president and general counsel. In July 2018, he was appointed MEI's chief operating officer. Previously, he was chief operating officer and general counsel at Tioga Pharmaceuticals, a privately held drug development company he co-founded in 2005 as a principal at Forward Ventures, where he was responsible for identifying and developing life science venture capital investments. Before joining Forward Ventures in 2002, David was director of corporate development and legal affairs at DNA Sciences. Previously, he worked as an attorney in the corporate securities and licensing groups at Wilson Sonsini Goodrich & Rosati LLP and Cooley Godward LLP, after beginning his career as a bench scientist at SmithKline Beecham and the University of Pennsylvania Medical School. Mr. Urso received a J.D. from Harvard Law School and a bachelor's degree in Molecular Biology and Philosophy from Reed College.

Steven D. Wood

Non-Executive Director

Mr. Wood, CFA, has been a director since October 2023. He is the founder and Chief Investment Officer of Greenwood Investors, LLC., an investment advisory firm established in 2010. Mr. Wood also currently serves as a Board Member of Leonardo SpA, an Italian-listed international Aerospace & Defense company, and CTT - Correios De Portugal, a publicly-listed Iberian logistics company. Prior to founding Greenwood Investors in 2010, Mr. Wood was a research analyst at Carr Securities from 2009 to 2013. Previously, Mr. Wood worked as an investment banking analyst for RBC Capital Markets in the Syndicated and Leveraged Finance group. He began his career with the special situations team at Kellogg Capital Group. Mr. Wood is a Chartered Financial Analyst charterholder. He received a triple degree, Cum Laude, from Tulane University in Economics, Political Economy and International Relations in 2005. We believe that Mr. Wood's prior experience as a Board Member and extensive experience identifying, funding and engaging in business development activities qualifies him to serve on the Board.

FOCUSED ON:
OUR PIPELINE

CLINICAL-STAGE DIVERSIFIED CLINICAL PIPELINE

INVESTIGATIONAL AGENTS	THERAPEUTIC AREA	COMBINATION	PHASE 1/1B	PHASE 2	PHASE 3
Voruciclib Oral CDK9 Inhibitor	Acute Myeloid Leukemia Relapsed/refractory (2L+)	Monotherapy VENCLEXTA® (venetoclax)	Completed Enrolling		
	HER2-Negative Breast Cancer*	AVASTIN® (Bevacizumab)	Completed		
ME-344 Mitochondrial Inhibitor	Colorectal Cancer Relapsed	AVASTIN® (Bevacizumab)	Enrolling		

*Phase 0 window of opportunity study: investigator initiated, controlled, open label.

➤ **Visit MEI's Pipeline Page to learn more:**

meipharma.com/pipeline

FOCUSED ON:

ENVIRONMENTAL, SOCIAL AND GOVERNANCE

MEI'S COMMITMENT TO ESG

THERE IS A WIDE RANGE OF APPROACHES TO ADDRESS ESG INITIATIVES.

At MEI, we have divided our ESG components into four categories:

Environmental, Health & Safety, Social Impact, Human Capital, and Governance.

We view each category as follows:

ENVIRONMENTAL, HEALTH & SAFETY

Criteria that examine how we contribute to and perform on environmental challenges and efforts to protect the health and safety of employees and the public from activities associated with our business. This includes energy use, waste, pollution, natural resource conservation, and practices to promote a safe and healthy work environment. The criteria can also be used in evaluating any environmental, health, or safety challenge we might face and how we manage related risks.

SOCIAL IMPACT

Criteria related to the relationship we have and the reputation we foster with the people and institutions in the communities where we do business. For MEI, as a pharmaceutical company focused on developing and ultimately commercializing medicines, a significant part of the Social Impact criteria relates to how we conduct clinical trials and work with patients, healthcare providers, advocates, professional organizations, and others in designing and conducting clinical trials, and potentially the commercialization of our drug candidates.

HUMAN CAPITAL

MEI recognizes that our success and the value we provide are based on the knowledge, skills, and experience employees bring to MEI. To capture the full value of the Human Capital inherent in our people, we are committed to providing the environment and the resources to support our employees properly. Essential elements of our Human Capital efforts concern workforce planning, talent acquisition, diversity, equity & inclusion, and workforce optimization the ongoing development of our workforce, we are building a sustainable organization for the future.

GOVERNANCE

The standards for running a company to manage a range of issues to help promote strong business practices include compliance, risk management, safety management, supply chain and materials sourcing, conflicts of interest, anti-competitive behavior, corruption, and bribery. At MEI, we are consistently enhancing the internal system of practices, controls, and procedures we adopt to govern the company, make effective decisions, comply with the law, and meet the needs of external stakeholders.

[See more information on the following pages](#)

MEI PHARMA'S ESG FRAMEWORK

There is a wide range of approaches to address ESG initiatives. At MEI, we have divided our ESG components into four categories: Environmental, Health & Safety, Social Impact, Human Capital, and Governance. We view each category as follows:



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ENVIRONMENTAL, HEALTH & SAFETY

ENERGY, RECYCLING, AND WASTE:

We promote and support energy-efficient practices in our offices, reduce waste, and responsibly recycle materials. Although, as lessees of our offices, we are somewhat limited in what actions we can take, our efforts include occupancy-sensor lighting and automatic temperature controls, waste-free practices to reduce single-use plastics where feasible in our offices (such as providing all employees with reusable water bottles and installing refillable water stations), purchasing ENERGY STAR certified office and IT equipment, and the collection and responsible recycling of electronic waste (e.g., batteries, laptops, computer monitors, and printers). We also strive to reduce our paper usage and recycle all paper, cardboard, and glass.

HEALTH AND SAFETY:

We are committed to providing our employees with a clean, safe, and healthy work environment. Providing HEPA filters for every employee workspace and directed our landlord to install an air purification system (at MEI's expense). Our efforts also include an Injury and Illness Prevention Program with a curriculum covering hazard identification and communication, ergonomics, injury response, emergency evacuation, and more.



SOCIAL IMPACT

EMPLOYEE VOLUNTEER INITIATIVES:

We are known as a company that supports volunteerism and giving back to our community. This includes our long-standing Volunteer Time Off (VTO) benefit.

QUALITY ASSURANCE:

Our Quality Assurance (QA) practices include a Quality Management System to ensure our products and services meet the highest standards of quality and safety for patients and Quality Training of employees, consultants, and contractors involved with Good Practice (GxP) processes, including clinical trials and manufacturing. We review our QA practices at least annually, including a review of our Quality Manual and training requirements.

SAFETY OF CLINICAL TRIALS:

We maintain robust standard operating procedures (SOPs) related to selecting research partners, monitoring clinical studies, and managing patient safety in our clinical development activities. MEI's SOPs require developing and maintaining a robust product safety governance structure, responsible for the identification, validation, assessment, quick escalation, communication, and mitigation of safety signals arising from MEI compounds under development. MEI Clinical Development Physicians and Drug Safety and Pharmacovigilance Medical Directors provide medical and safety oversight of ongoing clinical trials.



HUMAN CAPITAL

EMPLOYEE BENEFITS:

We invest in our workforce by offering competitive compensation and benefits package, including new hire and annual equity awards, designed to attract, engage, and retain employees. Recognizing the importance of work-life balance we offer remote and hybrid work models.

PROFESSIONAL DEVELOPMENT:

Our Professional Development Policy encourages career and leadership development. In addition, we offer the opportunity to attend seminars and conferences.

EMPLOYEE ENGAGEMENT:

We believe employee engagement is a continuous process that enriches the employee experience. We foster a loyal and productive workforce from recruitment through onboarding, training, and ongoing coaching and mentoring.

DIVERSITY, EQUITY, AND INCLUSION (DEI):

We are committed to cultivating a diverse, equitable, and inclusive environment where everyone feels valued and respected. Our senior leadership team is 40% female with 50% of those being from ethnically diverse cultures. Approximately 60% of MEI employees are female, with the majority identifying as non-white minorities.



GOVERNANCE

CODE OF BUSINESS CONDUCT AND ETHICS:

As indicated in our Code of Business Conduct and Ethics, we conduct business in a manner that demonstrates a commitment to the highest standards of ethics and integrity. Also review our Code of Business Conduct and Ethics, Corporate Disclosure Policy, and Insider Trading Policy with each new employee and annually with all employees.

WHISTLEBLOWER POLICY:

We encourage employees to report any wrongdoing or behavior that violates the provisions of our Code of Business Conduct and Ethics to our Audit Committee Chairperson. Reports can be made anonymously, and we do not tolerate harassment or retaliation of any kind against an employee who makes a good faith complaint.

CYBERSECURITY:

The Audit Committee of the Board has oversight of cybersecurity response and management at MEI and is updated by the Vice President of Information Technology on a semi-annual basis. Our Information Security Program is aligned with the Center for Internet Security Critical Security Controls that guide our security program. Employees receive training on our information security policy annually and on general cybersecurity quarterly. We also maintain data integrity, document management, and computer system assurance policies to uphold information integrity.



DOWNLOADS FORM 10-K AND PROXY MATERIALS

➤ To download the materials below, please visit:

investors.meipharma.com

2023 FORM 10K

2023 PROXY STATEMENT

VOTE PROXY

CONTACT:
MEI PHARMA, INC.
(858) 369-7100
INVESTOR@MEIPHARMA.COM

2023 ANNUAL REPORT

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended June 30, 2023

OR

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

For the transition period from _____ to _____.

Commission File Number: 000-50484

MEI Pharma, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of
incorporation or organization)

51-0407811
(I.R.S. Employer
Identification No.)

11455 El Camino Real, Suite 250, San Diego, CA 92130
(Address of principal executive offices) (Zip Code)

(858) 369-7100
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.0000002 par value	MEIP	The Nasdaq Stock Market LLC

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

None
(Title of Class)

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

Indicate by a 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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240,10D-1(b).

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 voting and non-voting common equity held by non-affiliates, based on the closing price per share of Registrant’s Common Stock on the Nasdaq Capital Market was approximately \$31.8 million as of December 31, 2022.

As of September 15, 2023, there were 6,662,857 shares of the registrant’s common stock, par value \$0.00000002 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Part III of this Annual Report on Form 10-K is incorporated by reference from the registrant’s definitive proxy statement for the annual meeting of stockholders to be held in December 2023, which will be filed with the Securities and Exchange Commission within 120 days after the close of the registrant’s fiscal year ended June 30, 2023.

MEI PHARMA, INC.
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Forward-Looking Statements

This Annual Report on Form 10-K ("Annual Report") includes forward-looking statements, which involve a number of risks and uncertainties. These forward-looking statements can generally be identified as such because the context of the statement will include words such as "may," "will," "intend," "plan," "believe," "anticipate," "expect," "estimate," "predict," "potential," "continue," "likely," or "opportunity," the negative of these words or other similar words. Similarly, statements that describe our future plans, strategies, intentions, expectations, objectives, goals or prospects and other statements that are not historical facts are also forward-looking statements. Discussions containing these forward-looking statements may be found, among other places, in "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Annual Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the time this Annual Report was filed with the Securities and Exchange Commission, or SEC. These forward-looking statements are based largely on our expectations and projections about future events and future trends affecting our business, and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. These risks and uncertainties include, without limitation, those discussed in "Risk Factors" and in "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report. Other sections of this report and our other filings with the SEC may include additional factors which could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. There is substantial uncertainty regarding the impact of activist investors, rising inflation and the increase in interest rates as a result, a potential economic downturn, the ongoing conflict in Ukraine on our business, industry, global economic conditions and government policy. New risk factors emerge from time to time and it is not possible for us to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Except as required by law, we undertake no obligation to update publicly or revise our forward-looking statements to reflect events or circumstances that arise after the filing of this Annual Report or documents incorporated by reference herein that include forward-looking statements.

Unless the context requires otherwise, references in this Annual Report to "MEI Pharma," "we," "us" and "our" refer to MEI Pharma, Inc.

MEI Pharma, Inc. and our corporate logo are registered service marks of MEI Pharma. Any other brand names or trademarks appearing in this Annual Report are the property of their respective holders.

PART I

Item 1. Business

Overview

MEI Pharma, Inc. (Nasdaq: MEIP) is a clinical-stage pharmaceutical company committed to developing novel and differentiated cancer therapies. We build our pipeline by acquiring promising cancer agents and creating value in programs through clinical development, strategic partnerships, and out-licensing or commercialization, as appropriate. Our approach to oncology drug development is to evaluate our drug candidates in combinations with standard-of-care therapies to overcome known resistance mechanisms and address clear medical needs to provide improved patient benefit. The drug candidate pipeline includes voruciclib, an oral cyclin-dependent kinase 9 ("CDK9") inhibitor, and ME-344, an intravenous small molecule mitochondrial inhibitor targeting the oxidative phosphorylation pathway. Our common stock is listed on the Nasdaq Capital Market under the symbol "MEIP."

In February 2023, we, Infinity Pharmaceuticals, Inc. ("Infinity"), and Meadow Merger Sub, Inc., our wholly owned subsidiary ("Merger Sub") entered into an agreement and plan of merger ("Merger Agreement"). The Merger was subject to approval by our stockholders. At a special meeting of our stockholders held on July 23, 2023, the transaction did not obtain the necessary approval from our stockholders. Accordingly, on July 23, 2023, MEI sent Infinity a notice terminating the Merger Agreement. Following the stockholder vote at the July 23, 2023 special meeting, we remain focused on advancing our current development pipeline: voruciclib and ME-344. Clinical data is expected to be reported from the voruciclib Phase 1 study early in calendar 2024, and safety and efficacy data from the first cohort of 20 patients in the ongoing ME-344 Phase 1b study is expected to be reported in the first half of calendar 2024.

In December 2022, we announced plans to realign our clinical development efforts after jointly deciding with our development partner, Kyowa Kirin Co., Ltd. ("KKC"), to discontinue development of our lead drug candidate, zandelisib, outside of Japan. In connection with the realignment, we focused our development efforts on our two clinical assets, voruciclib and ME-344 which are in Phase 1 and Phase 1b clinical programs, respectively. Additionally, we initiated a staggered workforce reduction, affecting 28 employees in December 2022 and an additional 26 employees through June 2023. As of September 15, 2023, we had 41 employees which reflects a 61% reduction in full-time employees since our announcement in December 2022. Following the completion of the close of the zandelisib development program and the workforce reductions, we believe our cash is sufficient to fund operations for at least 12 months and through the reporting of clinical data readouts from the ongoing and planned voruciclib and ME-344 Phase 1 and Phase 1b clinical programs, respectively.

In May 2023, our board of directors appointed David M. Urso to be President and Chief Executive Officer of MEI and terminated the employment of Daniel Gold, Ph.D., the then current Chief Executive Officer, in each case effective as of June 2, 2023.

Clinical Development Programs

Our clinical-stage drug candidate pipeline includes voruciclib, an oral CDK9 inhibitor and ME-344, an intravenous small molecule mitochondrial inhibitor targeting the oxidative phosphorylation pathway.

INVESTIGATIONAL AGENTS	THERAPEUTIC AREA	COMBINATION	PHASE 1/1B	PHASE 2	PHASE 3	CLINICAL DATA
Voruciclib Oral CDK9 Inhibitor	Acute Myeloid Leukemia Relapsed/refractory (2L+)	Monotherapy VENCLEXTA® (venetoclax)	Completed			~YE 2023
			Enrolling			
ME-344 Mitochondrial Inhibitor	HER2-negative breast cancer* Colorectal Cancer Relapsed	AVASTIN® (Bevacizumab)	Completed			H1 2024
			Enrolling			

*Phase 0 window of opportunity study: investigatory-initiated, multicenter, randomized, open-label.

Voruciclib: Potent Orally Administered CDK9 Inhibitor in Phase 1 Studies

Voruciclib is a potent and selective orally administered CDK9 inhibitor. Voruciclib is being studied in a Phase 1 trial evaluating dose and schedule in patients with acute myeloid leukemia ("AML") and B-cell malignancies as a single-agent, and in combination

with the B-cell lymphoma 2 (“BCL2”) inhibitor venetoclax (marketed as Venclexta®) in patients with AML. Voruciclib is also being evaluated in pre-clinical studies to explore potential activity in various solid tumor cancers including in combination with therapies that target the RAS signaling pathway, such as KRAS inhibitors.

Voruciclib Scientific Overview: Cell Cycle Signaling

CDK9 has important functions in cell cycle regulation, including the modulation of two therapeutic targets in cancer:

- CDK9 is a transcriptional regulator of the myeloid leukemia cell differentiation protein (“MCL1”), a member of the family of anti-apoptotic proteins which, when elevated, may prevent the cell from undergoing cell death and result in poor prognosis in cancer. Inhibition of CDK9 blocks the production of MCL1, which is also an established resistance mechanism to the BCL2 inhibitor venetoclax.
- CDK9 is a transcriptional regulator of the MYC proto-oncogene protein (“MYC”) which regulates cell proliferation and growth. Up regulation of MYC is implicated in many human cancers and is frequently associated with poor prognosis and unfavorable patient survival. CDK9, in addition to being a transcription factor for MYC, also decreases phosphorylation of MYC protein that is implicated in stabilizing MYC in KRAS mutant cancers.

Directly inhibiting MCL1 and MYC has historically been difficult, but CDK9 is a promising approach to indirectly target these oncogenes.

Voruciclib: Inhibition of MCL1

Over expression of MCL1 is frequently observed in many tumor types and is closely associated with tumorigenesis, poor prognosis and drug resistance. Further, up regulation of MCL1 is understood to play a role in resistance to venetoclax. CDK9 is a known transcriptional regulator of MCL1.

In pre-clinical studies voruciclib shows dose-dependent suppression of MCL1; in December 2017, a study of voruciclib published in the journal Nature Scientific Reports reported that the combination of voruciclib plus the BCL-2 inhibitor venetoclax was capable of inhibiting two master regulators of cell survival, MCL-1 and BCL-2, and achieved synergistic antitumor effect in an aggressive subset of DLBCL cells.

In a peer reviewed manuscript published in 2020, it was reported that the inhibition of CDK9 by voruciclib synergistically enhances cell death induced by the BCL-2 inhibitor venetoclax in preclinical models of AML. The data demonstrated that voruciclib synergizes with venetoclax to induce programmed cell death, or apoptosis, in both AML cell lines and primary patient samples. It was also demonstrated that voruciclib downregulates MCL1, which is relevant for the synergy between voruciclib and venetoclax, and further that voruciclib downregulates MYC, which also contributes to the synergies with venetoclax.

The research suggests that voruciclib is potentially an attractive therapeutic agent for treating cancers in combination with venetoclax or other BCL-2 inhibitors, to address potential resistance associated with MCL1, and is supportive of our ongoing clinical evaluation of voruciclib in B-cell malignancies and AML.

Voruciclib: Inhibition of MYC

Many cancers are associated with over expression of MYC, a transcription factor regulating cell proliferation and growth. CDK9 is a known regulator of MYC transcription and a modulator of MYC protein phosphorylation. Data reported at the American Association for Cancer Research (“AACR”) Annual Meeting 2021 in preclinical models demonstrated that voruciclib:

- Results in a rapid decrease in the phosphorylation of proteins that promote MYC transcription;
- Rapidly decreases phosphorylation of MYC protein on Ser62, a site implicated in stabilizing MYC in KRAS mutant cancers;
- Possesses single agent activity against multiple KRAS mutant cancer cell lines both in vitro and in vivo; and
- Synergistically inhibits KRAS G12C mutant cancer cell lines in combination with KRAS G12C inhibitors, both in vitro and in vivo.

The research presented suggests that voruciclib could be an attractive therapeutic agent for both hematological cancers, as well as solid tumors, dependent on the activity of MYC.

Clinical Programs

We are evaluating patients with hematological malignancies in a Phase 1 clinical trial evaluating the dose and schedule of voruciclib. The trial started with the evaluation of dose and schedule of voruciclib as a monotherapy in patients with relapsed and refractory B-cell malignancies and AML after failure of prior standard therapies to determine the safety, preliminary efficacy and maximum tolerated dose. After completing the monotherapy dose escalation stage of the study, we are now evaluating the dose and schedule of voruciclib in combination with venetoclax, a BCL2 inhibitor, initially in patients with AML. The primary goal of the Phase 1 study is to assess the safety, and possible synergies, of voruciclib administered in combination with venetoclax. Clinical data expected to be reported from the voruciclib Phase 1 study early in calendar 2024.

As we reported in May 2023, the voruciclib monotherapy dose escalation/expansion stage of the study, which enrolled 40 patients with relapsed and refractory (“R/R”) AML and B-cell malignancies, is complete. Of the 40 patients enrolled, the first 16 were dosed daily continuously at 50 and 100 mg and the following 24 were dosed on an intermittent schedule (14 consecutive days on therapy in a 28-day cycle) at 100, 150 and 200 mg. All patients were heavily pre-treated with a median of 3 prior therapies (range 1-8). The most common ($\geq 5\%$ of all patients) adverse events related to voruciclib were diarrhea (15%), nausea (10%) and fatigue (7.5%), all graded 1 or 2. On the intermittent dosing schedule selected for further development, no dose-limiting toxicities (DLT) were observed, there were no grade three or higher drug related toxicities, and dose escalation was stopped at 200 mg before reaching the maximum tolerated dose because plasma concentrations reached levels considered sufficient for target inhibition. Of the 10 AML patients treated at the highest dose evaluated, 200 mg daily on the intermittent schedule, the disease control rate among these patients was 50%, with a median duration on therapy of 72 days (range 27-127) at the time of evaluation.

As further reported in our May 2023 update, the second stage of the study evaluating the combination of voruciclib and venetoclax in patients with R/R AML is ongoing. The first cohort in the dose escalation stage enrolled 6 patients administered 50 mg of voruciclib every other day for 14 days followed by 14 days without any therapy in a 28-day cycle, plus standard dose venetoclax. All patients were heavily pre-treated with a median of three prior therapies. Notably, all patients previously progressed after receiving treatment with venetoclax. No DLTs or overlapping bone marrow toxicities were observed. The disease control rate was 50%, including one patient who received five prior therapies including stem cell transplant and who achieved a partial response after the 1st cycle of therapy and a 2nd patient with stable disease and a reduction in transfusion requirement. Subsequently, the study Safety Review Committee has cleared enrollment in the three dose levels: 50 mg, 100 mg and 150 mg administered daily for 14 consecutive days followed by 14 days without any therapy in a 28-day cycle.

Voruciclib was also previously evaluated in more than 70 patients with solid tumors in multiple Phase 1 studies. The totality of the clinical data, along with data from pre-clinical studies, suggests voruciclib’s ability to inhibit its molecular target at a projected dose as low as 150 mg daily. In one clinical study, voruciclib was evaluated in combination with vemurafenib (marketed as Zelboraf®) in nine patients with BRAF mutated advanced/ inoperable malignant melanoma. All three BRAF/MEK naive patients achieved a response: two partial responses and one complete response. In this study voruciclib was dosed at 150 mg daily plus vemurafenib 720 mg or 960 mg twice daily in 28-day cycles. The most common adverse events were fatigue, constipation, diarrhea, arthralgia and headache. One instance of grade 3 fatigue was dose limiting and no serious adverse events related to voruciclib were reported. Other clinical studies evaluated voruciclib at doses up to 850 mg in patients with solid tumors, demonstrating additional evidence of potential biologic activity and an adverse event profile generally consistent with other drugs in its class.

ME-344: Clinical-stage Mitochondrial Inhibitor with Combinatorial Potential

ME-344 is a novel mitochondrial inhibitor drug candidate that demonstrates tumor selective activity in pre-clinical studies. It targets the OXPHOS pathway involved in the production of adenosine triphosphate, or ATP. By disrupting the production of ATP, the main source of energy for cells, ME-344 has been shown pre-clinically to induce cancer cell death through the induction of DNA fragmentation and through a process known as autophagy, whereby a cell consumes itself. ME-344 has also demonstrated evidence of antitumor activity in preclinical and clinical studies.

ME-344 Scientific Overview: Cancer Metabolism

Energy supplied in the form of ATP fuels tumor metabolism supporting cell division and growth. Accordingly, tumor cells often display a high metabolic rate to support tumor cell survival and proliferation. This heightened metabolism requires a continual supply of energy in the form of ATP. The two major sources of ATP are oxidative phosphorylation in specialized cellular organelles termed mitochondria and through the metabolism of carbohydrates via the glycolysis pathway, which is frequently unregulated in cancer cells in a phenomenon called the Warburg Effect.

It is understood that anti-angiogenics, like the vascular endothelial growth factor (“VEGF”) inhibitor bevacizumab (marketed as Avastin®), may reduce the rate of glycolysis in tumors. As a result, tumor metabolism may then shift to mitochondria for energy

production. In such cases of tumor plasticity in the presence of treatment with anti-angiogenics, contemporaneously targeting the alternative metabolic source by also inhibiting ATP production with the mitochondrial drug inhibitor ME-344 presents an important therapeutic opportunity for clinical evaluation.

MEI is pursuing evaluation of ME-344 in combination with VEGF inhibition and obtained preliminary clinical validation of the approach in a completed investigator-initiated, multi-center, randomized, controlled, window of opportunity clinical trial in combination with bevacizumab that enrolled a total of 42 patients with human epidermal growth factor receptor 2 (“HER2”) negative breast cancer. Additionally, we are currently evaluating the combination of ME-344 and bevacizumab in patients with metastatic colorectal cancer.

Clinical Program

ME-344 has been evaluated pre-clinically and clinically as a single agent and in combination with anti-angiogenics such as bevacizumab. When evaluated as a single agent, ME-344 demonstrated evidence of activity against refractory solid tumors in a Phase 1b trial, and in pre-clinical studies tumor cells treated with ME-344 resulted in a rapid loss of ATP and cancer cell death. In addition to single agent activity, ME-344 has also demonstrated significant potential in combination with anti-angiogenic therapeutics.

Pre-clinical studies, have shown that one outcome of anti-angiogenics is a reduced rate of glycolysis in tumors as a mechanism to slow tumor growth. However, when faced with reduced glycolysis and reduced ATP production, tumor metabolism was able to shift to mitochondrial metabolism for energy production to support continued tumor proliferation. In such cases of tumor plasticity in the presence of treatment with anti-angiogenics, contemporaneously targeting the mitochondria as an alternative metabolic source of ATP with ME-344 may open an important therapeutic opportunity.

Support for this combinatorial use of ME-344 was first published in the June 2016 edition of Cell Reports; pre-clinical data from a collaboration with the Spanish National Cancer Research Centre in Madrid demonstrated mitochondria-specific effects of ME-344 in cancer cells, including substantially enhanced anti-tumor activity when combined with agents that inhibit the activity of VEGF. These data demonstrating the potential anti-cancer effects of combining ME-344 with a VEGF inhibitor due to an inhibition of both mitochondrial and glycolytic metabolism provided a basis for commencement of an investigator-initiated trial of ME-344 in combination with bevacizumab in HER2 negative breast cancer patients.

Results published in the November 2019 issue of Clinical Cancer Research from a multi-center, investigator-initiated, randomized, controlled, clinical trial that evaluated the combination of ME-344 and bevacizumab in 42 women with early HER2-negative breast cancer further support the combinatorial use of ME-344 with anti-angiogenic therapeutics.

The primary objective of the trial was to show proof of ME-344 biologic activity as measured by reductions in the nuclear protein Ki67 (expression of which is strongly associated with tumor cell proliferation and growth) from days 0 to 28 compared to the control group who received bevacizumab alone. Secondary objectives included determining whether ME-344 biologic activity correlates with vascular normalization. The data demonstrated significant biologic activity in the ME-344 treatment group:

- In ME-344 treated patients, mean absolute Ki67 decreases were 13.3 compared to an increase of 1.1 in the bevacizumab monotherapy group (P=0.01).
- In ME-344 treated patients, mean relative Ki67 decreases were 23% compared to an increase of 186% in the bevacizumab monotherapy group (P < 0.01).
- The mean relative Ki67 reduction in patients experiencing vascular normalization in the ME-344 treated patients was 33%, compared to an increase of 11.8% in normalized patients from the bevacizumab monotherapy group (P=0.09). Approximately one-third of patients in each arm had vascular normalization.

Treatment was generally well tolerated; three grade 3 adverse events of high blood pressure were reported, two in the ME-344 arm and one in the bevacizumab monotherapy arm.

Results from our earlier, first-in-human, single-agent Phase 1 clinical trial of ME-344 in patients with refractory solid tumors were published in the April 1, 2015 edition of Cancer. The results indicated that eight of 21 evaluable patients (38%) treated with ME-344 achieved stable disease or better, including five who experienced progression-free survival that was at least twice the duration of their last prior treatment before entry into the trial. In addition, one of these patients, a heavily pre-treated patient with small cell lung cancer, achieved a confirmed partial response and remained on study for two years. ME-344 was generally well tolerated at doses equal to or less than 10 mg/kg delivered on a weekly schedule for extended durations. Treatment-related adverse events included nausea, dizziness and fatigue. Dose-limiting toxicities were observed at both the 15 mg/kg and 20 mg/kg dose levels, consisting primarily of grade 3 peripheral neuropathy.

We are advancing ME-344 in combination with the anti-angiogenic antibody bevacizumab in a Phase 1b study evaluating patients with relapsed colorectal cancer. The study is enrolling patients with progressive disease after failure of standard therapies with patients treated until disease progression or intolerance. The primary objective is progression free survival. Secondary endpoints include overall response rate, duration of response, overall survival and safety. Safety and efficacy data from the first cohort of 20 patients in the ongoing ME-344 Phase 1b study is expected to be reported in the first half of calendar 2024.

Additionally, ME-344 may also have clinical potential against hematological malignancies. At the AACR Annual Meeting 2022, a poster presentation reported results from preclinical studies exploring the ability of ME-344 to enhance the activity of venetoclax against AML. Data from the in vitro and in vivo preclinical studies evaluating the combination of ME-344 with venetoclax in standard-of-care-resistant AML cell lines and relapsed or refractory AML patient samples suggest that ME-344, both alone and in combination with venetoclax, inhibits purine biosynthesis, suppresses oxidative phosphorylation, induces apoptosis and decreases MCL-1, which together target metabolic vulnerabilities of AML cells. The data demonstrated that ME-344 and venetoclax prolong survival in MV4-11 and MV4-11/AraC-R-derived xenograft AML models. The poster concluded that ME-344 enhances venetoclax activity against AML cells including resistant AML.

Zandelisib: PI3K δ Inhibitor Overview

Zandelisib is an oral, once-daily, selective PI3K δ inhibitor that we were jointly developing with KKC under a global license, development and commercialization agreement entered into in April 2020.

In March 2022, we and KKC reported the outcome of an end of Phase 2 meeting with the FDA wherein the agency discouraged a filing based on data from a single-arm Phase 2 trial, called TIDAL, evaluating zandelisib in patients with relapsed or refractory follicular lymphoma. At this meeting, the FDA stated that data generated from single arm studies such as the Phase 2 TIDAL trial are insufficient to adequately assess the risk/benefit of PI3K inhibitors evaluating indolent non-Hodgkin lymphoma. At that time, the FDA emphasized that the companies continue efforts with the ongoing randomized Phase 3 COASTAL trial evaluating patients with relapsed or refractory follicular or marginal zone lymphomas. Subsequently, at an April 2022 meeting of the FDA Oncology Drugs Advisory Committee, the committee voted that future approvals of PI3K inhibitors for hematologic malignancies should be supported by randomized data.

In November 2022, we and KKC met with the FDA in a follow-up meeting to the March 2022 end of Phase 2 meeting. At this meeting, the FDA provided further guidance regarding the design and statistical analysis for the Phase 3 COASTAL trial. Following the November meeting, the companies jointly concluded that a clinical trial consistent with the recent FDA guidance, including modification of the ongoing COASTAL trial, would likely not be feasible to complete within a time period that would support further investment or with sufficient certainty of the regulatory requirements for approval to justify continued global development efforts. As a result, we and KKC jointly decided to discontinue global development of zandelisib for indolent forms of non-Hodgkin lymphoma outside of Japan. The discontinuation of zandelisib development outside of Japan was a business decision based on the most recent regulatory guidance from the FDA and is not related to the zandelisib clinical data generated to date. After making the joint decision to terminate development outside of Japan, we and KKC began closing all ongoing zandelisib clinical studies outside of Japan, including the Phase 3 COASTAL trial, the Phase 2 TIDAL trial, and the Phase 2 CORAL trial.

Subsequently, in May 2023, KKC decided to discontinue development of zandelisib in Japan. The discontinuation of zandelisib in Japan was a business decision by KKC based on the most recent regulatory guidance from the PMDA and was not related to the zandelisib clinical data generated to date.

On July 14, 2023, we entered into a Termination Agreement (the “Termination Agreement”) with KKC to terminate all agreements between the parties and cease further zandelisib clinical development globally. We anticipate completing the wind down activities related to the KKC License, Development and Commercialization Agreement during the second quarter of fiscal year 2024.

KKC License, Development and Commercialization Agreement

In April 2020, we entered into the KKC Commercialization Agreement under which we granted to KKC a co-exclusive, sublicensable, payment-bearing license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in the U.S. (the “U.S. License”), and an exclusive (subject to certain retained rights to perform obligations under the KKC Commercialization Agreement), sublicensable, payment-bearing, license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in countries outside of the U.S. (the “Ex-U.S.” and the “Ex-U.S. License”). KKC granted to us a co-exclusive, sublicensable, license under certain patents and know-how controlled by KKC to develop and commercialize zandelisib for all human indications in the U.S., and a co-exclusive, sublicensable, royalty-free, fully paid license under certain patents and know-how controlled by KKC to perform our obligations in the Ex-U.S. under the KKC

Commercialization Agreement. KKC paid us an initial payment of \$100.0 million. Additionally, in Japan, the KKC Commercialization Agreement included potential regulatory and commercialization milestone payments plus royalties on net sales of zandelisib in Japan, which are tiered beginning in the teens.

Prior to the execution of the Termination Agreement on July 14, 2023, KKC was responsible for the development and commercialization of zandelisib in the Ex-U.S. and, subject to certain exceptions, solely responsible for all costs related thereto. We also provided to KKC certain drug supplies necessary for the development and commercialization of zandelisib in the Ex-U.S., with the understanding that KKC would have assumed responsibility for manufacturing for the Ex-U.S. as soon as practicable.

Competition

The marketplace for our drug candidates is highly competitive. A number of other companies have products or drug candidates in various stages of pre-clinical or clinical development that are intended for the same therapeutic indications for which our drug candidates are being developed. Some of these potential competing drug candidates are further advanced in development than our drug candidates and may be commercialized sooner. Even if we are successful in developing products that receive regulatory approval, such products may not compete successfully with products produced by our competitors or with products that may subsequently receive regulatory approval.

Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies active in different but related fields represent substantial competition for us. Many of our competitors developing oncology drugs have significantly greater capital resources, larger research and development staffs and facilities, and greater experience in drug development, regulation, manufacturing, marketing and commercialization than we do. They compete with us in recruiting sites and eligible patients to participate in clinical studies and in attracting development and/or commercialization partners. They also license technologies that are competitive with our technologies. As a result, our competitors may be able to more easily develop technologies and products that would render our technologies or our drug candidates obsolete or non-competitive.

Intellectual Property

We own, by assignment or exclusive license, worldwide rights to each of our current drug candidates. Our intellectual property portfolio includes approximately 37 issued U.S. patents, 213 issued foreign patents, 13 pending U.S. patent applications, and 67 pending foreign applications.

We have acquired exclusive worldwide rights to develop, manufacture and commercialize voruciclib from Presage Biosciences, Inc. (“Presage”). The U.S. Patent and Trademark Office (“USPTO”) has allowed or issued 17 U.S. patents covering the composition of matter, pharmaceutical compositions, and methods of use to treat cancer which are projected to expire between April 2024 and March 2037, not including any patent term extension. There are approximately 85 allowed or issued foreign patents, 7 pending U.S. patent applications, and 52 pending foreign patent applications for voruciclib, related compounds, and related methods of use.

We have acquired, by assignment, patents and patent applications from Novogen, our former majority shareholder, relating to a family of isoflavonoid compounds, including ME-344. The USPTO has issued 13 patents covering ME-344 as composition of matter, pharmaceutical compositions, and methods of use to treat cancer. There are approximately 78 foreign patents granted or allowed. The issued U.S. patents with composition of matter claims covering ME-344 are expected to expire between 2025 and 2031, not including patent term extension. There are four pending U.S. patent applications and seven pending foreign patent applications directed to ME-344 and related compounds or methods of use thereof.

We have acquired, by assignment, worldwide rights to zandelisib and other related compounds from Pathway Therapeutics, Inc. The USPTO has issued seven patents covering zandelisib as composition of matter, pharmaceutical compositions, and methods of use to treat cancer. The issued U.S. patents with composition of matter claims covering zandelisib are projected to expire between 2031 and 2032, not including any patent term extension. There are approximately 50 foreign patents granted or allowed. There are two pending U.S. patent applications and approximately 8 pending foreign patent applications directed to zandelisib and related compounds or methods of use thereof.

Our success depends in large part on our ability to protect our proprietary technologies, compounds and information, and to operate without infringing the proprietary rights of third parties. We rely on a combination of patent, trade secret, copyright, and trademark laws, as well as confidentiality, licensing and other agreements, to establish and protect our proprietary rights. We seek patent protection for our key inventions, including drug candidates we identify, routes for chemical synthesis and pharmaceutical formulations. There is no assurance that any of our pending patent applications will issue, or that any of our patents will be enforceable or will cover a drug or other commercially significant product or method. In addition, we regularly review our patent

portfolio to identify patents and patent applications that we deem to have relatively low value to our ongoing business operations for potential abandonment. There is also no assurance that we will correctly identify which of our patents and patent applications should be maintained and which should be abandoned. The term of most of our other current patents commenced, and most of our future patents, if any, will commence, on the date of issuance and terminate 20 years from the earliest effective filing date of the patent application. Because any marketing and regulatory approval for a drug often occurs several years after the related patent application is filed, the resulting market exclusivity afforded by any patent on our drug candidates and technologies will likely be substantially less than 20 years.

As most patent applications in the U.S. are maintained as confidential until published by the USPTO at 18 months from filing for all cases filed after November 29, 2000, or at issue, for cases filed prior to November 29, 2000, we cannot be certain that we or Presage were the first to make the inventions covered by the patents and applications referred to above. Additionally, publication of discoveries in the scientific or patent literature often lags behind the actual discoveries. Moreover, pursuant to the terms of the Uruguay Round Agreements Act, patents filed on or after June 8, 1995 have a term of twenty years from the date of such filing except for provisional applications, irrespective of the period of time it may take for such patent to ultimately issue. This may shorten the period of patent protection afforded to therapeutic uses of zandelisib, voruciclib or ME-344 as patent applications in the biopharmaceutical sector often take considerable time to issue. However, in some countries the patent term may be extended.

In order to protect the confidentiality of our technology, including trade secrets and know-how and other proprietary technical and business information, we require all of our consultants, advisors and collaborators to enter into agreements that prohibit the use or disclosure of information that is deemed confidential. These agreements also oblige our consultants, advisors and collaborators to assign to us, or negotiate a license to developments, discoveries and inventions made by such persons in connection with their work relating to our products. We cannot be sure that confidentiality will be maintained by those from whom we have acquired technology or disclosure prevented by these agreements. We also cannot be sure that our proprietary information or intellectual property will be protected by these agreements or that others will not independently develop substantially equivalent proprietary information or intellectual property.

The pharmaceutical industry is highly competitive, and patents may have been applied for by, and issued to, other parties relating to products competitive with zandelisib, voruciclib or ME-344. Use of these compounds and any other drug candidates may give rise to claims that they infringe the patents or proprietary rights of other parties, existing now and in the future. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties. We cannot be sure that any license required under any such patents or proprietary rights would be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we may encounter delays in product market introductions, or may find that the development, manufacture or sale of products requiring such licenses may be precluded.

Research and Development

The objective of our research and development program is the generation of data sufficient to achieve regulatory approval of our drug candidates in one or more dosage forms in major markets such as the U.S., to meet medical needs and develop a clinical and commercial profile with attractive attributes, and/or to allow us to enter into a development and/or commercial relationship with another party. The data are generated by our pre-clinical studies and clinical trial programs.

The key aspects of our research and development program are to provide more complete characterization of the following:

- the relevant molecular targets of action of our drug candidates;
- the relative therapeutic benefits and indications for use of our drug candidates as a monotherapy or as part of combinational therapy with other agents; and
- the most appropriate therapeutic indications and dosage forms for voruciclib, ME-344 and zandelisib.

Government Regulation

U.S. Regulatory Requirements

The FDA, and comparable regulatory agencies in other countries, regulate and impose substantial requirements upon the research, development, nonclinical and clinical testing, labeling, manufacture, quality control, storage, approval, advertising, promotion, marketing, distribution, import, and export of pharmaceutical products, as well as significant reporting and record-keeping obligations. State governments may also impose obligations in these and other areas. These requirements are extensive and are frequently changing.

In the U.S., pharmaceutical products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and other laws. The process required by the FDA before drugs may be marketed in the U.S. generally involves the following:

- nonclinical laboratory evaluations, including formulation and stability testing, and animal tests performed under the FDA’s Good Laboratory Practices (“GLP”) regulations to assess pharmacological activity and toxicity potential;
- submission and approval of an investigational new drug (“IND”) application, including results of nonclinical tests, manufacturing information, and protocols for clinical tests, which must become effective before clinical trials may begin in the U.S.;
- obtaining approval of IRBs to administer the products to human subjects in clinical trials;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for the product’s intended use;
- development of manufacturing processes which conform to the FDA’s current Good Manufacturing Practices (“cGMP”), as confirmed by FDA inspection or remote regulatory assessments;
- submission of results for nonclinical, toxicology, and clinical studies, and chemistry, manufacture and control information on the product to the FDA in a non-disclosure agreement (“NDA”); and
- FDA review and approval of an NDA, prior to any commercial sale or shipment of a product.

The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that we will be able to ultimately submit marketing applications for any of our product candidates, that our development efforts will prove to be successful, that our studies will have positive outcomes, or that any approval will be granted on a timely basis, if at all.

The results of the nonclinical studies, together with initial specified manufacturing information, the proposed clinical trial protocol, and information about the participating investigators are submitted to the FDA as part of an IND, which must become effective before we may begin human clinical trials in the U.S. Clinical trials must be conducted in accordance with federal regulations and Good Clinical Practice (“GCP”) requirements, and with investigational products that follow cGMP. GCPs include, among other requirements, the requirements related to monitoring, drug accountability, data integrity, and that all research subjects provide their informed consent in writing for their participation in any clinical trial. Recently, the FDA has issued a number of new guidance regarding the conduct of clinical studies. For instance, the FDA issued an updated guidance on good clinical practices, which is intended to modify the agency’s GCP guidelines, including with respect to clinical trial quality, the use of digital health technologies, computerized systems, and data governance. The FDA also issued guidance regarding the conduct of decentralized clinical trials, use of electronic records, systems and signatures in clinical trials, and the conduct of risk-based clinical trial monitoring. Following issuance of a final guidance, the FDA will further be requiring diversity action plans for certain clinical studies.

Additionally, an independent IRB must review and approve each study protocol and oversee conduct of the trial. An IND becomes effective 30-days after receipt by the FDA, unless the FDA, within the 30-day period, raises concerns or questions about the conduct of the trials as outlined in the IND and imposes a clinical hold. If the FDA imposes a clinical hold at any time before or during clinical trials, the IND sponsor must resolve the FDA’s concerns before clinical trials can begin or continue. Nonclinical tests and studies can take several years to complete, and there is no guarantee that an IND that is submitted based on such tests and studies will become effective within any specific time period, if at all.

Sponsors must make certain reports and submissions to the FDA and global health authorities, as appropriate, and to clinical investigators who, in turn, make certain reports and submissions to the IRB or ethics committee, including annual reports, and reports of investigator financial interests, serious adverse events and other significant safety information, study amendments, and new study protocols. Information about certain clinical trials, including a description of the study and study results, must also be submitted within specific time frames to the National Institutes of Health (the “NIH”), for public dissemination on the clinicaltrials.gov website. Sponsors of investigational products for serious diseases must also have a publicly available policy on requests for expanded access.

Investigational drugs and active ingredients imported into the U.S. are also subject to regulation by the FDA. Further, the export of investigational products outside of the U.S. is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

Human clinical trials are typically conducted in three sequential phases that may overlap.

- *Phase I:* The drug is initially introduced into healthy human subjects or patients and tested for safety and dosage tolerance. Absorption, metabolism, distribution, and excretion testing is generally performed at this stage.

- *Phase 2:* The drug is studied in controlled, exploratory therapeutic trials in a limited number of subjects with the disease or medical condition for which the new drug is intended to be used in order to identify possible adverse effects and safety risks, to determine the preliminary or potential efficacy of the product for specific targeted diseases or medical conditions, and to determine dosage tolerance and the optimal effective dose.
- *Phase 3:* When Phase 2 studies demonstrate that a specific dosage range of the drug may be efficacious and the drug has an acceptable safety profile for further investigation, controlled, large-scale therapeutic Phase 3 trials are undertaken at multiple study sites to demonstrate clinical efficacy and to further test for safety in an expanded patient population. Typically, two Phase 3 trials are required by the FDA for product approval. Under some limited circumstances, however, the FDA may approve an NDA based upon a single Phase 3 clinical study plus confirmatory evidence or a single large multi-center trial without confirmatory evidence.

Concurrent with clinical trials, companies usually complete additional non-clinical and toxicology studies and must also develop additional information about the CMC of the product candidate.

Some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data monitoring committee. This group reviews data and advises the study sponsor regarding the continuing safety of the trial. This group may also review interim data to assess the continuing validity and scientific merit of the clinical trial. The data monitoring committee may advise the sponsor to halt the clinical trial, modify the clinical trial, or continue the clinical trial depending on safety results and the trial's likelihood of success.

We cannot be certain that we will successfully complete clinical testing of our products within any specific time period, if at all. Furthermore, the FDA, the IRB or we may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable safety risk or noncompliance with applicable regulatory requirements.

Results of nonclinical and toxicology studies, and clinical trials, as well as detailed information about the manufacturing process, quality control methods, and product composition, among other things, are submitted to the FDA as part of an NDA seeking approval to market and commercially distribute the product on the basis of a determination that the product is safe and effective for its intended use. Once the FDA receives an application, it has 60 days to review the NDA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing. The FDA may request additional information rather than accept an application for filing. In this event, the application must be resubmitted with the additional information. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under the goals agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the agency currently aims to review 90% of all applications for new molecular entities within ten months of the 60-day filing date for a standard review. The PDUFA date is only a goal, thus, the FDA does not always meet its PDUFA dates. The PDUFA date may also be extended if the FDA requests or the sponsor provides substantial additional information regarding the submission.

The FDA may refer certain applications to an advisory committee, which is a panel of experts that make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured and may inspect the sponsor, clinical study vendors, and clinical sites at which the product candidate was studied and will not approve the product unless cGMP and GCP compliance are satisfactory. Inspections may be in-person or conducted remotely. If applicable regulatory criteria are not satisfied, the FDA may issue a complete response letter ("CRL") to the sponsor requiring additional non-clinical or clinical studies or data or additional CMC information. If a CRL is issued, the applicant may either: resubmit the marketing application, addressing all of the deficiencies identified in the letter; withdraw the application; or request an opportunity for a hearing.

Once the FDA determines that the approval requirements are met, it will issue an approval letter that authorizes commercial marketing of the product with specific prescribing information for specific indications. As a condition of approval, the FDA also may require post-marketing commitments and requirements, including studies, and/or surveillance to monitor the product's safety or efficacy. The FDA also may require a Medication Guide and also a risk evaluation and mitigation strategy ("REMS"), or other conditions for a product's approval or following approval to ensure that the benefits of the product candidate outweigh the risks. Moreover, even if the FDA approves a product, it may limit the approved indications or populations for use of the product, require that contraindications, warnings, or precautions be included in the product labeling, including a black box warning, impose other conditions, such as post-approval studies, or may not approve label statements that are necessary for successful commercialization and marketing.

Even after an NDA is approved, the FDA may impose additional obligations or restrictions (such as labeling changes, or clinical post-marketing requirements), or even suspend or withdraw a product approval or require additional testing or label revisions on the basis of data that arise after the product reaches the market, or if compliance with regulatory standards is not maintained. We cannot be certain that any NDA we submit will be approved by the FDA for full or accelerated approval on a timely basis, if at all. Also, any such approval may limit the indicated uses for which the product may be marketed. Any refusal to approve, delay in approval, suspension or withdrawal of approval, or restrictions on indicated uses could have a material adverse impact on our business prospects.

Each NDA must be accompanied by a substantial user fee pursuant to the requirements of the PDUFA and its amendments. Fee waivers or reductions are available in certain circumstances. Following product approval, drug products are also subject to annual program fees. The FDA adjusts the PDUFA user fees on an annual basis. A written request can be submitted for a waiver for the application fee for the first human drug application that is filed by a small business, but there are no small business waivers for program fees. Product candidates that are designated as orphan products are not subject to application user fees unless the application includes an indication other than the orphan indication and may be exempt from program fees if certain criteria are met. We are not at the stage of development with our products where we are subject to these fees, but they are significant expenditures that may be incurred in the future and must be paid at the time of application submissions to the FDA.

Satisfaction of FDA requirements typically takes many years. The actual time required varies substantially, based upon the type, complexity, and novelty of the pharmaceutical product, among other things. Government regulation imposes costly and time-consuming requirements and restrictions throughout the product life cycle and may delay product marketing for a considerable period of time, limit product marketing, or prevent marketing altogether. Success in nonclinical or early-stage clinical trials does not ensure success in later stage clinical trials. Data obtained from nonclinical and clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit, or prevent marketing approval. Even if a product receives marketing approval, the approval is limited to specific clinical indications. Further, even after marketing approval is obtained, the discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

After product approval, there are continuing significant regulatory requirements imposed by the FDA, including record-keeping requirements, obligations to report adverse side effects in patients using the products, and restrictions on advertising and promotional activities. Quality control and manufacturing procedures must continue to conform to cGMPs, and the FDA periodically inspects facilities, via in person inspections and remote regulatory assessments, to assess cGMP compliance. Additionally, post-approval changes in ingredient composition, manufacturing processes or facilities, product labeling, or other areas may require submission of an NDA Supplement to the FDA for review and approval. New indications will require additional clinical studies and submission of an NDA Supplement. Commercially distributed products are also subject to a variety of additional requirements, including requirements regarding tacking, tracing, and supply chain integrity; and requirements related to drug shortages and drug shortage prevention.

Failure to comply with the FDA's regulatory requirements may result in an enforcement action by the FDA, including clinical holds, refusal to approve marketing applications or supplements, Warning Letters, product recalls, suspension or revocation of product approval, seizure of product to prevent distribution, impositions of injunctions prohibiting product manufacture or distribution, and civil and criminal penalties, among other actions. Maintaining compliance is costly and time-consuming. We cannot be certain that we, or our present or future suppliers or third party manufacturers, will be able to comply with all FDA regulatory requirements, and potential consequences of noncompliance could have a material adverse impact on our business prospects.

The FDA's policies may change, and additional governmental regulations may be enacted that could delay, limit, or prevent regulatory approval of our products, that require that we implement additional compliance steps, or affect our ability to manufacture, market, or distribute our products after approval.

Our activities also may be subject to state laws and regulations that affect our ability to develop and sell our products. We are also subject to numerous federal, state, and local laws relating to such matters as safe working conditions, clinical, laboratory, and manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future, and the failure to comply may have a material adverse impact on our business prospects.

The FDCA includes provisions designed to facilitate the development and expedite the review of drugs intended for treatment of serious or life-threatening conditions that demonstrate the potential to address unmet medical needs for such conditions or present a significant improvement over existing therapy. These provisions set forth a procedure for designation of a drug as a "fast track product". The fast track designation applies to the combination of the product and specific indication for which it is being studied. A product designated as fast track is ordinarily eligible for additional programs for expediting development and review, such as increased FDA interactions and rolling submission of the application.

Products that are intended to treat serious or life-threatening conditions and that provide a meaningful therapeutic benefit over existing treatments may also be eligible for accelerated approval. Drug approval under the accelerated approval regulations may be based on evidence of clinical effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. A post-marketing clinical study will be required to be completed to verify clinical benefit, and other restrictions to assure safe use may be imposed. By the date of approval of an accelerated approval product, the FDA must specify the conditions for the required post approval studies, including enrollment targets, the study protocol, milestones, and target completion dates. The FDA may also require that the confirmatory Phase 4 studies be commenced prior to the FDA granting a product accelerated approval. Reports on the progress of the required Phase 4 confirmatory studies must be submitted to the FDA every 180 days after approval. Failure to conduct required post-approval studies, or confirm a clinical benefit, will allow the FDA to withdraw the drug or biologic from the market on a statutorily defined expedited basis. Failure to conduct the required Phase 4 confirmatory studies or to conduct such studies with due diligence, as well as failure to submit the required update reports can subject a sponsor to penalties. In recent years, the accelerated approval pathway has come under significant FDA and public scrutiny. Accordingly, the FDA may be more conservative in granting accelerated approval or, if granted, may be more apt to withdrawal approval if clinical benefit is not confirmed or the risk benefit assessment changes.

A third potential designation that may be available is breakthrough therapy designation. A breakthrough therapy is a product that is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Products designated as breakthrough therapies are eligible for intensive FDA guidance, a commitment from the FDA to involve senior managers and experienced review staff in a proactive collaborative and cross-disciplinary review, rolling submission of the application, and the facilitation of cross-disciplinary review.

Finally, if a product is intended to treat a serious condition and, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of the condition, the product may be eligible for priority review meaning that the FDA's goal for the review of an NDA is shortened to six months (after a two month period during which the FDA decides whether the application is ready for filing) rather than the standard review of ten months from application acceptance. If we should seek additional designations for any of our programs, we cannot be assured that it will be granted by the FDA. There is also no guarantee that we will be able to maintain any designation that we have received or may receive.

Following the FDA's approval of an NDA, sponsors are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. These patents are published in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can be cited by potential competitors as a reference listed drug in support of a 505(b)(2) NDA or an Abbreviated New Drug Application, ("ANDA"). In an effort to clarify which patents must be listed in the Orange Book, in January 2021, Congress passed the Orange Book Transparency Act of 2020, which largely codified the FDA's existing practices into the FDCA.

A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use as a previously approved product. ANDA applicants generally must only scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

Generally, the FDA may not approve an ANDA or 505(b)(2) NDA unless the reference listed drug's Orange Book listed patents have expired and/or if the applicant certifies that it is not seeking approval for a patented method of use. The FDA may approve these applications, however, if the 505(b)(2) NDA or ANDA sponsor certifies that the Orange Book listed patents for the reference listed drug are invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This later certification is called a paragraph IV certification. If the ANDA or 505(b)(2) NDA applicant has made a paragraph IV certification, following notice to the NDA and patent holders, the NDA and patent holders may then initiate a patent infringement lawsuit. If a lawsuit is brought, the FDA may not make an approval effective until the earlier of 30 months from the patent or application owner's receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent is favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court.

Congress and U.S. federal administrative agencies have taken certain measures to increase drug competition and thus decrease drug prices, including by facilitating 505(b)(2) NDAs and ANDAs, and by introducing additional products into the U.S. market. For example, the FDA finalized a rule and a guidance to facilitate drug importation. Congress also passed a bill requiring sponsors of

NDA products to provide sufficient quantities of drug product on commercially reasonable market-based terms to entities developing generic and 505(b)(2) products. This bill also included provisions on shared and individual REMS for generic drug products.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, a sponsor may obtain marketing exclusivity for a specified period of time following FDA approval of certain drug applications. For example, new drugs containing new chemical entities that have not been previously approved by the FDA may obtain five years of exclusivity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a paragraph IV certification. This exclusivity is not absolute. For instance, it will not delay the submission or approval of a full NDA; though, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Following NDA approval, a patent owner may obtain an extension of a single unexpired patent that has not previously been extended for a period equal to one-half the period of time elapsed between the filing of an IND and the filing of the corresponding NDA plus the period of time between the filing of the NDA and FDA approval, with a five year maximum patent extension. The total patent life of the product with the extension cannot exceed fourteen years from the product's approval date. The period of patent extension may also be reduced for any time that the applicant did not act with due diligence. We cannot be certain that we will be able to take advantage of either the patent term extension or marketing exclusivity provisions of these laws or that, if received, they will adequately protect any approved products from competition.

The Best Pharmaceuticals for Children Act ("BPCA") was reauthorized and amended by the FDA Amendments Act of 2007 ("FDAAA"). The reauthorization of BPCA adds an additional six months of marketing exclusivity and patent protection to unexpired exclusivities and unexpired patents listed with the FDA for NDA applicants that conduct acceptable pediatric studies of new and currently marketed drug products for which pediatric information would be beneficial, as identified by the FDA in a Pediatric Written Request. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly address the agreement between the sponsor and the FDA in the Pediatric Written Request, the additional protection is granted.

The Pediatric Research Equity Act ("PREA") also was reauthorized and amended by the FDAAA. The reauthorization of PREA requires that most applications for drugs include a pediatric assessment (unless waived or deferred) to ensure the drugs' safety and effectiveness in children. Such pediatric assessment must contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the drug product is safe and effective. The pediatric assessments can only be deferred provided there is a timeline for the completion of such studies. The FDA may waive (partially or fully) the pediatric assessment requirement for several reasons, including if the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed. Orphan products are also exempt from the PREA requirements. The Food and Drug Administration Safety and Innovation Act signed into law on July 9, 2012, permanently renewed and strengthened BPCA and PREA.

Under the FDA Reauthorization Act of 2017, sponsors submitting original applications on or after August 18, 2020, for product candidates intended for the treatment of adult cancer which are directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer must submit, prior to marketing application submission, an initial Pediatric Study Plan for FDA agreement, and with the application, reports from molecularly targeted pediatric cancer clinical investigations designed to yield clinically meaningful pediatric study data, using appropriate pediatric formulations, to inform potential pediatric labeling. While orphan products are not exempt from this requirement, the FDA may grant full or partial waivers, or deferrals, for submission of data.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition," which generally is a disease or condition that affects fewer than 200,000 individuals in the U.S. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain orphan drug designation if there is a product already approved by the FDA that is considered by the FDA to be the same as the already approved product and is intended for the same indication. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Orphan drug designation does, however, entitle a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and certain user-fee waivers. The tax advantages, however, were limited in the 2017 Tax Cuts and Jobs Act. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, i.e., the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, except in limited circumstances. By example, if there is already a product

approved by the FDA that is the same product for the same indication, the orphan designated product will only receive orphan drug exclusivity if the prior hypothesis of clinical superiority is demonstrated. Competitors may also be able to receive approval for different drugs for the indication for which the orphan product has exclusivity or the same drug for a different indication.

Notably, the exact scope of any period of orphan drug exclusivity may change. Specifically, 2021 judicial decision, *Catalyst Pharms., Inc. v. Becerra*, challenged and reversed an FDA decision on the scope of orphan product exclusivity for the drug, Firdapse. Under this decision, orphan drug exclusivity for Firdapse blocked approval of another company's application for the same drug for the entire disease or condition for which orphan drug designation was granted, not just the disease or condition for which approval was received. In a January 2023 Federal Register notice, however, the FDA stated that it intends to continue to apply its regulations tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved. The exact scope of orphan drug exclusivity will likely be an evolving area.

Pharmaceutical Coverage, Pricing and Reimbursement & Healthcare Reform

In addition, future sales of our products, if approved for marketing, will depend, in part, on the availability and extent of coverage and reimbursement by third-party payors, such as government health programs, including Medicare and Medicaid, commercial insurance, and managed healthcare organizations. These third-party payors are increasingly challenging the price and limiting the coverage and reimbursement amounts for medical products and services. There may be significant delays in obtaining coverage and reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authority in other countries. It is time-consuming and expensive to seek reimbursement from third-party payors. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but they also have their own methods and approval process apart from Medicare coverage and reimbursement determinations.

In addition, the containment of healthcare costs has become a priority for federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement, and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor to not cover our product candidates could reduce physician usage of the product candidate and have a material adverse effect on our sales, results of operations and financial condition. Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and drug price transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. On August 16, 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products, such as negotiated ceiling prices and penalties for price increases that exceed the rate of inflation, that are both sold into the Medicare program and throughout the United States.

Foreign Regulatory Requirements

Outside the U.S., our ability to market our products will also be contingent upon receiving marketing authorizations from the appropriate regulatory authorities and compliance with applicable post-approval regulatory requirements. Although the specific requirements and restrictions vary from country to country, as a general matter, foreign regulatory systems include risks similar to those associated with the FDA's regulations, described above.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or a decentralized procedure ("DCP"). Under the centralized procedure, a single application to the EMA leads to an approval granted by the European Commission which permits the marketing of the product throughout the EU. The centralized procedure is mandatory for certain classes of medicinal products such as new substances for the treatment of oncology. In addition, all medicinal products developed by certain biotechnological means, and those developed for cancer and other specified diseases and disorders, must be authorized via the centralized procedure. The centralized procedure will apply to any of our products that are developed by means of a biotechnology process or are intended for treatment of cancer. The DCP is used for products that are not eligible or not required to be authorized by the centralized procedure. The centralized procedure is optional for certain other products. Since the exit of the UK from the European Union, the UK has been excluded from the centralized procedure. It will be necessary for applicants to make a separate

application to the UK Medicines and Healthcare products Regulatory Agency (“MHRA”) for a UK marketing authorization. There is currently no procedure for mutual EU/UK recognition of new medicinal products although there is an expedited review procedure (the “EC Decision Reliance Procedure”) for approval in the UK of EU approved products which is currently to run to December 31, 2023. Thereafter a new international recognition framework will be in place, which will have regard to decisions already made by the European Medicines Agency. This means applications with a CHMP positive opinion received after December 31, 2023 will be eligible.

As with FDA approval, we may not be able to secure regulatory approvals in the EU in a timely manner, if at all. Additionally, as in the U.S., post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution, would apply to any product that is approved in the EU, and failure to comply with such obligations could have a material adverse effect on our ability to successfully commercialize any product.

The conduct of clinical trials in the European Union is governed by the European Clinical Trials Regulation (“CTR”), which was implemented in June 2022. This Regulation governs how regulatory bodies in member states control clinical trials. No clinical trial may be started without a clinical trial authorization granted by the national competent authority and favorable ethics approval. Under the Regulation, clinical trial sponsors were able to use the Clinical Trials Information System (“CTIS”) since January 31, 2022, but are not obliged to use it immediately, in line with a three-year transition period. National regulators in the EU Member States and EEA countries could use the CTIS since January 31, 2022. With the exit of the UK from the European Union, the UK did not implement the CTR and the UK provisions implementing the previous law as set out in the previous Clinical Trial Directive (which fundamentally covered the same area as the CTR but was far less detailed and predated the CTIS) will continue to apply until amended by the UK.

Accordingly, there is a marked degree of change and uncertainty both in the regulation of clinical trials and in respect of marketing authorizations which we face for our products in the EU.

Manufacturing

We do not have the facilities or capabilities to commercially manufacture any of our drug candidates. We are and expect to continue to be dependent on contract manufacturers for supplying our existing and future candidates for clinical trials and commercial scale manufacturing of our candidates in accordance with regulatory requirements, including cGMP. Contract manufacturers may utilize their own technology, technology developed by us, or technology acquired or licensed from third parties. FDA approval of the manufacturing procedures and the site will be required prior to commercial distribution.

Human Capital Management

As of June 30, 2023, we had 46 employees, 5 of whom hold a Ph.D. or M.D. degree, all of which reside in the United States. Of the 46 employees, 23 were engaged in research and development activities and 23 were engaged in business development, finance, information systems, facilities, human resources or administrative support. Other personnel resources are used from time to time as consultants or third party service organizations on an as-needed basis. All members of our senior management team have prior experience with pharmaceutical, biotechnology or medical product companies. We believe that we have been successful in attracting skilled and experienced personnel, but there can be no assurance that we will be able to attract and retain the individuals needed.

Our people are a critical component in our continued success. We strive to create a workplace of choice to attract, retain and develop top talent to achieve our strategic goals. We strive to maximize the potential of our human capital resources by creating a respectful, rewarding, and inclusive work environment that enables our employees to further our mission. We adhere to a philosophy that includes, among other things, commitments to create ongoing job opportunities, pay fair wages, and protect worker health and safety.

We invest in our workforce by offering competitive salaries and benefits. We endeavor to foster a strong sense of ownership by offering stock options under our equity incentive plan. We also offer comprehensive and locally relevant benefits for all eligible employees.

We focus on our culture through a combination of regular training for employees at all levels, policies and practices in support of these goals, and a variety of internal and community-based events and actions that reinforce the power of our values and the unique characteristics of each of our employees.

None of our employees are represented by a labor union or covered by collective bargaining agreements. We have never experienced a work stoppage and believe our relationship with our employees is good. Management considers our relations with employees to generally be positive.

Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed with or furnished to the SEC pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website at www.meipharma.com as soon as reasonably practicable after they are electronically filed with, or furnished to, the SSEC. Further, the SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, and can be found on our EDGAR page at <http://www.sec.gov>.

Item 1A. Risk Factors

Investment in our securities involves a high degree of risk. You should consider carefully the risks described below, together with other information in this Annual Report and other public filings, before making investment decisions regarding our securities. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties that you should consider before investing in our common stock. Set forth below is a summary of the principal risks we face:

- We are currently operating in a period of capital markets disruption and economic uncertainty;
- We will need substantial additional funds to progress the clinical trial programs for our drug candidates, to commercialize our drug candidates and to develop new compounds. The actual amount of funds we will need will be determined by a number of factors, some of which are beyond our control;
- We may be required to seek additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties at terms which maybe unfavorable to us;
- We are a clinical-stage pharmaceutical company focused on developing potential new therapies for cancer and are likely to incur operating losses for the foreseeable future;
- The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials;
- Changes in drug candidate manufacturing or formulation may result in additional costs or delay;
- If third parties with whom we collaborate on the development and commercialization of our drug candidates do not satisfy their obligations, do not otherwise pursue development or commercialization of our drug candidates or if they terminate their agreements with us, we may not be able to develop or commercialize our drug candidates;
- We are subject to significant obligations to Presage in connection with our license of voruciclib, and we may become subject to significant obligations in connection with future licenses we obtain, which could adversely affect the overall profitability of any products we may seek to commercialize, and such licenses of drug candidates, the development and commercialization for which we are solely responsible, may never become profitable;
- Our business strategy may include entry into additional collaborative or license agreements. We may not be able to enter into collaborative or license agreements or may not be able to negotiate commercially acceptable terms for these agreements;
- Final approval by regulatory authorities of our drug candidates for commercial use may be delayed, limited or prevented, any of which would adversely affect our ability to generate operating revenues;
- The FDA may determine that our drug candidates have undesirable side effects that could delay or prevent regulatory approval or commercialization;
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our completion of clinical trials and receipt of necessary regulatory approvals could be delayed or prevented;
- Changes in funding for the FDA and other government agencies or future government shutdowns could cause delays in the submission and regulatory review of marketing applications, which could negatively impact our business or prospects;
- Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products internationally;
- Any designation granted by the FDA for any of our product candidates may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval. We may also not be able to obtain or maintain any such designation;
- Any orphan drug designations we receive may not confer marketing exclusivity or other benefits;

- Even if we or our licensees receive regulatory approval to commercialize our drug candidates, our ability to generate revenues from any resulting products will be subject to a variety of risks, many of which are out of our control;
- If any products we develop become subject to unfavorable pricing regulations, third party reimbursement practices or healthcare reform initiatives, our ability to successfully commercialize our products will be impaired;
- Our drug candidates are subject to ongoing government regulation both before and after regulatory approval;
- We may not be able to establish the contractual arrangements necessary to develop, market and distribute our drug candidates;
- Our commercial opportunity will be reduced or eliminated if competitors develop and market products that are more effective, have fewer side effects or are less expensive than our drug candidates;
- Our product candidates may face competition sooner than anticipated;
- We rely on third parties to conduct our clinical trials and pre-clinical studies. If those parties do not successfully carry out their contractual duties or meet expected deadlines, our drug candidates may not advance in a timely manner or at all;
- We will depend on third party suppliers and contract manufacturers for the manufacturing of our drug candidates and have no direct control over the cost and timing of manufacturing our drug candidates. Increases in the cost of manufacturing our drug candidates or delays in manufacturing would increase our costs of conducting clinical trials and could adversely affect our future profitability;
- We rely on acquisitions or licenses from third parties to expand our pipeline of drug candidates;
- Our commercial success is dependent, in part, on obtaining and maintaining patent protection and preserving trade secrets, which cannot be guaranteed;
- Claims by other companies that we infringe on their proprietary technology may result in liability for damages or stop our development and commercialization efforts;
- We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property;
- We may be subject to substantial costs stemming from our defense against third party intellectual property infringement claims;
- We face a risk of product liability claims and claims may exceed our insurance limits;
- Our employees, independent contractors, consultants, commercial partners, principal investigators, or clinical contract research organizations ("CROs") may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business;
- Our business and operations would suffer in the event of system failures;
- Our efforts will be seriously jeopardized if we are unable to retain and attract key employees;
- Negative U.S. and global economic conditions may pose challenges to our business strategy, which relies on funding from the financial markets or collaborators;
- Laws, rules and regulations relating to public companies may be costly and impact our ability to attract and retain directors and executive officers;
- Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer;
- If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business;
- We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster;
- Limitations on the deductibility of net operating losses could adversely affect our business and financial condition;
- Our business could be negatively impacted as a result of any ongoing or future activism campaigns by Anson Advisors Inc. and Cable Car Capital LLC and other activist investors;
- The trading price of the shares of our common stock has been and may continue to be highly volatile and could decline in value and we may incur significant costs from class action litigation;
- Future sales of our common stock, including common stock issued upon exercise of outstanding warrants or options, may depress the market price of our common stock and cause stockholders to experience dilution;
- Because we do not intend to pay, and have not paid, any cash dividends on our shares of common stock, our stockholders will not be able to receive a return on their shares unless the value of our common stock appreciates and they sell their shares;
- We will have broad discretion over the use of the net proceeds from any exercise of outstanding warrants and options;
- We are authorized to issue blank check preferred stock, which could adversely affect the holders of our common stock;
- Anti-takeover provisions contained in our amended and restated certificate of incorporation and fifth amended and restated bylaws, as well as provisions of Delaware law, could impair a takeover attempt;
- Our fifth amended and restated bylaws require, to the fullest extent permitted by law, that derivative actions brought in our name, actions against our directors, officers, other employees or stockholders for breach of fiduciary duty and other

similar actions may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel, which may have the effect of discouraging lawsuits against our directors, officers, other employees or stockholders; and

- Our executive officers and directors may sell shares of their stock, and these sales could adversely affect our stock price.

Risks Related to Our Business

Risks Related to Our Development Stage

We are currently operating in a period of capital markets disruption and economic uncertainty.

The U.S. capital markets are currently experiencing extreme volatility and disruption following the global outbreak of COVID-19, high inflation and the government response thereto, potential economic downturn, publicized failures in the regional banking sector, the war in Ukraine, and other global events. Disruptions in the capital markets in the past have resulted in illiquidity in parts of the capital markets. Future market disruptions and/or illiquidity would be expected to have an adverse effect on our business, financial condition, results of operations and cash flows. Unfavorable economic conditions also would be expected to increase our funding costs, limit our access to the capital markets or result in a decision by lenders not to extend credit to us should that become required for us to fund ongoing operations. These events have limited and could continue to limit our capital investment considerations, limit our ability to fund further clinical development and have a material negative impact on our operating results.

We will need substantial additional funds to progress the clinical trial programs for our drug candidates, and to develop new compounds. The actual amount of funds we will need will be determined by a number of factors, some of which are beyond our control.

We will need substantial additional funds to progress the clinical trial programs for our drug candidates and to develop any additional compounds. The factors that will determine the actual amount of funds that we will need to progress the clinical trial programs may include, but are not limited to, the following:

- the therapeutic indications for use being developed;
- the clinical trial endpoints required to advance clinical development and achieve regulatory approval;
- the number of clinical trials required to achieve regulatory approval;
- the number of sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients who participate in the trials and the rate that they are recruited;
- the number of treatment cycles patients complete while they are enrolled in the trials;
- costs and potential difficulties encountered in manufacturing sufficient drug product for the trials; and
- the efficacy and safety profile of the product.

We have been opportunistic in our efforts to obtain funding, and we expect to continue to evaluate various funding alternatives from time to time. If we obtain additional funding, it may adversely affect the market price of our common stock and may be dilutive to existing stockholders. If we are unable to obtain additional funds on favorable terms or at all, we may be required to cease or reduce our operations. We may sell additional shares of common stock, and securities exercisable for or convertible into shares of our common stock, or we may seek to obtain debt financing, in each case, to satisfy our capital and operating needs; however, such transactions will be subject to market conditions and there can be no assurance any such transactions will be completed.

We may be required to seek additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties at terms which maybe unfavorable to us.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, intellectual property, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We could also be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us when we deem it is required, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our Common Stock to decline.

We are a clinical-stage pharmaceutical company focused on developing potential new therapies for cancer and are likely to incur operating losses for the foreseeable future.

You should consider our prospects in light of the risks and difficulties frequently encountered by clinical research stage and developmental companies. We have an accumulated deficit of \$406 million from our inception through June 30, 2023, including a net loss of \$33.4 million for the year ended June 30, 2023 (excluding \$1.6 million of non-cash gain resulting from a change in fair value of our warrant liability). We anticipate that we will incur operating losses and negative operating cash flow for the foreseeable future. We have not yet commercialized any drug candidates and cannot be sure that we will ever be able to do so, or that we may ever become profitable.

Risks Related to Our Clinical Trials

The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.

Pre-clinical studies and Phase 1 and Phase 2 clinical trials are an expensive and uncertain process that may take years to complete. Pre-clinical studies and Phase 1 and Phase 2 clinical trials are usually not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. Favorable results in early studies or trials, as well as small studies or trials, may not be repeated in later studies or trials, including ongoing pre-clinical studies, large-scale Phase 3 clinical trials, or other studies intended as registration trials, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. Interim and top-line results, as well as any results from post-hoc data analyses, may also not be predictive of the final results of a clinical study and/or may not support product approval. The FDA also generally does not accept post-hoc data analyses as support for regulatory approval.

Comparisons of results across different studies should be viewed with caution as such comparisons are limited by a number of factors, including differences in study designs and populations. Such comparisons also will not provide a sufficient basis for any comparative claims following product approval. Unfavorable results from ongoing pre-clinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a clinical program. Pre-clinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program to be abandoned.

Changes in drug candidate manufacturing or formulation may result in additional costs or delay.

As drug candidates are developed through preclinical studies to late-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, manufacturing sites, formulation, and methods of delivery are altered along the way in an effort to optimize processes and results. Any of these changes could cause our drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional studies to demonstrate the comparability of the product candidate using prior processes, formulation, or manufacturers, FDA notification, or FDA approval. Any of the foregoing could limit our future revenues and growth.

Risks Related to Our Licensing and Collaboration Agreements

If third parties with whom we collaborate on the development and commercialization of our drug candidates do not satisfy their obligations, do not otherwise pursue development or commercialization of our drug candidates or if they terminate their agreements with us, we may not be able to develop or commercialize our drug candidates.

We have in the past and may in the future enter into agreements to collaborate with other third parties on the development, manufacturing or commercialization of our drug candidates in the future. In connection with these agreements, we may grant certain rights regarding the use of our patents and technology. The counterparties may be responsible for development, manufacturing or commercialization of our drug candidates and the costs related thereto.

Our counterparties might not fulfill all of their obligations to us. In addition, the agreements with our counterparties provide the counterparties with substantial control of the development and commercialization of our drug candidates and discretion whether to devote resources to the full pursuit thereof or otherwise fail to fully pursue the development and commercialization of our drug candidates. Even without breaching their obligations to us, our counterparties may not devote adequate resources or otherwise pursue the development and commercialization of our drug candidates, whether as a result of their assessment of the likelihood of success of such efforts, for financial reasons or otherwise. Our ability to receive revenue from our drug candidates may be dependent upon their efforts. If they fail to devote adequate resources or otherwise do not successfully develop, commercialize or manufacture our drug

candidates, we may not receive the future milestone payments or royalties provided for in the agreement. In addition, under certain circumstances, including our failure to satisfy our obligations under the agreement, the counterparty may have the right to terminate the agreement.

We could also become involved in disputes with our counterparties, which could lead to delays in or termination of the agreement and time-consuming and expensive litigation or arbitration.

If our counterparties are unwilling or unable to fulfill their obligations or otherwise fail to fully pursue the development and commercialization of our drug candidates or if the agreement is terminated, we may lack sufficient resources to develop and commercialize our drug candidates on our own and may be unable to reach agreement with a suitable alternative collaborator. The failure to develop and commercialize our drug candidates would have a material adverse effect on our business, operating results, prospects and financial condition.

We are subject to significant obligations to Presage in connection with our license of voruciclib, and we may become subject to significant obligations in connection with future licenses we obtain, which could adversely affect the overall profitability of any products we may seek to commercialize, and such licenses of drug candidates, the development and commercialization for which we are solely responsible, may never become profitable.

In September 2017, we entered into a license agreement with Presage (“the Presage License Agreement”). Under the terms of the agreement, Presage granted us exclusive worldwide rights to develop, manufacture and commercialize voruciclib, a clinical-stage, oral and selective CDK inhibitor, and related compounds. In exchange, we paid Presage \$2.9 million and are obligated for additional potential payments of up to \$181 million upon the achievement of certain development, regulatory and commercial milestones. We will also pay mid-single-digit tiered royalties on the net sales of any product successfully developed pursuant to such agreement. We may enter into similar agreements in the future that require us to make significant payments upon obtainment of development, regulatory or commercial milestones. We may be obligated to make milestone or royalty payments when we do not have the cash on hand to make these payments or have available cash for our other development efforts. These milestone and royalty payments could adversely affect the overall profitability for us of any products that we may seek to commercialize. In addition, if we fail to comply with our obligations under the license agreement, the counterparty may have the right to terminate the agreement. In such a case, we would lose our rights to the intellectual property covered by the license agreement and we would not be able to develop, manufacture or commercialize our drug candidates.

The profitability of our license agreement with Presage depends on the successful development, regulatory approval and commercialization of voruciclib. We are solely responsible for the development and commercialization of voruciclib, including the related costs. Drug development is a long, expensive and uncertain process and delay or failure can occur at any stage of our clinical trials. We cannot be certain that we will ever receive regulatory approval for voruciclib or that we will be successfully commercialized, even if approved.

Our business strategy may include entry into additional collaborative or license agreements. We may not be able to enter into collaborative or license agreements or may not be able to negotiate commercially acceptable terms for these agreements.

Our current business strategy may include the entry into additional collaborative or license agreements for the development and commercialization of our drug and drug candidates. The negotiation and consummation of these types of agreements typically involve simultaneous discussions with multiple potential collaborators or licensees and require significant time and resources. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators or licensees, we compete with numerous other third parties with product opportunities as well as the collaborators’ or licensees’ own internal product opportunities. We may not be able to consummate collaborative or license agreements, or we may not be able to negotiate commercially acceptable terms for these agreements.

If we do enter into such arrangements, we could be dependent upon the subsequent success of these other parties in performing their respective responsibilities and the cooperation of our partners. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators’ resources that will be devoted to researching our product candidates pursuant to our collaborative agreements with them or whether our collaborators will comply with the applicable regulatory requirements. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us.

Under agreements with any collaborators or licensees we may work with in the future, we may rely significantly on them to, among other activities:

- fund research and development activities with us;
- pay us fees upon the achievement of milestones; and
- market for or with us any commercial products that result from our collaborations.

If we do not consummate collaborative or license agreements, we may use our financial resources more rapidly on our drug development efforts, continue to defer certain development activities or forego the exploitation of certain geographic territories, any of which could have a material adverse effect on our business prospects. Further, we may not be successful in overseeing any such collaborative arrangements. If we fail to establish and maintain necessary collaborative or license relationships, our business prospects could suffer.

Collaboration agreements may not lead to development or commercialization of drug candidates in the most efficient manner, or at all. If any collaborations we might enter into do not result in the successful development and commercialization of drug candidates or if one of our collaborators subsequently terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under the agreements, our development of our drug candidates could be delayed, and we may need additional resources to develop our drug candidates and our product platform. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report also apply to the activities of our collaborators. Moreover, should our collaborators not comply with the applicable regulatory or legal requirements, we and/or they, may be subject to regulatory enforcement action.

Risks Related to FDA and Non-U.S. Regulation

Final approval by regulatory authorities of our drug candidates for commercial use may be delayed, limited or prevented, any of which would adversely affect our ability to generate operating revenues.

We will not generate any operating revenue until we, a licensee, or a potential collaborator successfully commercialize one of our drug candidates. Currently, we have drug candidates at different stages of development, and each will need to successfully complete certain clinical studies and obtain regulatory approval before potential commercialization. We may experience unforeseen events during product development that may substantially delay or prevent product approval. For example, the FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or if the trial poses an unexpected serious harm to clinical trial patients. The FDA or an IRB may also impose conditions on the conduct of a clinical trial. Clinical trial sponsors may also choose to discontinue clinical trials as a result of risks to clinical trial patients, a lack of favorable results, data monitoring committee recommendations or changing business priorities.

The pre-clinical and clinical development, manufacturing, labeling, packaging, storage, recordkeeping, export, marketing and distribution, and other possible activities relating to our drug candidates are subject to extensive regulation by the FDA and other regulatory agencies. Failure to comply with applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions that may negatively impact the approval of one or more of our drug candidates or otherwise negatively impact our business.

Neither collaborators, licensees nor we are permitted to market a drug candidate in the U.S. until the particular drug candidate is approved for marketing by the FDA. Specific pre-clinical data, chemistry, manufacturing and controls data, a proposed clinical trial protocol and other information must be submitted to the FDA as part of an IND application, and clinical trials may commence only after the IND application becomes effective. To market a new drug in the U.S., we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and pre-clinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. Regulatory approval of an NDA is not guaranteed. The number and types of pre-clinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target and the regulations applicable to any particular drug candidate. The FDA may also require additional studies or data after a trial has begun or more studies or data than we otherwise have anticipated. Despite the time and expense exerted in pre-clinical and clinical studies, failure can occur at any stage, and we could encounter problems that delay our product candidate development, trigger additional requirements from the FDA, or that cause us to abandon clinical trials or to repeat or perform additional pre-clinical studies and clinical trials. The FDA can delay, limit or deny approval of a drug candidate for many reasons, and product candidate development programs may be delayed or may not be successful for many reasons including but not limited to, the following:

- the FDA or IRBs may not authorize us to commence, amend, or continue clinical studies;
- we may be required to amend our clinical studies in such a way that it compromises the study data or makes the ongoing conduct of the study is impracticable;
- there may be deviations from the clinical study protocol that may result in the need to drop patients from the study, increase the study enrollment size or duration, or that may compromise the reliability of the study and the resulting data;
- we may not be able to enroll a sufficient number of qualified patients for clinical trials in a timely manner or at all, patients may drop out of our clinical trials or be lost to follow-up at a higher rate than we anticipate, patients may not follow the clinical trial procedures, or the number of patients required for clinical trials may be larger than we anticipate;

- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate, including as a result of global trade policies;
- a drug candidate may not be deemed adequately safe or effective for an intended use;
- the FDA may not find the data from pre-clinical studies and clinical trials sufficient;
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development;
- the FDA or comparable foreign regulatory authorities may disagree with our chosen endpoints;
- results from our non-primary endpoints may contradict the results of our primary endpoints, raising questions regarding product efficacy;
- the FDA or comparable foreign regulatory authorities may not find our dose-finding clinical trials and data from other sources adequate and/or may disagree with our proposed product dosages for administration. By example, FDA may require us to conduct additional dose optimization studies beyond any that may be planned, to not only determine the maximum tolerated dose but also the minimum effective dose. Such efforts have been emphasized through FDA initiatives, such as Project Optimus, which has the goal “to educate, innovate, and collaborate with companies, academia, professional societies, international regulatory authorities, and patients to move forward with a dose-finding and dose optimization paradigm across oncology that emphasizes selection of a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well”;
- there may be changes to standard of care that impact the design and conduct of our trial, may result in studies no longer being clinically significant, may require that we change our studies once they have already commenced, or may result in other products being preferred over our product candidates, if they are approved;
- to the extent that we are developing drug candidates for use in combination with other products, clinical trials may be more complex, resulting data may be more difficult to interpret, we may not be able to demonstrate that clinical trial results are attributable to our drug candidate, or developments with respect to the other product or standard of care may impact our ability to obtain product approval for our drug candidate or to successfully market our drug candidate;
- even if our product candidates perform satisfactorily in clinical studies, regulatory authorities may still have remaining questions or concerns based on outcomes observed with respect to other products and product candidates in the same pharmacologic class;
- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;
- the FDA may require that we conduct additional pre-clinical or clinical studies, change our manufacturing process, or gather additional manufacturing information above what we currently have planned for;
- the FDA’s interpretation and our interpretation of data from pre-clinical studies and clinical trials may differ significantly;
- the FDA may not agree with our intended indications, the design of our clinical or pre-clinical studies, or there may be a flaw in the design that does not become apparent until the studies are well advanced;
- we may not be able to establish agreements with contractors or collaborators, including clinical trial sites and CROs, or they or we may fail to comply with applicable FDA, protocol, and other regulatory requirements, including those identified in other risk factors;
- the FDA may not approve the manufacturing processes or facilities;
- the FDA may change its approval policies or adopt new laws, guidance, or regulations and our development program may not meet newly imposed requirements;
- the cost of clinical trials of our product candidates may be greater than we anticipate or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of a marketing application; or
- the FDA may not accept an NDA or other submission due to, among other reasons, the content or formatting of the submission.

Our pre-clinical and clinical data, other information and procedures relating to a drug candidate may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory authority, or regulatory interpretation of these data and procedures may be unfavorable. We may not be successful in any effort to take advantage of expedited regulatory pathways for serious or life-threatening illnesses or to secure marketing authorization from the FDA. We may not be able to demonstrate that our product candidates provide a benefit over existing therapies and, when used in combination with other therapies, we may not be able to demonstrate that our product candidates contributed to any observed effect. We cannot be certain that any NDA we submit will be approved by the FDA for full or accelerated approval on a timely basis, if at all. Securing accelerated approval requires demonstrating a meaningful therapeutic benefit over available existing treatments. Accelerated approvals are based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. If approved, the FDA

will require post-marketing studies to be completed to verify clinical benefit. By the date of approval of an accelerated approval product, FDA must specify the conditions for the required post approval studies, including enrollment targets, the study protocol, milestones, and target completion dates. FDA may also require that the confirmatory Phase 4 studies be commenced prior to FDA granting a product accelerated approval. Reports on the progress of the required Phase 4 confirmatory studies must be submitted to FDA every 180 days after approval. Failure to conduct required post-approval studies, or confirm a clinical benefit, will allow the FDA to withdraw the drug or biologic from the market on a statutorily defined expedited basis. Failure to conduct the required Phase 4 confirmatory studies or to conduct such studies with due diligence, as well as failure to submit the required update reports can subject a sponsor to penalties. Indeed, companies have previously withdrawn approved indications following failure to confirm a clinical benefit for their products. Moreover, in recent years, the accelerated approval pathway has come under significant FDA and public scrutiny. Accordingly, the FDA may be more conservative in granting accelerated approval or, if granted, may be more apt to withdrawal approval if clinical benefit is not confirmed.

Should we decide to seek accelerated approval, the FDA may not agree that the accelerated approval pathway is appropriate, may disagree with our chosen surrogate endpoints, or may find that the accelerated approval criteria are not met. Should the FDA disagree with our approach, we would be required to conduct additional clinical studies prior to submitting an NDA and prior to the FDA granting marketing approval. Moreover, should we receive accelerated approval for a product candidate, the FDA-approved label will indicate that the clinical benefit of the product has not been established and that continued approval is contingent upon verification of a clinical benefit in confirmatory trials.

Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our drug candidates. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we develop. Additionally, other factors may serve to delay, limit or prevent the final approval by regulatory authorities of our drug candidates for commercial use, including, but not limited to:

- voruciclib is in Phase 1 studies and ME-344 is in Phase 1b studies, and we or our potential licensees will need to conduct significant clinical testing and development work to demonstrate the quality, safety, and efficacy of these drug candidates before applications for marketing can be filed with the FDA, or with the regulatory authorities of other countries;
- development and testing of product formulation, including identification of suitable excipients, or chemical additives intended to facilitate delivery of our drug candidates;
- it may take us many years to complete the testing of our drug candidates, and failure can occur at any stage of this process; and
- negative or inconclusive results, statistically or clinically insignificant results, or adverse medical events during a clinical trial could cause us to delay or terminate our development efforts.

Significant delays relating to any preclinical or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do. This may prevent us from receiving marketing approvals and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. If we experience delays in obtaining approval, if we fail to obtain approval of a product candidate or if the label for a product candidate does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, the commercial prospects for such product candidate may be harmed and our ability to generate revenues from that product candidate will be materially impaired. Accordingly, the successful development of any of our drug candidates is uncertain and, accordingly, we may never commercialize any of these drug candidates or generate significant revenue.

The FDA may determine that our drug candidates have undesirable side effects that could delay or prevent regulatory approval or commercialization.

Undesirable side effects caused by our drug candidates could cause us, IRBs, and other reviewing entities or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Undesirable side effects may also result in requirements for costly post-marketing testing and surveillance, or other requirements, including REMS, to monitor the safety or efficacy of the products. These could prevent us from commercializing and generating revenues from the sale of our drug candidates.

Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause side effects that prevented further development of the compound. In addition, adverse events which had initially been considered unrelated to the study treatment may later be found to be caused by the study treatment. Moreover, incorrect or improper use of our drug candidates could cause unexpected side effects or adverse events. If any of our drug candidates is associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon development or limit development of that drug candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The therapeutic-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition, results of operations, and prospects.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our completion of clinical trials and receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue conducting clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U.S. Competitors may also have ongoing clinical trials for drug candidates that are intended to treat the same indications as our drug candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates. Patient enrollment is affected by other factors including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the existence of current treatments for the indications for which we are conducting clinical trials;
- the eligibility criteria for and design of the clinical trial in question, including factors such as frequency of required assessments, length of the study and ongoing monitoring requirements;
- the perceived risks and benefits of the drug candidate, including the potential advantages or disadvantages of the drug candidate being studied in relation to other available therapies;
- competition in recruiting and enrolling patients in clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- effectiveness of publicity created by clinical trial sites regarding the trial;
- patients' ability to comply with the specific instructions related to the trial protocol, proper documentation, and use of the drug candidate;
- an inability to obtain or maintain patient informed consents;
- the risk that enrolled patients will drop out before completion or not return for post-treatment follow-up;
- the ability to monitor patients adequately during and after treatment;
- the ability to compensate patients for their time and effort; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. In particular, there may be low or slow enrollment, and the studies may enroll subjects that do not meet the inclusion criteria, requiring the erroneously enrolled subjects to be excluded and the trial population to be increased. Moreover, patients in our clinical trials may be at risk for dropping out of our studies if they are not experiencing relief of their disease. A significant number of withdrawn patients would compromise the quality of our data.

Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, or the inability to complete development of our drug candidates, which would cause the value of our company to decline, limit our ability to obtain additional financing, and materially impair our ability to generate revenues.

Changes in funding for the FDA and other government agencies or future government shutdowns could cause delays in the submission and regulatory review of marketing applications, which could negatively impact our business or prospects.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept submission, applications, and the payment of user fees, and statutory, regulatory, and policy changes, including the Congressional reauthorization of the FDA's user fee bills. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, including as a result of pandemics like COVID-19 and legislative actions, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, Congress is currently negotiating reauthorization of the FDA user fee bills, which are critical to the FDA's operations. Moreover, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, if the FDA is required to furlough review staff or other necessary employees, or if agency operations are otherwise impacted, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business or prospects.

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products internationally.

We may attempt to have our drug candidates marketed outside the U.S. In order to market our products in many non-U.S. jurisdictions, we must obtain separate international regulatory approvals and comply with numerous and varying regulatory

requirements. To date, we have not filed for marketing approval for any of our drug candidates and may not receive the approvals necessary to commercialize our drug candidates in any market.

The approval procedure varies among countries and may include all of the risks associated with obtaining FDA approval. Further, the time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval, and additional pre-clinical studies, clinical trials, other testing and data review may be required. We may not obtain foreign regulatory approvals on a timely basis, if at all. Additionally, approval by the FDA does not ensure approval by regulatory agencies in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. The failure to obtain regulatory approval in foreign jurisdictions could limit commercialization of our products, reduce our ability to generate profits and harm our business.

Any designation granted by the FDA for any of our product candidates may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval. We may also not be able to obtain or maintain any such designation.

There are a number of FDA programs that are intended to speed the development of drugs that are intended to treat serious diseases and conditions when there is an unmet need, including Fast Track and Break Through Therapy Designation. Receipt of such designations is within the discretion of the FDA. Accordingly, even if we believe one of our drug candidates meets the criteria for a designation, the FDA may disagree. If we receive any designation, the potential reduced timelines associated with designation may introduce significant chemistry, manufacturing and controls challenges for product development as manufacturing development may need to take place at a faster pace than would otherwise be required because the FDA will expect that properly qualified and manufactured product be available at the time of product approval. In any event, the receipt of a designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even after granting a designation, the FDA may later decide that such product candidates no longer meet the conditions for qualification and rescind such designations.

Any orphan drug designations we receive may not confer marketing exclusivity or other benefits.

In the U.S., under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition. Such diseases and conditions are those that affect fewer than 200,000 individuals in the U.S., or if they affect more than 200,000 individuals in the U.S., there is no reasonable expectation that the cost of developing and making a drug available in the U.S. for these types of diseases or conditions will be recovered from sales of the drug. Orphan drug designation must be requested before submitting an NDA. If the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by that agency. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, but it can lead to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. The EMA and the UK also have programs for orphan drugs.

There is no guarantee that a drug candidate will receive orphan drug designation. There is also no guarantee that we would be able to maintain any designations that we receive. For instance, orphan drug designation in the U.S., EU or UK may be revoked for a number of reasons. If a drug that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the drug is entitled to orphan drug marketing exclusivity for a period of seven years. Orphan drug marketing exclusivity generally prevents the FDA from approving another application, including a full NDA, to market the same drug or biological product for the same orphan use for seven years, except in limited circumstances, including if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. For purposes of small molecule drugs, the FDA defines "same drug" as a drug that contains the same active moiety and is intended for the same use as the drug in question. We may not be able to obtain future orphan drug designations that we may apply for or maintain any orphan drug designations that we may receive. A designated orphan drug also may not receive orphan drug marketing exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation or if it is deemed to be the same drug as a previously approved drug and cannot demonstrate clinical superiority. Similarly, in the EMA (and the MHRA), orphan drugs can receive an exclusivity period of ten years, but can be reduced to six years if the drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Orphan drug exclusivity may be lost if the FDA, EMA or MHRA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug exclusivity also may not protect a product from competition. For instance, the FDA may approve a drug that is the same drug with orphan exclusivity for a different indication or a different drug for the same indication as the orphan product. Even after an orphan product is approved, the FDA can also subsequently approve a product containing the same principal molecular features for the same condition if the FDA concludes that the latter product is clinically superior. The FDA may further grant orphan designation to multiple sponsors for the same compound or active molecule and for the same indication. If another sponsor receives

FDA approval for such product before we do, we would be prevented from launching our product in the U.S. for the orphan indication for a period of at least seven years unless we can demonstrate clinical superiority.

Risks Related to the Commercialization of Our Drug Candidates

Even if we or our licensees receive regulatory approval to commercialize our drug candidates, our ability to generate revenues from any resulting products will be subject to a variety of risks, many of which are out of our control.

Even if our drug candidates obtain regulatory approval, resulting products may not gain market acceptance among physicians, patients, healthcare payers or the medical community. We believe that the degree of market acceptance and our ability to generate revenues from such products will depend on a number of factors, including, but not limited to, the following:

- timing of market introduction of our drugs and competitive drugs;
- actual and perceived efficacy and safety of our drug candidates;
- prevalence and severity of any side effects;
- potential or perceived advantages or disadvantages over alternative treatments;
- potential post-marketing commitments imposed by regulatory authorities, such as patient registries;
- strength of sales, marketing and distribution support;
- price of our future products, both in absolute terms and relative to alternative treatments;
- the effect of current and future healthcare laws on our drug candidates; and
- availability of coverage and reimbursement from government and other third party payers.

If any of our drugs are approved and fail to achieve market acceptance, we may not be able to generate significant revenue to achieve or sustain profitability.

If any products we develop become subject to unfavorable pricing regulations, third party reimbursement practices or healthcare reform initiatives, our ability to successfully commercialize our products will be impaired.

Our future revenues, profitability and access to capital will be affected by the continuing efforts of governmental and private third party payers to manage, contain or reduce the costs of health care through various means, such as capping prices, limiting price increases, reducing reimbursement, and requiring rebates. We are also unsure of the impact of any future health care reform legislation or other changes in healthcare policy may have on our business or what actions federal, state, foreign and private payers may take or reforms that may be implemented in the future. Therefore, it is difficult to predict the effect of any potential reform on our business. Our ability to commercialize our drug candidates successfully will depend, in part, on the extent to which reimbursement for the cost of such drug candidates and related treatments will be available from government health administration authorities, such as Medicare and Medicaid in the U.S., private health insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products, particularly for indications for which there is no current effective treatment or for which medical care typically is not sought. Adequate third party coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in research and development. If adequate coverage and reimbursement levels are not provided by government and third party payers for use of our products, our products may fail to achieve market acceptance without a substantial reduction in price or at all and our results of operations will be harmed. In addition, government regulation may restrict our business and financial relationships with health care providers and managed care intermediaries in ways that could impact our ability successfully to market our products.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted bills by Congress and the states designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Most recently, in August 2022, President Biden signed into the law the Inflation Reduction Act of 2022 (the "IRA") which among other things, contains multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States.

In addition, the U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement, requirements for substitution of generic products for branded prescription drugs, and permitting importation of drugs from outside the U.S. to limit the growth of government paid health care costs. For example, the U.S. government has passed legislation requiring pharmaceutical manufacturers that participate in federal healthcare programs to provide rebates and discounts to certain entities and governmental payors. Further, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the U.S. have also been increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access

and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Our drug candidates are subject to ongoing government regulation both before and after regulatory approval.

Both before and after regulatory approval, our drug candidates are subject to strict and ongoing regulation. Compliance with such regulations may consume substantial financial and management resources and expose us and our collaborators to the potential for other adverse circumstances. For example, a regulatory authority can place restrictions on the sale or marketing of a drug in order to manage the risks identified during initial clinical trials or after the drug is on the market. A regulatory authority can condition the approval for a drug on costly post-marketing follow-up studies. Based on these studies, if a regulatory authority does not believe that the drug demonstrates a clinical benefit to patients or an acceptable safety profile, it could limit the indications for which a drug may be sold or revoke the drug's marketing approval. In addition, identification of certain side effects either during clinical trials or after a drug is on the market may result in reformulation of a drug, additional pre-clinical and clinical trials, labeling changes, termination of ongoing clinical trials or withdrawal of approval. Any of these events could delay or prevent us from generating revenue from the commercialization of these drugs and cause us to incur significant additional costs.

Compliance with the applicable regulatory requirements may result in significant expenses and we and our third party contractors and collaborators may be subject to unannounced FDA and other regulatory authority inspections and assessments. Any failure to comply with the applicable regulatory requirements or problems with our drug candidates may result in regulatory enforcement or other actions, including:

- restrictions on manufacturing or distribution, or marketing of any approved products;
- restrictions on the labeling, including restrictions on the indication or approved patient population, and required additional warnings, such as black box warnings, contraindications, and precautions;
- modifications to promotional pieces or issuance of corrective information;
- requirements to conduct post-marketing studies or other clinical trials;
- clinical holds or termination of clinical trials;
- requirements to establish or modify a REMS or a comparable foreign authority may require that we establish or modify a similar strategy;
- changes to the way the product is administered;
- liability for harm caused to patients or subjects;
- reputational harm;
- the product becoming less competitive;
- warning, untitled, or cyber letters;
- suspension of marketing or withdrawal of the products from the market;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention;
- FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or
- injunctions or the imposition of civil or criminal penalties, including imprisonment.

Non-compliance with any foreign jurisdictions' requirements, including requirements regarding the protection of personal information, can also lead to significant penalties and sanctions.

Any of these events could prevent us from achieving or maintaining regulatory product approval and market acceptance of the particular drug candidate, if approved, or could substantially increase the costs and expenses of developing and commercializing such product, which in turn could delay or prevent us from generating significant revenues from our sale.

Other changes may also impact our ability to conduct studies and the approvability or marketability of our drug candidates, including changes in law, government regulation, or FDA policy, including review policies, which may be due to changes in the U.S. government and U.S. administration, or changes in medical practice or standard of care.

If we are slow or unable to adapt to changes in existing requirements, standards of care, or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and

be subject to regulatory enforcement action. Should any of the above actions take place, they could adversely affect our ability to achieve or sustain profitability.

We may not be able to establish the contractual arrangements necessary to develop, market and distribute our drug candidates.

A key part of our strategy is to establish contractual relationships with third parties to package, market and distribute our drug candidates. There is no assurance that we will be able to negotiate commercially acceptable licensing or other agreements for the future exploitation of our drug candidates, including continued clinical development, manufacture or marketing. If we are unable to successfully contract for these services, or if arrangements for these services are terminated, we may have to delay our commercialization program which will adversely affect our ability to generate operating revenues.

Our commercial opportunity will be reduced or eliminated if competitors develop and market products that are more effective, have fewer side effects or are less expensive than our drug candidates.

The development of drug candidates is highly competitive. A number of other companies have products or drug candidates that have either been approved or are in various stages of pre-clinical or clinical development that are intended for the same therapeutic indications for which our drug candidates are being developed. Some of these potential competing drug candidates are further advanced in development than our drug candidates and may be commercialized sooner. Even if we are successful in developing effective drugs, our compounds may not compete successfully with products produced by our competitors.

Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies active in different but related fields represent substantial competition for us. Many of our competitors developing oncology drugs have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us and our service providers, to recruit qualified personnel, and with us to attract partners for joint ventures and to license technologies that are competitive with us. As a result, our competitors may be able to more easily develop technologies and products that would render our technologies or our drug candidates obsolete or non-competitive.

Our product candidates may face competition sooner than anticipated.

Our product candidates, if approved, may face competition from other products that are the same as or similar to our product candidates. If the FDA or comparable foreign regulatory authorities approve generic or similar versions of any of our product candidates that receive marketing approval, or such authorities do not grant our products appropriate periods of regulatory exclusivity before approving generic or similar versions of our products, the sales of our products could be adversely affected.

Once an NDA is approved, the product will become a “reference listed drug” in the FDA’s Orange Book. Other applicants may then seek approval of generic versions of our products through submission of Abbreviated New Drug Applications (“ANDA”) in the U.S. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices, and are generally preferred by third party payors. As a result, the FDA, the administration and Congress have recently taken steps to encourage increased generic drug competition in the market in an effort to bring down drug costs. Following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product. Moreover, in addition to generic competition, we could face competition from other companies seeking approval of drug products that are similar to ours using the 505(b)(2) regulatory pathway. Such applicants may be able to rely on our product candidates, if approved, or other approved drug products or published literature to develop drug products that are similar to ours. The introduction of a drug product similar to our product candidates could expose us to increased competition.

Any ANDA or 505(b)(2) applicants seeking to rely upon any of our product candidates, if such product candidates are approved, would need to submit patent certification statements with their applications for any of our patents that are listed in the FDA’s Orange Book. There are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, an ANDA or 505(b)(2) applicant would not have to submit a patent certification with regard to such patent to the FDA, in which case, we would not receive the protections provided by the Hatch Waxman Act.

Moreover, if an ANDA or 505(b)(2) applicant files a paragraph IV challenge to any patents that we may list in the FDA’s Orange Book and if we do not file a timely patent infringement lawsuit, the ANDA or 505(b)(2) applicant would not be subject to a 30-month stay. If we did file such an action, the litigation or other proceedings to enforce or defend our intellectual property rights would likely be complex in nature, may be expensive and time consuming, may divert our management’s attention from our core business, and may result in unfavorable results that could adversely impact our ability to prevent third parties from competing with our products. Accordingly, upon approval of our product candidates we may be subject to generic competition or competition from similar products, or may need to commence patent infringement proceedings, which would divert our resources.

We currently anticipate that we may be eligible for five years of non-patent marketing exclusivity in the U.S. This exclusivity, however, would not prevent other companies from submitting full NDAs. To the extent we do not receive any anticipated periods of regulatory exclusivity or to the extent the FDA or foreign regulatory authorities approve any generic, similar, or other competing products, our business would be adversely impacted. Competition that our products may face from generic, similar, or other competing products could materially and adversely impact our future revenue, profitability, and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our clinical trials and pre-clinical studies. If those parties do not successfully carry out their contractual duties or meet expected deadlines, our drug candidates may not advance in a timely manner or at all.

In the course of our pre-clinical testing and clinical trials, we rely on third parties, including laboratories, investigators, CROs, manufacturers, and distributors to perform critical services for us. For example, we rely on third parties to conduct our clinical trials and many of our pre-clinical studies, which are required to be conducted consistent with regulations on GLPs and GCPs. CROs and study sites are responsible for many aspects of the trials, including finding and enrolling subjects for testing and administering the trials. Although we rely on these third parties to conduct our pre-clinical and clinical trials, we are responsible for ensuring that each of our trials is conducted in accordance with its investigational plan and protocol and that the integrity of the studies and resulting data is protected. While we have agreements governing the activities of such third parties, we have limited influence and control over their actual performance and activities. Moreover, the FDA and foreign regulatory authorities require us to comply with regulations and standards, commonly referred to as GCPs, for conducting, monitoring, recording, and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. These third parties may not be available when we need them or, if they are available, may not devote sufficient time or resources to our studies, may not comply with all regulatory and contractual requirements, or may not otherwise perform their services in a timely or acceptable manner, and we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. These independent third parties may also have relationships with other commercial entities, some of which may compete with us. In addition, if such third parties fail to perform their obligations in compliance with our protocols or the applicable regulatory requirements, our trials may not meet regulatory requirements or may need to be repeated, we may not receive marketing approvals, or we or such third parties may face regulatory enforcement.

Agreements with third parties conducting or otherwise assisting with our clinical or preclinical studies might terminate for a variety of reasons, including a failure to perform by the third parties. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, if we need to enter into alternative arrangements, it could delay our product development activities and adversely affect our business. Though we carefully manage our relationships with our third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects, and results of operations.

Accordingly, as a result of our dependence on third parties, we may face delays, failures or cost increases outside of our direct control. These risks also apply to the development activities of collaborators, and we do not control their research and development, clinical trial or regulatory activities.

In addition, we will be required to report certain financial interests of our third party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

We also cannot assure you that upon inspection or review by a given regulatory authority, such regulatory authority will determine that any of our trials complies with the applicable regulatory requirements. In addition, our clinical trials must be conducted with drug candidates that were produced under cGMP conditions. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified time frames. Failure to do so can result in enforcement actions and adverse publicity.

We will depend on third party suppliers and contract manufacturers for the manufacturing of our drug candidates and have no direct control over the cost and timing of manufacturing our drug candidates. Increases in the cost of manufacturing our drug candidates or delays in manufacturing would increase our costs of conducting clinical trials and could adversely affect our future profitability.

We do not intend to manufacture our drug candidates ourselves, and we will rely on third parties for our drug supplies both for clinical trials and for commercial quantities in the future. We have taken the strategic decision not to manufacture active

pharmaceutical ingredients (“API”), nor finished product, for our drug candidates, as these can be more economically supplied by third parties with particular expertise in this area. We have identified contract facilities that are registered with the FDA, have a track record of large-scale API and drug product manufacturing, and have already invested in capital and equipment. We have no direct control over the manufacturing of our drug candidates, or the cost thereof. If the contract manufacturers are unable to produce sufficient quantities of our drug candidates, as a result of a lack of available materials or otherwise, our ability to complete product candidate development and our future profitability would be adversely affected. If the cost of manufacturing increases, or if the cost of the materials used increases, these costs will be passed on to us, making the cost of conducting clinical trials more expensive. Increases in manufacturing costs could adversely affect our future profitability if we are unable to pass all of the increased costs along to our customers.

If these third party suppliers and contract manufacturers do not successfully carry out their contractual duties, meet expected deadlines or manufacture our drug candidates in accordance with regulatory requirements, if there are disagreements between us and such parties, or if such parties are unable to expand capacities to support commercialization of any of our drug candidates for which we obtain marketing approval, we may not be able to produce, or may be delayed in producing sufficient drug candidates to meet our supply requirements. Any delays in obtaining adequate supplies with respect to our drug candidates and components may delay the development or commercialization of our drug candidates.

Further, we, along with our contract manufacturers, are required to comply with FDA requirements for cGMPs, related to product testing, quality assurance, manufacturing and documentation. Our contract manufacturers may not be able to comply with the applicable FDA regulatory requirements, which could result in delays to our product development programs, could result in adverse regulatory actions against us or our contract manufacturers, and could prevent us from ultimately receiving product marketing approval. They also generally must pass an FDA pre-approval inspection or assessment for conformity with cGMPs before we can obtain approval to manufacture our drug candidates and will be subject to ongoing, periodic, unannounced inspection or assessment by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other applicable government regulations and corresponding foreign standards. If we and our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP, we may experience manufacturing errors resulting in defective products that could be harmful to patients, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, clinical trial or other development program delays, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business. Not complying with FDA requirements could result in a product recall, costly and time-consuming corrective or preventative actions, or prevent commercialization of our drug candidates and delay our business development activities. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter or take other regulatory or legal enforcement action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, and potentially civil and/or criminal penalties depending on the matter.

If we need to replace any of our manufacturers or establish additional manufacturing arrangements, we may not succeed in our efforts. Our drug candidates may compete with other products and drug candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. If our existing third party manufacturers, or the third parties that we engage in the future to manufacture a product or component for commercial sale or for our clinical trials should cease to continue to do so for any reason, we likely would experience delays in obtaining sufficient quantities of our drug candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. These third party facilities may also be affected by natural disasters, such as floods or fire, or such facilities could face manufacturing issues, such as contamination or regulatory findings following a regulatory inspection or assessment of such facility. In such instances, we may need to locate an appropriate replacement third party relationship, which may not be readily available or on acceptable terms, which would cause additional delay and increased expense. The addition of a new or alternative manufacturer may also require FDA approvals and may have a material adverse effect on our business.

We or our third party manufacturers may also encounter shortages in the raw materials, therapeutic substances, or active pharmaceutical ingredients necessary to produce our drug candidates in the quantities needed for our clinical trials or, if our drug candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand. Such shortages may occur for a variety of reasons, including capacity constraints, delays or disruptions in the market, and shortages caused by the purchase of such materials by our competitors or others. Our or our third party manufacturers’ failure to obtain the raw materials, therapeutic substances, or active pharmaceutical ingredients necessary to manufacture sufficient quantities of our drug candidates may have a material adverse effect on our business. If for any reason we are unable to obtain adequate supplies of our drug candidates or the components used to manufacture them, it will be more difficult for us to develop our drug candidates and compete effectively.

We rely on acquisitions or licenses from third parties to expand our pipeline of drug candidates.

We are not presently engaged in drug discovery activities. In order to expand our pipeline of drug candidates for future development, we may need to purchase or in-license any such drug candidates. The success of this strategy depends in large part on the combination of our regulatory and development capabilities and expertise and our ability to identify, select and acquire or in-

license clinically-enabled product candidates on terms that are acceptable to us. Identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical expertise, and we have limited experience in identifying and integrating any acquired product candidates into our current infrastructure. Efforts to do so may not result in the actual acquisition or in-license of a particular drug candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to identify, select and acquire or license suitable product candidates from third parties on terms acceptable to us, our business and prospects may be limited.

Risks Related to Our Intellectual Property

Our commercial success is dependent, in part, on obtaining and maintaining patent protection and preserving trade secrets, which cannot be guaranteed.

Patent protection and trade secret protection are important to our business and our future will depend, in part on our ability to maintain trade secret protection, obtain patents and operate without infringing the proprietary rights of others both in the U.S. and abroad. Litigation or other legal proceedings may be necessary to defend against claims of infringement, to enforce our patents or to protect our trade secrets. Such litigation could result in substantial costs and diversion of our management's attention.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. We acquired patents and patent applications related to voruciclib from Presage in 2017, and acquired both issued patents and pending patent applications related to ME-344 from Novogen in relation to its Isoflavone-based compounds, which we previously licensed from Novogen, in 2011. Additionally, Novogen had previously applied for patents in a number of countries with respect to the use of their isoflavone compounds, including ME-344. Finally, in September 2013, we acquired patents and patent applications related to zandelisib from Pathway Therapeutics, Inc.

The patent applications may not proceed to grant or may be amended to reduce the scope of protection of any patent granted. The applications and patents may also be opposed or challenged by third parties. Our commercial success will depend, in part, on our ability to obtain and maintain effective patent protection for our compounds and their use in treating, preventing, or curing cancer, and to successfully defend patent rights in those technologies against third party challenges. As patent applications in the U.S. are maintained in secrecy until published or issued and as publication of discoveries in the scientific or patent literature often lag behind the actual discoveries, we cannot be certain that we or Presage were the first to make the inventions covered by the pending patent applications or issued patents referred to above or that we or they were the first to file patent applications for such inventions. Additionally, the breadth of claims allowed in biotechnology and pharmaceutical patents or their enforceability cannot be predicted. We cannot be sure that, should any patents issue, we will be provided with adequate protection against potentially competitive products. Furthermore, we cannot be sure that should patents issue, they will be of commercial value to us, or that private parties, including competitors, will not successfully challenge our patents or circumvent our patent position in the U.S. or abroad.

Claims by other companies that we infringe on their proprietary technology may result in liability for damages or stop our development and commercialization efforts.

The pharmaceutical industry is highly competitive, and patents have been applied for by, and issued to, other parties relating to products competitive with the compounds that we have acquired. Therefore voruciclib, ME-344, and zandelisib, and any other drug candidates, may give rise to claims that they infringe the patents or proprietary rights of other parties existing now and in the future.

Furthermore, to the extent that we or our consultants or research collaborators use intellectual property owned by others in work performed for us, disputes may also arise as to the rights in such intellectual property or in resulting know-how and inventions. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties.

We have contracted formulation development and manufacturing process development work for our product candidates. This process has identified a number of excipients, or additives to improve drug delivery, which may be used in the formulations. Excipients, among other things, perform the function of a carrier of the active drug ingredient. Some of these identified excipients or carriers may be included in third party patents in some countries. We intend to seek a license if we decide to use a patented excipient in the marketed product or we may choose one of those excipients that does not have a license requirement.

We cannot be sure that any license required under any such patents or proprietary rights would be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we may encounter delays in product market introductions, or may find that the development, manufacture or sale of products requiring such licenses may be precluded.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees and the employees of KKC and third parties upon which we rely to conduct our clinical trials were previously employed at universities or at other biotechnology or pharmaceutical companies, some of which may be competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants, advisors and collaborators who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

We may be subject to substantial costs stemming from our defense against third party intellectual property infringement claims.

Third parties may assert that we are using their proprietary information without authorization. Third parties may also have or obtain patents and may claim that technologies licensed to or used by us infringe their patents. If we are required to defend patent infringement actions brought by third parties, or if we sue to protect our own patent rights, we may be required to pay substantial litigation costs and managerial attention may be diverted from business operations even if the outcome is not adverse to us. In addition, any legal action that seeks damages or an injunction to stop us from carrying on our commercial activities relating to the affected technologies could subject us to monetary liability and require us or any third party licensors to obtain a license to continue to use the affected technologies. We cannot predict whether we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms or at all.

General Business Risks

We face a risk of product liability claims and claims may exceed our insurance limits.

Our business exposes us to the risk of product liability claims. This risk is inherent in the manufacturing, testing and marketing of human therapeutic products. Moreover, regardless of merit or eventual outcome, liability claims can have other adverse consequences, including:

- loss of revenue from decreased demand for our products and/or drug candidates;
- impairment of our business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- diversion of management attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize our drug candidates;
- significant negative media attention;
- decrease in our stock price; or
- initiation of investigations, and enforcement actions by regulators; and product recalls, withdrawals, revocation of approvals, or labeling, marketing or promotional restrictions.

Our product liability insurance coverage is subject to deductibles and coverage limitations. We may not be able to obtain or maintain adequate protection against potential liabilities, or claims may exceed our insurance limits. If we cannot or do not sufficiently insure against potential product liability claims, we may be exposed to significant liabilities, which may materially and adversely affect our business development and commercialization efforts.

Our employees, independent contractors, consultants, commercial partners, principal investigators, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, manufacturers, investigators, or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, comply with federal procurement rules or contract terms, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter this type of misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a False Claims Act, (“FCA”), case against us even if the government considers the claim unmeritorious and declines to intervene, which could require us to incur costs defending against such a claim. Further, due to the risk that a judgment in an FCA case could result in exclusion from federal health programs or debarment from government contracts, whistleblower cases often result in large settlements. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, and results of operations, including the imposition of significant fines or other sanctions.

Our business and operations would suffer in the event of system failures.

Our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug candidate development and, if such drug candidates are approved commercialization programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and regulatory enforcement actions, and the further development of any of our drug candidates could be delayed.

Our efforts will be seriously jeopardized if we are unable to retain and attract key employees.

Our success depends on the continued contributions of our principal management, development and scientific personnel. We face competition for such personnel, and we believe that risks and uncertainties related to our business, including the timing and risk associated with research and development, our available and anticipated cash resources, and the volatility of our stock price, may impact our ability to hire and retain key and other personnel. The loss of services of our Chief Executive Officer or other key employees could adversely impact our operations and ability to generate or raise additional capital.

Negative U.S. and global economic conditions may pose challenges to our business strategy, which relies on funding from the financial markets or collaborators.

Negative conditions in the U.S. or global economy, including financial markets, may adversely affect our business and the business of current and prospective vendors, licensees and collaborators, and others with whom we do or may conduct business. The duration and severity of these conditions is uncertain. If negative economic conditions occur, we may be unable to secure funding on terms satisfactory to us to sustain our operations or to find suitable collaborators to advance our internal programs, even if we achieve positive results from our drug development programs.

Laws, rules and regulations relating to public companies may be costly and impact our ability to attract and retain directors and executive officers.

Laws and regulations affecting public companies, including rules adopted by the SEC and by Nasdaq, may result in increased costs to us. These laws, rules and regulations could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as executive officers. We cannot estimate accurately the amount or timing of additional costs we may incur to respond to these laws, rules and regulations.

Security breaches and privacy issues could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers, as well as personally identifiable information of clinical trial participants and employees. Similarly, our third party providers possess certain of our sensitive protected health data. The secure maintenance of this information is critical to our operations and business strategy. Despite our reasonable security measures, our information technology and infrastructure may be vulnerable to cyber attacks or breached due to employee error, malfeasance or other disruptions. Cyber attacks and other security incidents are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become more sophisticated, and such systems, controls and processes may not be successful in preventing a breach or other incident. Any such security incident could compromise our networks and the information stored there could be accessed, publicly disclosed, encrypted, lost or stolen. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber attacks and other related security incidents.

The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including compliance with the Health Insurance Portability and Accountability Act of 1996 and state laws requiring security breach notification. The collection and use of personal health data of individuals in the European Union is also governed by strict data protection laws. In addition to existing laws, since May 25, 2018, the General Data Protection Regulation (“GDPR”) has imposed obligations with respect to European Union data and substantial fines for breaches of the data protection rules. The GDPR increased our responsibility and potential liability in relation to personal data that we process, and we were required to implement additional mechanisms to comply with the GDPR and related European Union data protection rules. Enforcement uncertainty and the costs associated with ensuring GDPR compliance may be onerous and adversely affect our business, operating results, prospects and financial condition.

We continue to evaluate the legal issues that arise concerning transfer of personal data of residents of the European Economic Area (“EEA”) member states or the U.K. to the U.S. or other jurisdictions that are not deemed adequate by the European Commission. Among other steps, we are implementing the new standard contractual clauses issued on June 4, 2021 by the European Commission. It remains uncertain how these standard contractual clauses will be implemented by the data exporters and data importers and whether they will ultimately be deemed sufficient by European courts. MEI Pharma observes the developments and will agree to the appropriate data transfer mechanism. In addition to standard contractual clauses, we may rely on individual contents of the patients where appropriate and necessary to safeguard the data flow from the EU to the U.S. Present solutions to legitimize transfers of personal data from the EEA may be challenged or deemed insufficient. We may, in addition to other impacts, experience additional costs associated with increased compliance burdens, and we and our customers face the potential for regulators in the EEA or U.K. to apply different standards to the transfer of personal data from the EEA/ U.K. to the U.S., and to block, or require ad hoc verification of measures taken with respect to, certain data flows from the EEA or U.K. to the U.S. We also may be required to engage in new contract negotiations with third parties that aid in processing data on our behalf. We may experience reluctance or refusal by current or prospective European clinical trial sites and CROs to use our products, and we may find it necessary or desirable to make further changes to our processing of personal data of EEA or U.K. data subjects.

Additionally, California has the California Consumer Privacy Act (“CCPA”), which creates individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA may significantly impact our business activities and require substantial compliance costs that adversely affect business, operating results, prospects and financial condition. Amendments to the CCPA mandated by the California Privacy Rights Act (“CPRA”) will impose additional privacy requirements, effective on January 1, 2023. Similarly comprehensive state consumer privacy laws in other states, such as Virginia, Utah, Connecticut and Colorado will also become effective in 2023. These new state privacy measures may reflect the start of a movement in other state legislatures to enact more comprehensive privacy laws, which would create a more complex privacy regulatory landscape for our business in the U.S. In addition, there is privacy legislation and rule making efforts at the federal level which may increase our privacy obligations in the U.S.

Thus, any access, disclosure or other loss of information, including our data being breached at our partners or third party providers, along with violations of privacy laws that exist and are increasing around the world, could result in legal claims or proceedings and liability under laws that protect the privacy of personal information, disrupt our operations and damage our reputation, which could adversely affect our business.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste. Even if we contract with third parties for the disposal of these materials and waste, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Events outside of our control, including natural disasters and public health emergencies, could severely disrupt our operations and have a material adverse effect on our business, operating results, prospects or financial condition. If a natural disaster, or public health emergency such as COVID-19, power outage or other event occurred that prevented us from conducting our clinical trials, including by damaging our critical infrastructure, such as third party facilities, or that otherwise disrupted operations and travel, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business, operating results, prospects or financial condition.

Limitations on the deductibility of net operating losses could adversely affect our business and financial condition.

We have a history of net operating losses. In December 2017, the U.S government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act limits the deduction of net operating losses to 80% of current year taxable income. The limitations on the net operating loss deduction, as well other changes in tax policy, may subject us to additional taxation, adversely affecting our results of operations and financial condition.

Risks Related to Securities Markets and Investment in our Stock

Our business could be negatively impacted as a result of any future activism campaigns by Anson Advisors Inc. and Cable Car Capital LLC and other activist investors.

Anson Advisors Inc. holds approximately 13.0% of our outstanding common stock and Cable Car Capital LLC holds approximately 6.9% of our outstanding common stock, and each have sought to exert influence on our business operations and Board of Directors, and we expect that each will or may continue to do so.

In July 2023, Anson Advisors Inc. and Cable Car Capital LLC initiated a consent solicitation to seek the consent of our stockholders holding at least a majority of our outstanding shares of common stock to, among other things, remove and replace all members of our Board of Directors. On September 18, 2023, we filed our definitive consent revocation statement urging stockholders to revoke their consents and reject the Consent Solicitation.

The Consent Solicitation and our response to it resulted in significant distraction for management and additional capital outlays by us. Continued pursuit or further activities by Anson Advisors Inc. and Cable Car Capital LLC, or by other activist shareholders, could result in yet additional distractions and costs and could lead to a materially adverse impact on our business or operating results.

The trading price of the shares of our common stock has been and may continue to be highly volatile and could decline in value and we may incur significant costs from class action litigation.

The trading price of our common stock could be highly volatile in response to various factors, many of which are beyond our control, including, but not limited to, the following:

- failure to successfully develop our drug candidates;
- design, results and timing of clinical trials and pre-clinical studies;
- announcements of technological innovations by us or our competitors;
- new products introduced or announced by us or our competitors;
- changes in financial estimates by securities analysts;
- actual or anticipated variations in operating results;
- expiration or termination of licenses, research contracts or other collaboration agreements;
- conditions or trends in the regulatory climate and the biotechnology, pharmaceutical and genomics industries;
- instability in the stock market as a result of current or future domestic and global events;
- changes in the market valuations of similar companies;
- the liquidity of any market for our securities; and
- threatened or actual delisting of our common stock from a national stock exchange.

Equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. In addition, changes in economic conditions in the U.S., the Europe or globally, particularly in the context of current global events, could impact upon our ability to grow profitably. Adverse economic changes are outside our control and may result in material adverse impacts on our business or our results of operations. These broad market and industry factors may materially affect the market price of shares of our common stock, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources.

Future sales of our common stock, including common stock issued upon exercise of outstanding warrants or options, may depress the market price of our common stock and cause stockholders to experience dilution.

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, including upon exercise of outstanding warrants or stock options, and any subsequent sales of such shares. As of June 30, 2023, we had outstanding warrants exercisable to purchase 102,513 shares of common stock at an exercise price of \$6.80 per share, which expire in October 2027. We also have outstanding options to purchase 1,284,907 shares of common stock. We may seek additional capital through one or more additional equity transactions in the future; however, such transactions will be subject to market conditions and there can be no assurance any such transactions will be completed. If we sell shares in the future, the prices at which we sell these future shares will vary, and these variations may be significant. Stockholders will experience significant dilution if we sell these future shares at prices significantly below the price at which such previous stockholders invested.

Because we do not intend to pay, and have not paid, any cash dividends on our shares of common stock, our stockholders will not be able to receive a return on their shares unless the value of our common stock appreciates and they sell their shares.

We have never paid or declared any cash dividends on our common stock, and we intend to retain any future earnings to finance the development and expansion of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Therefore, our stockholders will not be able to receive a return on their investment unless the value of our common stock appreciates and they sell their shares.

We will have broad discretion over the use of the net proceeds from any exercise of outstanding warrants and options.

We will have broad discretion to use the net proceeds to us upon any exercise of outstanding warrants and options, and investors in our stock will be relying on the judgment of our board of directors and management regarding the application of these proceeds. Although we expect to use a substantial portion of the net proceeds from any exercise of the warrants and options for general corporate purposes and progression of our clinical trial programs, we have not allocated these net proceeds for specific purposes.

We are authorized to issue blank check preferred stock, which could adversely affect the holders of our common stock.

Our amended and restated certificate of incorporation allows us to issue blank check preferred stock with rights potentially senior to those of our common stock without any further vote or action by the holders of our common stock. The issuance of a class of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of our common stock or

could adversely affect the rights and powers, including voting rights, of such holders. In certain circumstances, such issuance could have the effect of decreasing the market price of our shares or making a change in control of the company more difficult.

Anti-takeover provisions contained in our amended and restated certificate of incorporation and fifth amended and restated bylaws, as well as provisions of Delaware law, could impair a takeover attempt.

Our amended and restated certificate of incorporation and fifth amended and restated bylaws contain provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. We are also subject to anti-takeover provisions under Delaware law, which could delay or prevent a change of control. Together, these provisions may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities. These provisions include:

- a staggered board providing for three classes of directors, which limits the ability of a stockholder or group to gain control of our board;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the right of our board to elect a director to fill a vacancy created by the expansion of our board or the resignation, death or removal of a director in certain circumstances, which prevents stockholders from being able to fill vacancies on our board; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board or to propose matters to be acted upon at a meeting of stockholders, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Our fifth amended and restated bylaws require, to the fullest extent permitted by law, that derivative actions brought in our name, actions against our directors, officers, other employees or stockholders for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel, which may have the effect of discouraging lawsuits against our directors, officers, other employees or stockholders.

Our fifth amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for any stockholder to bring (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of ours to us or our stockholders, (iii) any action asserting a claim pursuant to any provision of the Delaware General Corporation Law, or (iv) any action asserting a claim governed by the internal affairs doctrine, and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel, provided, however, that, in each case, if the Court of Chancery does not have jurisdiction, the forum for such action shall be another state court located within the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal district court for the District of Delaware, in all cases subject to the court having personal jurisdiction over the indispensable parties named as defendants therein.

Any person or entity purchasing or otherwise acquiring or holding any interest in our shares of capital stock shall be deemed to have notice of and consented to such provisions.

Notwithstanding the foregoing, the forum selection provision of our fifth amended and restated bylaws will not apply to suits brought to enforce any liability or duty created by the federal securities laws or any other claim for which the federal district courts of the U.S. of America shall be the sole and exclusive forum.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision contained in our fifth amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

Our executive officers and directors may sell shares of their stock, and these sales could adversely affect our stock price.

Sales of our stock by our executive officers and directors, or the perception that such sales may occur, could cause the market price of our common stock to decline or could make it more difficult for us to raise funds through the sale of equity in the future, either as part, or outside, of trading plans under Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We occupy approximately 45,100 square feet of office space in San Diego, California under a lease that expires in November 2029. We believe our current office space is adequate for our immediate needs and that suitable additional space will be available as and when needed.

Item 3. Legal Proceedings

We are not currently a party to a significant legal proceeding that we believe will have a material adverse effect on our business or financial conditions.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is listed on the Nasdaq Capital Market under the symbol "MEIP".

Holdings

As of September 8, 2023, there were 6,662,857 shares of our common stock outstanding and 360 holders of record of our common stock. This number was derived from our stockholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

For a discussion of outstanding warrants and other securities exercisable for or convertible into shares of our common stock, see *Note 6 - Stockholders' Equity* and *Note 7 - Share-based Compensation* under *Item 8* in this Annual Report.

Dividends

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

Securities authorized for issuance under equity compensation plans

The table below shows, as of June 30, 2023, information for equity compensation plans previously approved by stockholders and for compensation plans not previously approved by stockholders.

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 security holders (1)	1,162,810	\$39.88	573,773
Equity compensation plans not approved by security holders (2)	122,097	23.43	94,903
Total	1,284,907	\$38.32	668,676

- (1) Consists of 1,162,810 shares of common stock issuable upon exercise of options granted under the MEI Pharma, Inc. Amended and Restated 2008 Stock Omnibus Equity Compensation Plan ("Omnibus Plan"), under which 1,850,739 shares of common stock are authorized for issuance. The Omnibus Plan provides for the grant of options and/or other stock-

based or stock-denominated awards to our non-employee directors, officers, employees and advisors. The weighted-average exercise price presented is the weighted-average exercise price of vested and unvested options.

- (2) Consists of 122,097 shares of common stock issuable upon exercise of options granted under the MEI Pharma, Inc. 2021 Inducement Plan (“Inducement Plan”), under which 217,000 shares of common stock are authorized for issuance. The Inducement Plan provides for the grant of options and/or other stock-based or stock-denominated awards to attract and retain selected individuals to serve as employees. The weighted-average exercise price presented is the weighted-average exercise price of vested and unvested options.

Item 6. [Reserved]

Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with “*Item 8. Consolidated Financial Statements and Supplementary Data*” included below in this Annual Report. Operating results are not necessarily indicative of results that may occur in future periods.

This discussion and analysis contains forward-looking statements that involve a number of risks, uncertainties and assumptions. Actual results may differ materially from those anticipated in the forward-looking statements as a result of many factors including, but not limited to, those set forth under “Cautionary Statement About Forward-Looking Statements” and “Risk Factors” in *Item 1A. Risk Factors* included above in this Annual Report. All forward-looking statements included in this Annual Report are based on the information available to us as of the time we file this Annual Report, and except as required by law, we undertake no obligation to update publicly or revise any forward-looking statements.

Overview

MEI Pharma, Inc. (Nasdaq: MEIP) is a clinical-stage pharmaceutical company committed to developing novel and differentiated cancer therapies. We build our pipeline by acquiring promising cancer agents and creating value in programs through development, strategic partnerships, and out-licensing or commercialization, as appropriate. Our approach to oncology drug development is to evaluate our drug candidates in combinations with standard-of-care therapies to overcome known resistance mechanisms and address clear medical needs to provide improved patient benefit. Our pipeline includes voruciclib, an oral cyclin-dependent kinase 9 (“CDK9”) inhibitor, and ME-344, an intravenous small molecule mitochondrial inhibitor targeting the oxidative phosphorylation pathway. Our common stock is listed on the Nasdaq Capital Market under the symbol “MEIP.”

Clinical Development Programs

Our clinical-stage drug candidate pipeline includes voruciclib, an oral cyclin-dependent kinase 9 (“CDK9”) inhibitor and ME-344, an intravenous small molecule targeting the oxidative phosphorylation pathway in the mitochondria.

For a more complete discussion of our business, see the section of this Annual Report “*Item 1. Business*” above.

Recent Developments

Merger with Infinity Pharmaceuticals, Inc.

In February 2023, we, Infinity Pharmaceuticals, Inc. (“Infinity”), and Meadow Merger Sub, Inc., our wholly owned subsidiary (“Merger Sub”) entered into an agreement and plan of merger (“Merger Agreement”). The Merger Agreement provided that Merger Sub will merge with and into Infinity, with Infinity being the surviving entity as a wholly owned subsidiary of us and was subject to approvals by our and Infinity’s stockholders, respectively. On July 23, 2023, we convened our Special Meeting of Stockholders at which time our stockholders did not approve the proposed transaction and subsequently, we delivered a letter to Infinity which terminated the Merger Agreement pursuant to Section 7.2(c) of the Merger Agreement, effective July 23, 2023.

Kyowa Kirin License, Development and Commercialization Agreement

On April 13, 2020, we entered into a License, Development and Commercialization Agreement (the “Original Agreement”) with KKC, effective as of April 13, 2020. Pursuant to the terms of the Original Agreement, We and KKC agreed to terminate the License, Development and Commercialization Agreement dated October 31, 2018 (the “JP Agreement”) and to expand the scope of the JP Agreement to collaborate on the development, manufacturing and commercialization of ME-401 globally in accordance with the Original Agreement.

On July 14, 2023, we entered into a Termination Agreement with KKC to mutually terminate the Original Agreement, effective July 14, 2023, and all other related agreements between the parties. Pursuant to the Termination Agreement:

- We regained full, global rights to develop, manufacture and commercialize ME-401, subject to KKC's limited rights to use ME-401 for “compassionate use” (as more specifically defined in the Termination Agreement) in certain expanded access programs for the existing patients who have been enrolled in Japanese clinical trial sponsored by KKC until November 30, 2027, and for which KKC is fully liable;
- each party released the other party from any and all claims, demands, etc. arising from the Original Agreement, excluding certain surviving claims; and
- we are obligated to deliver a discrete quantity of materials to facilitate KKC's activities.

We anticipate completing the wind down activities related to the KKC License, Development and Commercialization Agreement during the second quarter of fiscal year 2024.

Consent Solicitation

In July 2023, Anson Advisors Inc. and Cable Car Capital LLC initiated a consent solicitation to seek the consent of our stockholders holding at least a majority of our outstanding shares of common stock to, among other things, remove and replace all members of our Board of Directors for cause (the “Consent Solicitation”). On September 18, 2023, we filed our definitive consent revocation statement urging stockholders to revoke their consents and reject the Consent Solicitation.

Equity Transactions

Underwritten Registered Offering

During the year ended June 30, 2022, we completed an underwritten registered offering of 1,006,250 shares of common stock at a price per share of \$52.00 for net cash proceeds of \$48.7 million, after offering costs of \$3.7 million.

Shelf Registration Statement

We had a shelf registration statement that permits us to sell, from time to time, up to \$200.0 million of common stock, preferred stock and warrants. The shelf registration was filed and declared effective in May 2020, replacing a prior shelf registration statement that was filed and declared effective in May 2017, and carried forward approximately \$107.5 million of unsold securities registered under the prior shelf registration statement. The shelf registration expired on May 18, 2023.

At-The-Market Equity Offering

On November 10, 2020, we entered into an At-The-Market Equity Offering Sales Agreement (the “2020 ATM Sales Agreement”), pursuant to which we may sell an aggregate of up to \$60.0 million of our common stock pursuant to the shelf registration statement. There were no sales under the 2020 ATM Sales Agreement during the years ended June 30, 2023 and 2022, and the 2020 ATM Sales Agreement expired in conjunction with the shelf registration on May 18, 2023.

Warrants

In May 2023, outstanding warrants to purchase 802,949 shares of our common stock expired. The warrants were fully vested and exercisable at a price of \$50.80 per share. Pursuant to the terms of the warrants, we could have been required to settle the warrants in cash in the event of an acquisition of the company and, as a result, the warrants were required, prior to their expiration, to be measured at fair value and reported as a liability in the consolidated balance sheets. As of June 30, 2022 the warrants were valued at \$1.6 million. Prior to their expiration, the warrants had been revalued to \$0, as of December 31, 2022. All corresponding changes in fair value were recorded as a component of other income (expense) in our consolidated statements of operations. No warrants were exercised during the years ended June 30, 2023 and 2022. The warrants expired in May 2023.

As of June 30, 2023, we have outstanding warrants to purchase 102,513 shares of our common stock, all issued to Torreya Partners. The warrants are fully vested, exercisable at a price of \$6.80 per share and expire in October 2027.

Critical Accounting Estimates

Critical accounting policies are those most important to the portrayal of our financial condition and results of operations and require management's difficult, subjective, or complex judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Certain accounting estimates are particularly sensitive because of their significance to financial statements and because of the possibility future events affecting the estimate may differ

significantly from management's current judgments. We believe the following critical accounting policies involve the most significant estimates and judgments used in the preparation of our consolidated financial statements.

There have been no material changes from the critical accounting estimates identified below nor our significant accounting policies set forth in *Note 1—The Company and Summary of Significant Accounting Policies*.

Revenue Recognition

We apply the five-step revenue recognition model within the scope of ASC Topic 606, Revenue from Contracts with Customers (ASC 606). Under this model, we: (i) identify the contract, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when, or as, a company satisfies a performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service and is the unit of accounting in ASC 606. A contract's transaction price is allocated among each distinct performance obligation based on relative standalone selling price and recognized as revenue when, or as, the applicable performance obligation is satisfied.

The terms of our arrangements include upfront and license fees, research and development services, milestone and other contingent payments for the achievement of defined objectives and certain preclinical, clinical, regulatory and sales-based events, as well as royalties on sales of commercialized products. Agreements with certain upfront payments may require deferral of revenue recognition to a future period until we perform the obligations under these agreements. We use the most likely amount method to estimate variable consideration for event-based milestones and other contingent payments. Given the high degree of uncertainty around the occurrence of such events, the event-based milestones and other contingent payments have been fully constrained until any uncertainty associated with these payments is resolved. Revenue from sales-based milestones and royalty payments is recognized at the later of when or as the sales occur or when the related performance obligation has been satisfied or partially satisfied. We continue to re-evaluate the transaction price in each reporting period as contingencies are resolved and other changes in circumstances occur.

Revenue recognition is subject to uncertainty due to the variable consideration estimates required to be made. These estimates include the level of effort required to satisfy our obligations under our research and development services arrangements. These amounts are estimated at the inception of the services arrangement and are re-evaluated at each reporting period. To accomplish this, we rely on management's experience, relevant internal data reports and regulatory approvals. The recorded variable consideration is directly sensitive to the estimated inputs made by management used in the calculation. Changes in estimates are accounted for prospectively.

As discussed above in *Recent Developments*, in response to the discontinuance of zandelisib development with KKC during the year ended June 30, 2023, we updated our estimated costs to complete each of the performance obligations, which resulted in a higher progress towards completion based on the ratio of costs incurred to date to the total estimated costs and a corresponding decrease in our deferred revenue. Additionally, we recognized revenue related to non-refundable payments for performance obligations that have not commenced and will no longer be initiated.

Research and Development Costs

Research and development costs are expensed as incurred and include costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials. Clinical trial costs, including costs associated with third-party contractors, are a significant component of research and development expenses and we expense research and development costs based on work performed. In determining the amount to expense, management relies on estimates of total costs based on contract components completed, the enrollment of subjects, the completion of trials, and other events. Costs incurred related to the purchase or licensing of in-process research and development for early-stage products or products that are not commercially viable and ready for use, or have no alternative future use, are charged to expense in the period incurred.

As part of the process of preparing the consolidated financial statements, we are required to estimate expenses resulting from obligations under contracts with vendors, clinical research organizations (CROs), consultants and under clinical site agreements relating to conducting clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

Our objective is to reflect the appropriate clinical trial expenses in our consolidated financial statements by recording those expenses in the period in which services are performed and efforts are expended. We account for these expenses according to the progress of the clinical trial as measured by patient progression and the timing of various aspects of the trial. Management determines accrual estimates through financial models and discussions with applicable personnel and outside service providers as to the progress of clinical trials.

During a clinical trial, we adjust the clinical expense recognition if actual results differ from our estimates. We make estimates of accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. Our clinical trial accruals

are partially dependent upon accurate reporting by CROs and other third-party vendors. Our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in changes in our estimates.

Results of Operations

Comparison of Years Ended June 30, 2023 and 2022

Revenue: We recognized revenue of \$48.8 million for the year ended June 30, 2023, compared to \$40.7 million for the year ended June 30, 2022. As a result of the discontinuation of the zandelisib program, we updated our estimated costs to complete each performance obligation, resulting in a higher progress towards completion based on the ratio of costs incurred to date to the total estimated costs, resulting in the recognition of \$16.6 million of previously deferred revenue related to performance obligations that are being closed. We also recognized \$8.6 million of previously deferred revenue related to performance obligations associated with clinical trials that have not commenced and will no longer be initiated. This increase in revenue is offset by a decrease in reimbursement of expenses from KKC due to the discontinuation of the zandelisib program in December 2022.

Research and Development: The following table illustrates the components of our research and development expenses for the years presented (in thousands):

	Years Ended June 30,	
	2023	2022
zandelisib	\$ 25,900	\$ 54,764
voruciclib	2,335	5,475
ME-344	1,137	2,915
Other	23,078	22,487
Total research and development expenses	<u>\$ 52,450</u>	<u>\$ 85,641</u>

Research and development expenses consist primarily of clinical trial costs, including payments to contract research organizations ("CROs"), pre-clinical study costs, and costs to manufacture our drug candidates for non-clinical and clinical studies. Other research and development expenses consist primarily of salaries and personnel costs, share-based compensation, legal costs, and other costs not allocated to specific drug programs. Costs related to zandelisib decreased \$28.9 million primarily as a result of the discontinuation of the program during the year ended June 30, 2023, which resulted in decreased clinical trial, manufacturing, and consultant costs. Costs related to voruciclib decreased \$3.1 million due to lower drug manufacturing costs and clinical costs related to the Phase 1 study. Costs related to ME-344 decreased \$1.8 million primarily due to decreased drug manufacturing costs. Other research and development costs increased \$0.6 million primarily due to a \$2.8 million increase in severance costs due to a reduction in force during the year ended June 30, 2023 and an increase in payroll and related expenses of \$0.4 million, partially offset by a decrease of \$1.9 million in noncash stock-based compensation and \$0.9 million decrease in recruitment costs.

General and Administrative: General and administrative expenses increased \$2.6 million to \$33.1 million for the year ended June 30, 2023, compared to \$30.5 million for the year ended June 30, 2022. The net increase was primarily due to \$2.0 million in severance costs due to our reduction in force in the current year with no similar expense in the prior year, as well as increases in external professional services of \$1.8 million, corporate overhead costs of \$1.2 million and payroll and related expenses of \$0.5 million, partially offset by a \$2.9 million decrease in noncash stock-based compensation.

Other Income, Net: Other income, net, decreased by \$16.1 million to \$4.9 million for the year ended June 30, 2023, as compared to \$21.0 million for the year ended June 30, 2022. We recorded a noncash gain of \$1.6 million during the year ended June 30, 2023, due to a change in the fair value of our warrant liability compared to a noncash gain of \$20.8 million during the year ended June 30, 2022. The warrants expired in May 2023. Additionally, we received interest and dividend income of \$3.3 million for the year ended June 30, 2023, compared to \$0.3 million for the year ended June 30, 2022. The increase is primarily due to higher yields during the year ended June 30, 2023, compared to the prior period.

New Accounting Pronouncements

See *Note 1. "The Company and Summary of Significant Accounting Policies,"* to the Consolidated Financial Statements included in *Item 8* of this Annual Report.

Liquidity and Capital Resources

We have accumulated losses of \$406 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of June 30, 2023, we had \$101 million in cash, cash equivalents and short-term investments. We believe our cash balance is sufficient to fund operations for at least the next 12 months, and through the reporting of clinical data readouts from the ongoing and planned voruciclib and ME-344 Phase 1 and Phase 1b clinical programs, respectively. Our

current business operations are focused on continuing the clinical development of our drug candidates. Changes to our research and development plans or other changes affecting our operating expenses may affect actual future use of existing cash resources. Our research and development expenses are expected to increase in the foreseeable future. We cannot determine with certainty costs associated with ongoing and future clinical trials or the regulatory approval process. The duration, costs and timing associated with the development of our product candidates will depend on a variety of factors, including uncertainties associated with the results of our clinical trials.

To date, we have obtained cash and funded our operations primarily through equity financings and license agreements. In order to continue the development of our drug candidates, at some point in the future we expect to pursue one or more capital transactions, whether through the sale of equity securities, debt financing, license agreements or entry into strategic partnerships. There can be no assurance that we will be able to continue to raise additional capital in the future.

Sources and Uses of Our Cash

Net cash used in operating activities for the year ended June 30, 2023, of \$52.5 million consisted of our net loss of \$31.8 million and \$24.9 million cash used by operating activities partially offset by \$4.3 million for noncash items. Net cash used in in operating activities during the year ended June 30, 2022, of \$48.7 million (\$68.7 million, net of \$20.0 million of milestone payments received from KKC) consisted of our net loss of \$54.5 million and adjustments for noncash items of \$11.2 million partially offset by cash provided by operating activities of \$16.9 million.

Net cash provided by investing activities for the year ended June 30, 2023, was \$53.7 million compared to \$6.9 million for the year ended June 30, 2022. The increase in net cash provided by investing activities was due to a higher amount of maturities and fewer purchases of short-term investments during the year ended June 30, 2023, due to maturities being utilized to fund ongoing operations when compared to the level of maturities and purchases for the year ended June 30, 2022.

Net cash used in financing activities for the year ended June 30, 2023, was immaterial compared to \$49.1 million of cash provided by financing activities for the year ended June 30, 2022. The decrease from prior year was primarily due to cash raised during the year ended June 30, 2022, that included \$48.7 million of net proceeds from the issuance of common stock.

Capital Resource Requirements

In January 2022, we amended our facility lease for an additional 20 months through November 2029. The amended lease agreement also provided for additional lease space that we took control over on July 1, 2022. Under the terms of the lease, we are obligated to make aggregate remaining lease payments as of June 30, 2023, of \$16.4 million, excluding common area maintenance and other variable consideration due under the lease agreement. Estimated lease payments for the fiscal year ended June 30, 2024 are expected to be \$2.3 million, excluding common area maintenance and other variable consideration due under the lease agreement.

As of June 30, 2023, we have the following potential purchase obligations for which the timing and/or likelihood of occurrence is unknown; however, if such claims arise in the future, they could have a material effect on our financial position, results of operations, and cash flows.

- Under our remaining license agreements, we have payment obligations, which are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and are required to make royalty payments in connection with the sales of products developed under those agreements. For additional details regarding these agreements, see the section titled *Note 3—Other License Agreements* and *Note 8—Commitments and Contingencies* to our consolidated financial statements and related notes included elsewhere in this Annual Report;
- Obligations under contracts which are cancelable without significant penalty;
- Purchase orders issued in the ordinary course of business as they represent authorizations to purchase the items rather than binding agreements; and
- Contracts in the normal course of business with clinical supply manufactures and with vendors for preclinical studies, research supplies and other services and products for operating purposes. These contracts are cancelable and generally provide for termination after a notice period.

Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of establishing or contracting for sales, marketing and distribution capabilities if we obtain regulatory approvals to market our product candidates;

- the costs of securing and producing drug substance and drug product material for use in preclinical studies, clinical trials and for use as commercial supply;
- the costs of securing manufacturing arrangements for development activities and commercial production;
- the scope, prioritization and number of our research and development programs;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Item 7a. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Our exposure to market interest rates relates primarily to our cash, cash equivalents and short-term investments. We have cash reserves held in U.S. dollars, and we place funds on deposit with financial institutions, which are readily available. Our short-term investments consist solely of U.S. government securities with a maturity of three to twelve months.

We place our cash deposits with high credit quality financial institutions and, by policy, limit the amount of credit exposure to any one corporation or bank. These deposits are in excess of the Federal Deposit Insurance Corporation insurance limits. We are adverse to principal loss and we ensure the safety and preservation of our invested funds by limiting default risk, market risk and reinvestment risk. We seek to mitigate default risk by depositing funds with high credit quality financial institutions, by limiting the amount of credit exposure to any one corporation or bank, by purchasing short-term investments consisting of U.S. government securities, and by positioning our portfolio to respond appropriately to a significant reduction in a credit rating of any such financial institution.

We do not consider the effects of interest rate movements to be a material risk to our financial condition.

Inflation Risk

Inflation generally affects us by increasing our clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations during the years ended June 30, 2023 and 2022.

Item 8. Consolidated Financial Statements and Supplementary Data

MEI Pharma, Inc.

Index to Consolidated Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and Board of Directors

MEI Pharma, Inc.

San Diego, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of MEI Pharma, Inc. (the "Company") as of June 30, 2023 and 2022, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at June 30, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Estimation of accrued pre-clinical and clinical trial expenses

As described in Notes 1 and 5 of the consolidated financial statements, the Company had accrued pre-clinical and clinical trial expenses of \$3.7 million as of June 30, 2023. Clinical trial costs, including costs associated with third-party contractors, are a significant

component of research and development expenses. In determining the amount of accrued pre-clinical and clinical trial expenses incurred, management relies on estimates of total costs based on contract components completed, the enrollment of subjects, the completion of trials, and other events.

We identified the estimation of accrued pre-clinical and clinical trial expenses as a critical audit matter. Evaluating the progress or stage of completion of the activities under the Company's research and development agreements is dependent upon multiple points of data from third-party service providers and internal clinical personnel. Additionally, due to the duration of clinical-related development activities, the estimate of accrued pre-clinical and clinical trial expenses incurred requires judgment based on the nature and amounts of ongoing activities, the status of each activity, and the estimated progress for each key activity. Auditing these elements involved especially challenging and subjective auditor judgment due to the nature and extent of auditor effort required to address the matter.

The primary procedures we performed to address this critical audit matter included:

- Assessing the nature and extent of progress of clinical trial activities based on inquiries of the Company's research and development personnel, which were corroborated through inspection of meeting minutes maintained by the Company related to clinical trial and project status meetings held with various third parties.
- Developing independent estimates of the costs incurred for certain activities performed by third parties utilizing information from internal and external sources and comparing expected amounts to the amounts recorded by the Company.
- Evaluating the completeness of the accrued clinical trial expenses by comparing invoices received by the Company subsequent to June 30, 2023 to the amounts accrued by the Company.

/s/ BDO USA, P.C.

We have served as the Company's auditor since 2011.

San Diego, California

September 26, 2023

MEI PHARMA, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value amounts)

	June 30,	
	2023	2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 16,906	\$ 15,740
Short-term investments	83,787	137,512
Unbilled receivables	85	10,044
Prepaid expenses and other current assets	6,750	3,830
Total current assets	107,528	167,126
Operating lease right-of-use asset	11,972	9,054
Property and equipment, net	1,309	1,660
Total assets	<u>\$ 120,809</u>	<u>\$ 177,840</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 6,134	\$ 7,918
Accrued liabilities	12,461	10,820
Deferred revenue	317	4,834
Operating lease liability	1,428	871
Total current liabilities	20,340	24,443
Deferred revenue, long-term	64,545	90,610
Operating lease liability, long-term	11,300	8,771
Warrant liability	—	1,603
Total liabilities	96,185	125,427
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 100 shares authorized; none outstanding	—	—
Common stock, \$0.00000002 par value; 226,000 shares authorized; 6,663 and 6,658 shares issued and outstanding at June 30, 2023 and 2022, respectively.	—	—
Additional paid-in capital	430,621	426,572
Accumulated deficit	(405,997)	(374,159)
Total stockholders' equity	24,624	52,413
Total liabilities and stockholders' equity	<u>\$ 120,809</u>	<u>\$ 177,840</u>

See accompanying notes to consolidated financial statements.

MEI PHARMA, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Years Ended June 30,	
	2023	2022
Revenue	\$ 48,816	\$ 40,697
Operating expenses:		
Research and development	52,450	85,641
General and administrative	33,130	30,540
Total operating expenses	85,580	116,181
Loss from operations	(36,764)	(75,484)
Other income (expense):		
Change in fair value of warrant liability	1,603	20,752
Interest and dividend income	3,345	284
Other expense, net	(22)	(6)
Total other income, net	4,926	21,030
Net loss	\$ (31,838)	\$ (54,454)
Net loss:		
Basic	\$ (31,838)	\$ (54,454)
Diluted	\$ (31,838)	\$ (62,500)
Net loss per share:		
Basic	\$ (4.78)	\$ (8.75)
Diluted	\$ (4.78)	\$ (9.99)
Weighted-average shares used in computing net loss per share:		
Basic	6,663	6,224
Diluted	6,663	6,257

See accompanying notes to consolidated financial statements.

MEI PHARMA, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Common Shares	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at June 30, 2021	5,631	\$ 369,171	\$ (319,705)	\$ 49,466
Net loss	—	—	(54,454)	(54,454)
Issuance of common stock, net of issuance costs of \$3,652	1,006	48,673	—	48,673
Issuance of common stock for vested restricted stock units	3	(194)	—	(194)
Exercise of stock options	18	572	—	572
Share-based compensation expense	—	8,350	—	8,350
Balance at June 30, 2022	6,658	426,572	(374,159)	52,413
Net loss	—	—	(31,838)	(31,838)
Issuance of common stock for vested restricted stock units	5	(40)	—	(40)
Issuance of warrants	—	500	—	500
Share-based compensation expense	—	3,589	—	3,589
Balance at June 30, 2023	<u>6,663</u>	<u>\$ 430,621</u>	<u>\$ (405,997)</u>	<u>\$ 24,624</u>

See accompanying notes to consolidated financial statements.

MEI PHARMA, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended June 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (31,838)	\$ (54,454)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of warrant liability	(1,603)	(20,752)
Share-based compensation	3,589	8,350
Issuance of warrants	500	—
Non-cash lease expense	1,429	909
Depreciation expense	386	326
Changes in operating assets and liabilities:		
Unbilled receivables	9,959	(2,462)
Prepaid expenses and other current assets	(2,920)	(21)
Accounts payable	(1,784)	1,563
Accrued liabilities	1,641	2,418
Deferred revenue	(30,582)	16,222
Operating lease liability	(1,261)	(845)
Net cash used in operating activities	<u>(52,484)</u>	<u>(48,746)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(35)	(479)
Purchases of short-term investments	(101,764)	(272,652)
Proceeds from maturity of short-term investments	155,489	280,023
Net cash provided by investing activities	<u>53,690</u>	<u>6,892</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock, gross	—	52,325
Payment of issuance costs	—	(3,652)
Proceeds from exercise of stock options	—	572
Payments of tax withholdings related to vesting of restricted stock units	(40)	(194)
Net cash (used in) provided by financing activities	<u>(40)</u>	<u>49,051</u>
Net increase in cash and cash equivalents	1,166	7,197
Cash and cash equivalents at beginning of the year	15,740	8,543
Cash and cash equivalents at end of the year	<u>\$ 16,906</u>	<u>\$ 15,740</u>
Supplemental cash flow information:		
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	\$ 4,347	\$ 2,189

See accompanying notes to consolidated financial statements.

MEI PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. The Company and Summary of Significant Accounting Policies

The Company

MEI Pharma, Inc. (Nasdaq: MEIP) is a clinical-stage pharmaceutical company committed to developing novel and differentiated cancer therapies. We build our pipeline by acquiring promising cancer agents and creating value in programs through development, strategic partnerships, and out-licensing or commercialization, as appropriate. Our approach to oncology drug development is to evaluate our drug candidates in combinations with standard-of-care therapies to overcome known resistance mechanisms and address clear medical needs to provide improved patient benefit. Our pipeline includes voruciclib, an oral cyclin-dependent kinase 9 (“CDK9”) inhibitor, and ME-344, an intravenous small molecule mitochondrial inhibitor targeting the oxidative phosphorylation pathway. Our common stock is listed on the Nasdaq Capital Market under the symbol “MEIP.”

On April 14, 2023, we amended our Certificate of Incorporation to affect a combination of our issued and outstanding common stock at a ratio of one-for-twenty (“Reverse Stock Split”). The par value and authorized shares of our common stock were not adjusted as a result of the Reverse Stock Split. The Reverse Stock Split was effective on April 14, 2023, with a market effective date of April 17, 2023. All historical share and per share amounts have been adjusted to reflect the Reverse Stock Split for all periods presented. All stock options, restricted stock units and warrants outstanding were ratably adjusted to give effect to the Reverse Stock Split.

Merger with Infinity Pharmaceuticals, Inc.

In February 2023, we, Infinity Pharmaceuticals, Inc. (“Infinity”), and Meadow Merger Sub, Inc., our wholly owned subsidiary (“Merger Sub”) entered into an agreement and plan of merger (“Merger Agreement”). The Merger Agreement provided that Merger Sub will merge with and into Infinity, with Infinity being the surviving entity as a wholly owned subsidiary of us (transaction referred to as the “Merger”) and was subject to approvals by our and Infinity’s stockholders, respectively. On July 23, 2023, we convened our Special Meeting of Stockholders at which time our stockholders did not approve the proposed transaction and subsequently, we delivered a letter to Infinity which terminated the Merger Agreement pursuant to Section 7.2(c) of the Merger Agreement, effective July 23, 2023.

Basis of Presentation and Consolidation

We prepared the consolidated financial statements in accordance with accounting principles generally accepted in the United States (GAAP) and the rules and regulations of the Securities and Exchange Commission (SEC) related to annual reports on Form 10-K. The accompanying consolidated financial statements include the accounts of MEI Pharma, Inc. and our wholly owned subsidiary, Meadow Merger Sub, Inc. We have eliminated all significant intercompany accounts and transactions in consolidation.

Current Events and Reduction in Force

In November 2022, we and Kyowa Kirin Co., Ltd. (“KKC”) met with the U.S. Food and Drug Administration (“FDA”) in a follow-up meeting to the March 2022 end of Phase 2 meeting related to zandelisib. At this meeting, the FDA provided further guidance regarding the design and statistical analysis for the COASTAL trial. Following the November meeting, the companies jointly concluded that a clinical trial consistent with the recent FDA guidance, including modification of the ongoing COASTAL trial, would likely not be feasible to complete within a time period that would support further investment or with sufficient certainty of the regulatory requirements for approval to justify continued global development efforts. As a result, we and KKC jointly decided to discontinue global development of zandelisib for indolent forms of non-Hodgkin lymphoma outside of Japan.

The discontinuation of zandelisib development outside of Japan was a business decision based on the most recent regulatory guidance from the FDA and is not related to the zandelisib clinical data generated to date. KKC is continuing certain ongoing Japanese clinical trials, including the Phase 2 MIRAGE trial evaluating Japanese patients with relapsed or refractory indolent B-cell non-Hodgkin lymphomas, and will explore submitting the MIRAGE and TIDAL trials for marketing authorization in Japan. MIRAGE is a Phase 2 trial, similar in design to the global Phase 2, single-arm, TIDAL trial. In November 2022, we and KKC announced positive top line data from the Phase 2 MIRAGE trial. KKC has been evaluating whether to continue developing zandelisib in Japan and after meeting with the Pharmaceuticals and Medical Devices Agency (“PMDA”) has concluded that conducting a randomized study consistent with agency guidance to support a marketing application would likely not be feasible to complete within a time period that would support further investment. As a result, in May 2023, KKC decided to discontinue development of zandelisib in Japan. The discontinuation of zandelisib in Japan was a business decision by KKC based on the most recent regulatory guidance from the PMDA and is not related to the zandelisib clinical data generated to date.

In light of KKC’s decision to discontinue development of zandelisib in Japan, as well as the prior joint decision to discontinue zandelisib development outside of Japan, on July 14, 2023, the parties entered into a Termination Agreement to mutually terminate the

global License, Development and Commercialization Agreement executed in April 2020, as further discussed in *Note 11. Subsequent Events*.

Prior to June 30, 2023, we and KKC had begun closing all ongoing zandelisib clinical studies outside of Japan, including the Phase 3 COASTAL trial, the Phase 2 TIDAL trial, and the Phase 2 CORAL trial.

In connection with our joint decision to discontinue development of zandelisib outside of Japan, in December 2022, we announced a realignment of our clinical development efforts that streamline our organization towards the continued clinical development of our two earlier clinical-stage assets, voruciclib and ME-344. As a result, also in December 2022, our board of directors approved a staggered workforce reduction (the "Reduction in Force"), initially affecting 28 employees in December 2022 and an additional 26 employees through June 2023, representing an aggregate 51% Reduction in Force. In connection with the Reduction in Force, we incurred aggregate termination costs, related to severance, benefits and related employee costs ("the Termination Benefits") of \$3.6 million for the fiscal year ended June 30, 2023, of which \$2.8 million was recorded as research and development expense and \$0.8 million was recorded as general and administrative expense. We have paid \$2.6 million in termination costs and we had \$1.0 million in unpaid Termination Benefits in accrued liabilities in the consolidated balance sheets as of June 30, 2023.

Liquidity

We have accumulated losses of \$406 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of June 30, 2023, we had \$101 million in cash, cash equivalents and short-term investments. We believe that these resources will be sufficient to meet our obligations and fund our liquidity and capital expenditure requirements for at least the next 12 months from the issuance of these consolidated financial statements and through the reporting of clinical data readouts from the ongoing and planned voruciclib and ME-344 Phase 1 and Phase 1b clinical programs, respectively. Our current business operations are focused on continuing the clinical development of our drug candidates. Changes to our research and development plans or other changes affecting our operating expenses may affect actual future use of existing cash resources. Our research and development expenses are expected to increase in the foreseeable future. We cannot determine with certainty costs associated with ongoing and future clinical trials or the regulatory approval process. The duration, costs and timing associated with the development of our product candidates will depend on a variety of factors, including uncertainties associated with the results of our clinical trials.

To date, we have obtained cash and funded our operations primarily through equity financings and license agreements. In order to continue the development of our drug candidates, at some point in the future we expect to pursue one or more capital transactions, whether through the sale of equity securities, debt financing, license agreements or entry into strategic partnerships. There can be no assurance that we will be able to continue to raise additional capital in the future.

Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and disclosures made in the accompanying notes to the consolidated financial statements. We use estimates that affect the reported amounts (including assets, liabilities, revenues and expenses) and related disclosures. Actual results could materially differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and highly liquid investments with original maturities of three months or less when purchased. Cash is maintained at financial institutions and, at times, balances may exceed federally insured limits. We have not experienced any losses related to these balances.

We attempt to minimize credit risk associated with our cash and cash equivalents by periodically evaluating the credit quality of our primary financial institutions. Our investment portfolio is maintained in accordance with our investment policy, which is designed to preserve capital, safeguard funds and limit exposure to risk. While we maintain cash deposits in FDIC insured financial institutions

in excess of federally insured limits, we do not believe we are exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. We have not experienced any losses on such accounts.

Short-term Investments

Short-term investments are marketable securities with maturities greater than three months but less than one year from date of purchase. As of June 30, 2023 and 2022, our short-term investments consisted of \$83.8 million and \$137.5 million, respectively, in United States government securities. The short-term investments held as of June 30, 2023 and 2022 are considered to be “held to maturity” and are carried at amortized cost. As of June 30, 2023 and 2022, the gross unrealized gains and losses were immaterial.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value is as follows:

- Level 1 — Observable inputs such as quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Property and Equipment

Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets (generally three to seven years) using the straight-line method. Leasehold improvements are stated at cost and are amortized over the shorter of the estimated useful lives of the assets or the lease term.

Leases

We account for our leases under ASC Topic 842, *Leases* (“Topic 842”). Leases which are identified within the scope of Topic 842 and which have a term greater than one year are recognized on our consolidated balance sheets as right-of-use (“ROU”) assets and lease liabilities. Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected remaining lease term. The lease term includes any renewal options and termination options that we are reasonably certain to exercise. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, we use our incremental borrowing rate. The incremental borrowing rate is determined based on the rate of interest that we would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment. The interest rate implicit in lease contracts to calculate the present value is typically not readily determinable. As such, significant management judgment is required to estimate the incremental borrowing rate.

Operating lease expense for operating leases is recognized on a straight-line basis over the lease term based on the total lease payments. We have elected the practical expedient to not separate lease and non-lease components for our real estate leases. Our non-lease components are primarily related to property maintenance, which varies based on future outcomes, and thus is recognized in operating lease expense when incurred.

Revenue Recognition

Revenue from Customers

In accordance with ASC Topic 606, *Revenue from Contracts with Customers* (“Topic 606”), we recognize revenue when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. For enforceable contracts with our customers, we first identify the distinct performance obligations – or accounting units – within the contract. Performance obligations are commitments in a contract to transfer a distinct good or service to the customer.

Payments received under commercial arrangements, such as licensing technology rights, may include non-refundable fees at the inception of the arrangements, milestone payments for specific achievements designated in the agreements, and royalties on the sale of products. At the inception of arrangements that include milestone payments, we use judgment to evaluate whether the milestones are probable of being achieved, and we estimate the amount to include in the transaction price using the most likely method. If it is probable that a significant revenue reversal will not occur, the estimated amount is included in the transaction price. Milestone payments that are not within our or the licensee's control, such as regulatory approvals, are not included in the transaction price until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of development milestones and any related constraint and, as necessary, we adjust our estimate of the overall transaction price.

We may enter into arrangements that consist of multiple performance obligations. Such arrangements may include any combination of our deliverables. To the extent a contract includes multiple promised deliverables, we apply judgment to determine whether promised deliverables are capable of being distinct and are distinct in the context of the contract. If these criteria are not met, the promised deliverables are accounted for as a combined performance obligation. For arrangements with multiple distinct performance obligations, we allocate variable consideration related to our 50-50 cost share for development services directly to the associated performance obligation and then allocate the remaining consideration among the performance obligations based on their relative stand-alone selling price.

Stand-alone selling price is the price at which we would sell a promised good or service separately to the customer. When not directly observable, we typically estimate the stand-alone selling price for each distinct performance obligation. Variable consideration that relates specifically to our efforts to satisfy specific performance obligations is allocated entirely to those performance obligations. Other components of the transaction price are allocated based on the relative stand-alone selling price, over which management has applied significant judgment. We develop assumptions that require judgment to determine the stand-alone selling price for license-related performance obligations, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical, regulatory and commercial success. We estimate stand-alone selling price for research and development performance obligations by forecasting the expected costs of satisfying a performance obligation plus an appropriate margin.

In the case of a license that is a distinct performance obligation, we recognize revenue allocated to the license from non-refundable, up-front fees at the point in time when the license is transferred to the licensee and the licensee can use and benefit from the license. For licenses that are bundled with other distinct or combined obligations, we use judgment to assess the nature of the performance obligation to determine whether the performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. If the performance obligation is satisfied over time, we evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. From time to time, we perform additional services for KKC. at their request, the costs of which are fully reimbursed to us. The cost of these services is recognized in the consolidated statements of operations as research and development expense.

The selection of the method to measure progress towards completion requires judgment and is based on the nature of the products or services to be provided. Revenue is recorded proportionally as costs are incurred. We generally use the cost-to-cost measure of progress because it best depicts the transfer of control to the customer which occurs as we incur costs. Under the cost-to-cost measure of progress, the extent of progress towards completion is measured based on the ratio of costs incurred to date to the total estimated costs at completion of the performance obligation (an "input method" under Topic 606). We use judgment to estimate the total cost expected to complete the research and development performance obligations, which include subcontractors' costs, labor, materials, other direct costs and an allocation of indirect costs. We evaluate these cost estimates and the progress each reporting period and, as necessary, we adjust the measure of progress and related revenue recognition.

For arrangements that include sales-based or usage-based royalties, we recognize revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, we have not recognized any sales-based or usage-based royalty revenue from license agreements.

In connection with our License, Development and Commercialization Agreement (the "KKC Commercialization Agreement") with KKC, we perform development services related to our 50-50 cost sharing arrangement for which revenue is recognized over time. Additionally, we perform services for KKC at their request, the costs of which are fully reimbursed to us. We record the reimbursement for such pass through services as revenue at 100% of reimbursed costs, as control of the additional services for KKC is transferred at the time we incur such costs. The costs of these services are recognized in the consolidated statements of operations as research and development expense.

We recognized revenue associated with the KKC Commercialization Agreement for the periods presented (in thousands):

	Years Ended June 30,	
	2023	2022
Revenue	\$ 48,816	\$ 40,697
Timing of Revenue Recognition:		
Services performed over time	\$ 47,729	\$ 37,304
Pass through services at a point in time	1,087	3,393
	<u>\$ 48,816</u>	<u>\$ 40,697</u>

Contract Balances

Accounts receivable are included on our consolidated balance sheets in “Prepaid expenses and other current assets”, and contract liabilities are included in “Deferred revenue” and “Deferred revenue, long-term” in our consolidated balance sheets. The following table presents changes in accounts receivable, unbilled receivables and contract liabilities accounted for under Topic 606 for the periods presented (in thousands):

	Years Ended June 30,	
	2023	2022
Accounts receivable		
Accounts receivable, beginning of year	\$ —	\$ —
Amounts billed	28,087	54,611
Payments received	(28,087)	(54,611)
Accounts receivable, end of year	<u>\$ —</u>	<u>\$ —</u>
Unbilled receivables		
Unbilled receivables, beginning of year	\$ 10,044	\$ 7,582
Billable amounts	18,128	56,816
Amounts billed	(28,087)	(54,354)
Unbilled receivables, end of year	<u>\$ 85</u>	<u>\$ 10,044</u>
Contract liabilities		
Contract liabilities, beginning of year	\$ 30,900	\$ 14,677
Payments received	—	20,000
Revenue recognized	(5,411)	(3,777)
Revenue recognized from change in estimate for performance obligations that are being closed ⁽¹⁾	(16,565)	—
Revenue recognized for performance obligations that will no longer commence ⁽¹⁾	(8,607)	—
Contract liabilities, end of year	<u>\$ 317</u>	<u>\$ 30,900</u>

(1) See discussion in *Note 2 - License Agreements*

The timing of revenue recognition, invoicing and cash collections results in billed accounts receivable and unbilled receivables (contract assets) and deferred revenue (contract liabilities). We invoice our customers in accordance with agreed-upon contractual terms, typically at periodic intervals or upon achievement of contractual milestones. Invoicing may occur subsequent to revenue recognition, resulting in unbilled receivables. We may receive advance payments from our customers before revenue is recognized, resulting in contract liabilities. The unbilled receivables and deferred revenue reported on the consolidated balance sheets relate to the KKC Commercialization Agreement.

As of June 30, 2023 and 2022, we had \$64.9 million and \$95.4 million, respectively, of deferred revenue associated with the KKC Commercialization Agreement, of which \$64.5 million, relates to the U.S. license which is a unit of account under the scope of ASC Topic 808, *Collaborative Arrangements* ("Topic 808") and is not a performance obligation under Topic 606. The decrease in deferred revenue comes as a result of our winding down of all zandelisib studies outside of Japan. During the year ended June 30, 2023, we updated our estimated costs to complete each of the performance obligations, resulting in a higher progress towards completion based on the ratio of costs incurred to date to the total estimated costs and we recognized revenue related to non-refundable payments for performance obligations that have not commenced and will no longer be initiated, as further discussed in *Note 2. License Agreements*.

Our contract liabilities accounted for under Topic 606 relate to the amount of initial upfront consideration that was allocated to the development services performance obligations. Contract liabilities are recognized over the duration of the performance obligations based on the costs incurred relative to total expected costs.

Revenue from Collaborators

At contract inception, we assess whether the collaboration arrangements are within the scope of Topic 808, to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed based on the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of Topic 808 that contain multiple units of account, we first determine which units of account within the arrangement are within the scope of Topic 808 and which elements are within the scope of Topic 606. For units of account within collaboration arrangements that are accounted for pursuant to Topic 808, an appropriate recognition method is determined and applied consistently, by analogy to authoritative accounting literature. For elements of collaboration arrangements that are accounted for pursuant to Topic 606, we recognize revenue as discussed above. Consideration received that does not meet the requirements to satisfy Topic 606 revenue recognition criteria is recorded as deferred revenue in the accompanying consolidated balance sheets, classified as either current or long-term deferred revenue based on our best estimate of when such amounts will be recognized.

Research and Development

Research and development costs are expensed as incurred and include costs paid to third party contractors to perform research, conduct clinical trials and develop and manufacture drug materials. Clinical trial costs, including costs associated with third party contractors, are a significant component of research and development expenses. We expense research and development costs based on work performed. In determining the amount to expense, management relies on estimates of total costs based on contract components completed, the enrollment of subjects, the completion of trials, and other events. Costs incurred related to the purchase or licensing of in-process research and development for early-stage products or products that are not commercially viable and ready for use, or have no alternative future use, are charged to expense in the period incurred.

As part of the process of preparing the consolidated financial statements, we are required to estimate expenses resulting from obligations under contracts with vendors, clinical research organizations (CROs), consultants and under clinical site agreements relating to conducting clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

Our objective is to reflect the appropriate clinical trial expenses in our consolidated financial statements by recording those expenses in the period in which services are performed and efforts are expended. We account for these expenses according to the progress of the clinical trial as measured by patient progression and the timing of various aspects of the trial. Management determines accrual estimates through financial models and discussions with applicable personnel and outside service providers as to the progress of clinical trials.

During a clinical trial, we adjust the clinical expense recognition if actual results differ from our estimates. We make estimates of accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. Our clinical trial accruals are partially dependent upon accurate reporting by CROs and other third-party vendors. Our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in changes in our estimates.

Share-based Compensation

Share-based compensation expense for stock options and restricted stock units ("RSUs") granted to employees and directors is recognized in the consolidated statements of operations based on estimated amounts. The cost of stock options is measured at the grant date, based on the estimated fair value of the stock option using the Black-Scholes valuation model, which incorporates various assumptions including expected volatility, risk-free interest rate, the expected term of the award and the dividend yield on the underlying stock. Expected volatility is calculated based on the historical volatility of our stock over the expected option life and other appropriate factors. The expected option term is computed using the "simplified" method as permitted under the provisions of ASC 718-10-S99. We use the simplified method to calculate the expected term of share options and similar instruments as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. Risk-free interest rates are calculated based on continuously compounded risk-free rates for the appropriate term. The dividend yield is assumed to be zero as we have never paid or declared any cash dividends and do not intend to do so in the foreseeable future. For RSUs, we estimate the grant date fair value using our closing stock price on the date of grant. The estimated fair value of stock options and RSUs is amortized over the requisite service period, adjusted for actual forfeitures at the time they occur. The requisite service period is generally the time over which our share-based awards vest.

Interest and Dividend Income

Interest on cash balances is recognized when earned. Dividend income is recognized when the right to receive the payment is established.

Income Taxes

Our income tax expense consists of current and deferred income tax expense or benefit. Current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for the future tax consequences attributable to tax credits and loss carryforwards and to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. As of June 30, 2023 and 2022, we have established a valuation allowance to fully reserve our net deferred tax assets. Tax rate changes are reflected in income during the period such changes are enacted. Changes in our ownership may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income.

The Financial Accounting Standards Board ("FASB") Topic on income taxes prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. There were no unrecognized tax benefits as of June 30, 2023 and 2022.

Net Loss Per Share

Basic and diluted net loss per share are computed using the weighted-average number of shares of common stock outstanding during the period, less any shares subject to repurchase or forfeiture. There were no shares of common stock subject to repurchase or forfeiture for the years ended June 30, 2023 and 2022. Diluted net loss per share is computed based on the sum of the weighted-average number of common shares and potentially dilutive common shares outstanding during the period.

The following table presents the calculation of net loss used to calculate basic loss and diluted loss per share (in thousands):

	Years Ended June 30,	
	2023	2022
Net loss—basic	\$ (31,838)	\$ (54,454)
Change in fair value of warrant liability	—	(8,046)
Net loss—diluted	<u>\$ (31,838)</u>	<u>\$ (62,500)</u>

Shares used in calculating net loss per share was determined as follows (in thousands):

	Years Ended June 30,	
	2023	2022
Shares used in calculating basic net loss per share	6,663	6,224
Effect of potentially dilutive common shares from equity awards and liability-classified warrants	—	33
Shares used in calculating diluted net loss per share	<u>6,663</u>	<u>6,257</u>

Our potentially dilutive shares, which include outstanding stock options, restricted stock units and warrants, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. The assessment of dilution is made on a quarterly basis and therefore the annual determination of diluted net loss per share only includes those quarters in which the potential common stock equivalents were determined to be dilutive. The following table presents potentially dilutive shares that have been excluded from the calculation of net loss per share because of their anti-dilutive effect (in thousands):

	Years Ended June 30,	
	2023	2022
Stock options	1,285	1,024
Warrants	103	402
Restricted stock units	—	11
Total anti-dilutive shares	<u>1,388</u>	<u>1,437</u>

Segment Information

We have one operating segment which is the development of pharmaceutical compounds. All of our assets and liabilities were located in the U.S. as of June 30, 2023 and 2022.

Recent Accounting Pronouncement

In June 2016, the Financial Accounting Standards Board issued Accounting Standards Update 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), as amended. The amendments in ASU 2016-13 require, among other things, financial assets measured at amortized cost basis to be presented at the net amount expected to be collected as compared to previous U.S. GAAP which delayed recognition until it was probable a loss had been incurred. The amendments in ASU 2016-13 are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact that adoption of ASU 2016-13 will have on our financial statements and related disclosures.

Other accounting standard updates effective for interim and annual periods beginning after June 30, 2023 are not expected to have a material impact on our consolidated financial position, results of operations or cash flows.

Note 2. License Agreements

KKC License, Development and Commercialization Agreement

In April 2020, we entered into the KKC Commercialization Agreement under which we granted to KKC a co-exclusive, sublicensable, payment-bearing license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in the U.S. (the "U.S. License"), and an exclusive (subject to certain retained rights to perform obligations under the KKC Commercialization Agreement), sublicensable, payment-bearing, license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in countries outside of the U.S. (the "Ex-U.S." and the "Ex-U.S. License"). KKC granted to us a co-exclusive, sublicensable, license under certain patents and know-how controlled by KKC to develop and commercialize zandelisib for all human indications in the U.S., and a co-exclusive, sublicensable, royalty-free, fully paid license under certain patents and know-how controlled by KKC to perform our obligations in the Ex-U.S. under the KKC Commercialization Agreement. KKC paid us an initial payment of \$100.0 million.

Prior to the execution of the Termination Agreement, KKC was responsible for the development and commercialization of zandelisib in Ex-U.S. and, subject to certain exceptions, was solely responsible for all costs related thereto. We also provided to KKC certain drug supplies necessary for the development and commercialization of zandelisib in the Ex-U.S., with the understanding that KKC would have assumed responsibility for manufacturing for the Ex-U.S. as soon as practicable.

We assessed the KKC Commercialization Agreement in accordance with Topic 808 and Topic 606 and determined that our obligations comprise the U.S. License, the Ex-U.S. License, and development services (the "Development Services"). We determined that the KKC Commercialization Agreement is a collaborative arrangement in accordance with Topic 808 that contains multiple units of account, as we and KKC are both active participants in the development and commercialization activities and are exposed to significant risks and rewards that are dependent on commercial success of the activities of the arrangement. The U.S. License is a unit of account under the scope of Topic 808 and is not a deliverable under Topic 606, while the Ex-U.S. License and Development Services performance obligations are under the scope of Topic 606.

As discussed in *Note 1 - The Company and Summary of Significant Accounting Policies*, we and KKC jointly decided to discontinue zandelisib development in the U.S. During fiscal year 2023, we updated our assessment of the total transaction price from

the KKC Commercialization Agreement to be \$213.1 million, comprised of the upfront payment of \$100.0 million, milestone payments of \$20.0 million, estimated development cost-sharing of \$87.9 million, and deferred revenue of \$5.2 million. The updated assessment reflects a decrease in estimated variable consideration related to development cost sharing of \$147.0 million from June 30, 2022. In December 2022, we announced our plan to discontinue the global development of zandelisib outside of Japan. As a result, we decreased our estimate for variable consideration related to development cost sharing. During the second quarter of the year ended June 30, 2023, we recognized revenue of \$16.6 million from the change in estimate. Additionally, we recognized \$8.6 million of revenue related to non-refundable payments for performance obligations that have not commenced and will no longer be initiated. Any variable consideration related to sales-based royalties and commercial milestones related to licenses of intellectual property will be determined when the sale or usage occurs, and is therefore excluded from the transaction price. In addition, we are eligible to receive future development and regulatory milestones upon the achievement of certain criteria; however, these amounts are excluded from variable consideration as the risk of significant revenue reversal will only be resolved depending on future research and development and/or regulatory approval outcomes. We re-evaluate the estimated variable consideration included in the transaction price and any related constraints at the end of each reporting period.

We allocated the transaction price to each unit of account. Variable consideration that relates specifically to our efforts to satisfy specific performance obligations are allocated entirely to those performance obligations. Other components of the transaction price are allocated based on the relative stand-alone selling price, over which management has applied significant judgment. We developed the estimated stand-alone selling price for the licenses using the risk-adjusted net present values of estimated cash flows, and the estimated stand-alone selling price of the development services performance obligations by estimating costs to be incurred, and an appropriate margin, using an income approach.

The \$64.5 million transaction price allocated to the U.S. License obligation accounted for under Topic 808 is included as noncurrent deferred revenue as of June 30, 2023 and June 30, 2022. As of June 30, 2023 and June 30, 2022, we also have deferred revenue of \$317,000 and \$30.9 million, respectively, related to the transaction price allocated to the Development Services performance obligations and are recognizing the remaining revenue based on the proportional performance of these development activities. As discussed in *Note 11. Subsequent Events*, the KKC Commercialization Agreement was terminated on July 14, 2023.

Note 3. Other License Agreements

Presage License Agreement

In September 2017, we, as licensee, entered into a license agreement with Presage Biosciences, Inc. (“Presage”). Under the terms of the license agreement, Presage granted to us exclusive worldwide rights to develop, manufacture and commercialize voruciclib, a clinical-stage, oral and selective CDK inhibitor, and related compounds. In exchange, we paid \$2.9 million to Presage. With respect to the first indication, an incremental \$2.0 million payment, due upon dosing of the first subject in the first registration trial, will be owed to Presage, for total payments of \$4.9 million prior to receipt of marketing approval of the first indication in the U.S., EU or Japan. Additional potential payments of up to \$179 million will be due upon the achievement of certain development, regulatory and commercial milestones. We will also pay mid-single digit tiered royalties on the net sales of any product successfully developed. As an alternative to milestone and royalty payments related to countries in which we sublicense product rights, we will pay to Presage a tiered percentage (which decreases as product development progresses) of amounts received from such sublicensees. During the years ended June 30, 2023 and 2022, we made no payments under the Presage license agreement.

BeiGene Collaboration

In October 2018, we entered into a clinical collaboration with BeiGene, Ltd. (“BeiGene”) to evaluate the safety and efficacy of zandelisib in combination with BeiGene’s zanubrutinib (marketed as Brukinsa®), an inhibitor of Bruton’s tyrosine kinase, for the treatment of patients with B-cell malignancies. Under the terms of the clinical collaboration agreement, we amended our ongoing Phase 1b trial to include evaluation of zandelisib in combination with zanubrutinib in patients with B-cell malignancies. Study costs are being shared equally by the parties, and we agreed to supply zandelisib and BeiGene agreed to supply zanubrutinib. We record the costs reimbursed by BeiGene as a reduction of our research and development expenses. We retained full commercial rights for zandelisib and BeiGene retained full commercial rights for zanubrutinib. With the discontinuation of the zandelisib program outside of Japan, this clinical collaboration will be concluding with the discontinuation of the Phase 1b trial.

Note 4. Fair Value Measurements

The carrying amounts of financial instruments such as cash equivalents, short-term investments and accounts payable approximate the related fair values due to the short-term maturities of these instruments. We invest our excess cash in financial instruments which are readily convertible into cash, such as money market funds and U.S. government securities. Cash equivalents and short-term investments are classified as Level 1 as defined by the fair value hierarchy.

In May 2018, we issued warrants in connection with our private placement of shares of common stock, which expired in May 2023. Pursuant to the terms of the warrants, we could have been required to settle the warrants in cash in the event of an acquisition of the company and, as a result, the warrants were required to be measured at fair value and reported as a liability in the consolidated balance sheets. We recorded the fair value of the warrants upon issuance using the Black-Scholes valuation model and are required to revalue the warrants at each reporting date with any changes in fair value recorded on our consolidated statements of operations. The valuation of the warrants is considered under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. Inputs used to determine the estimated fair value of the warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. The significant unobservable inputs used in the fair value measurement of the warrant liabilities were the volatility rate and the estimated term of the warrants. Generally, increases or decreases in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement. The changes in the fair value of the Level 3 warrant liability are reflected on the consolidated statements of operations for the years ended June 30, 2023 and 2022. During the years ended June 30, 2023 and 2022, there were no transfers into or out of Level 3 of the fair value hierarchy.

To calculate the fair value of the warrant liability, the following assumptions were used for the period presented:

	June 30,	
	2023	2022
Risk-free interest rate	4.4%	2.8%
Expected life (years)	0.5	0.9
Expected volatility	128.7%	139.4%
Dividend yield	—%	—%
Weighted-average grant date fair value	\$ 0.02	\$ 0.10

The following table sets forth a summary of changes in the estimated fair value of our Level 3 warrant liability for the years ended June 30, 2023 and 2022 (in thousands):

	Fair Value of Warrants Using Significant Unobservable Inputs (Level 3)	
	2023	2022
Beginning Balance	\$ 1,603	\$ 22,355
Change in estimated fair value of liability classified warrants	(1,603)	(20,752)
Ending Balance	<u>\$ —</u>	<u>\$ 1,603</u>

Note 5. Balance Sheet Details

Property and Equipment

Property and equipment consisted of the following, in thousands:

	June 30,	
	2023	2022
Furniture and equipment	\$ 1,374	\$ 1,254
Leasehold improvements	969	1,054
	<u>2,343</u>	<u>2,308</u>
Less: accumulated depreciation	(1,034)	(648)
Property and equipment, net	<u>\$ 1,309</u>	<u>\$ 1,660</u>

Depreciation expense of property and equipment for the years ended June 30, 2023 and 2022 are presented in the consolidated statements of cash flows.

Accrued Liabilities

Accrued liabilities consisted of the following, in thousands:

	June 30,	
	2023	2022
Accrued pre-clinical and clinical trial expenses	\$ 3,663	\$ 5,264
Accrued compensation and benefits	7,189	4,346
Accrued legal and professional services expenses	1,423	1,036
Other	186	174
Total accrued liabilities	<u>\$ 12,461</u>	<u>\$ 10,820</u>

Note 6. Stockholders' Equity

Equity Transactions

Underwritten Registered Offering

During the year ended June 30, 2022, we completed an underwritten registered offering of 1,006,250 shares of common stock at a price per share of \$52.00 for net cash proceeds of \$48.7 million, after offering costs of \$3.7 million.

Shelf Registration Statement

We had a shelf registration statement that permitted us to sell, from time to time, up to \$200.0 million of common stock, preferred stock and warrants. The shelf registration was filed and declared effective in May 2020, replacing a prior shelf registration statement that was filed and declared effective in May 2017, and carried forward approximately \$107.5 million of unsold securities registered under the prior shelf registration statement. The shelf registration expired on May 18, 2023.

At-The-Market Equity Offering

On November 10, 2020, we entered into an At-The-Market Equity Offering Sales Agreement (the "2020 ATM Sales Agreement"), pursuant to which we could sell an aggregate of up to \$60.0 million of our common stock pursuant to the shelf registration statement. There were no sales under the 2020 ATM Sales Agreement during the years ended June 30, 2023 and 2022, and the 2020 ATM Sales Agreement expired in conjunction with the shelf registration on May 18, 2023.

Warrants

In May 2023, outstanding warrants to purchase 802,949 shares of our common stock expired. The warrants were fully vested and exercisable at a price of \$50.80 per share. As of June 30, 2022, the warrants were valued at \$1.6 million. Prior to their expiration, the warrants had been previously revalued to \$0, as of December 31, 2022. All corresponding changes in fair value were recorded as a component of other income (expense) in our consolidated statements of operations. No warrants were exercised during the years ended June 30, 2023 and 2022. The warrants expired in May 2023.

As of June 30, 2023, we have outstanding warrants to purchase 102,513 shares of our common stock, all issued to Torrey Partners. The warrants are fully vested, exercisable at a price of \$6.80 per share and expire in October 2027.

Description of Capital Stock

Our total authorized share capital is 226,100,000 shares consisting of 226,000,000 shares of common stock, \$0.00000002 par value per share, and 100,000 shares of preferred stock, \$0.01 par value per share.

Common Stock

The holders of common stock are entitled to one vote per share. In the event of a liquidation, dissolution or winding up of our affairs, holders of the common stock will be entitled to share ratably in all our assets that are remaining after payment of our liabilities and the liquidation preference of any outstanding shares of preferred stock. All outstanding shares of common stock are fully paid and non-assessable. The rights, preferences and privileges of holders of common stock are subject to any series of preferred stock that we have issued or that we may issue in the future. The holders of common stock have no preemptive rights and are not subject to future calls or assessments by us.

Preferred Stock

Our board of directors has the authority to issue up to 100,000 shares of preferred stock with a par value of \$0.01 per share in one or more series and to fix the rights, preferences, privileges and restrictions in respect of that preferred stock, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption (including sinking fund provisions), redemption prices and liquidation preferences, and the number of shares constituting such series and the designation of any such series, without future vote or action by the stockholders. Therefore, the board of directors, without the approval of the stockholders, could authorize the issue of preferred stock with voting, conversion and other rights that could affect the voting power, dividend and other rights of the holders of shares or that could have the effect of delaying, deferring or preventing a change of control. There were no shares of preferred stock outstanding as of June 30, 2023 or 2022.

Note 7. Share-based Compensation

We use equity-based compensation programs to provide long-term performance incentives for our employees. These incentives consist primarily of stock options and RSUs. In December 2008, we adopted the MEI Pharma, Inc. 2008 Stock Omnibus Equity Compensation Plan (the "Omnibus Plan"), as amended and restated from time to time, under which 1,850,739 shares of common stock are authorized for issuance. The Omnibus Plan provides for the grant of options and/or other stock-based or stock-denominated awards to our non-employee directors, officers, employees and advisors. As of June 30, 2023, there were 573,773 shares available for future grant under the Omnibus Plan.

In May 2021, we adopted the 2021 Inducement Plan ("Inducement Plan"), under which 125,000 shares of common stock were authorized for issuance. On June 9, 2023 our board of directors approved an amendment and restatement of the Inducement Plan to increase the aggregate number of shares of common stock authorized for issuance by 92,000 shares. The Inducement Plan is intended to assist us in attracting and retaining selected individuals to serve as employees who are expected to contribute to our success, by providing an inducement for such individuals to enter into employment with us, and to achieve long-term objectives that will benefit our stockholders. As of June 30, 2023, there were 94,903 shares available for future grant under the Inducement Plan.

Total share-based compensation expense for all stock awards consists of the following, in thousands:

	Years Ended June 30,	
	2023	2022
Research and development	\$ 724	\$ 2,610
General and administrative	2,865	5,740
Total share-based compensation	<u>\$ 3,589</u>	<u>\$ 8,350</u>

Stock Options

Stock options granted to employees vest 25% one year from the date of grant and ratably each month thereafter for a period of 36 months and expire ten years from the date of grant. Stock options granted to directors vest ratably each month for a period of 12 months from the date of grant and expire ten years from the date of grant. As of June 30, 2023, there were a total of 1,284,907 options outstanding of which 1,162,810 were granted under the Omnibus Plan and 122,097 were granted under the Inducement Plan.

A summary of our stock option activity and related data follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at June 30, 2022	996,700	\$57.00		
Granted	682,074	\$9.63		
Forfeited	(393,867)	\$35.56		
Outstanding at June 30, 2023	<u>1,284,907</u>	\$38.32	7.5	\$—
Vested and exercisable at June 30, 2023	<u>759,825</u>	\$52.66	6.3	\$—

As of June 30, 2023, the aggregate intrinsic value of outstanding options is calculated as the difference between the exercise price of the underlying options and the closing price of our common stock of \$6.58 on that date. The total fair value of options that vested during the years ended June 30, 2023 and 2022 was \$8.9 million and \$9.0 million, respectively.

Unrecognized compensation expense related to non-vested stock options totaled \$2.8 million as of June 30, 2023. Such compensation expense is expected to be recognized over a weighted-average period of 1.7 years. As of June 30, 2023, we expect all outstanding options to vest.

We use a Black-Scholes valuation model to estimate the grant date fair value of stock options. To calculate these fair values, the following weighted-average assumptions were used:

	Years Ended June 30,	
	2023	2022
Risk-free interest rate	3.2%	1.3%
Expected life (years)	6.0	6.0
Expected volatility	85.5%	69.6%
Dividend yield	—%	—%
Weighted-average grant date fair value	\$ 7.04	\$ 31.40

Restricted Stock Units (RSU)

A summary of our RSU activity and related data follows:

	Number of RSUs	Weighted-Average Grant Date Fair Value
Non-vested at June 30, 2022	9,220	\$ 69.80
Vested	(9,220)	\$ 69.80
Forfeited	—	\$ —
Non-vested at June 30, 2023	—	\$ —

Each RSU represents the contingent right to receive one share of our common stock. Under the terms of the Omnibus Plan, each of the RSUs is calculated as 1.25 shares of common stock for purposes of determining the number of shares available for future grant.

Note 8. Commitments and Contingencies

We have contracted with various consultants and third parties to assist us in pre-clinical research and development and clinical trials work for our leading drug compounds. The contracts are terminable at any time, but obligate us to reimburse the providers for any time or costs incurred through the date of termination. We also have employment agreements with certain of our current employees that provide for severance payments and accelerated vesting for share-based awards if their employment is terminated under specified circumstances.

Litigation

From time to time, the Company may be involved in various lawsuits, legal proceedings, or claims that arise in the ordinary course of business. Management believes there are no claims or actions pending against the Company as of June 30, 2023 which will have, individually or in the aggregate, a material adverse effect on its business, liquidity, financial position, or results of operations. Litigation, however, is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm the Company's business.

Indemnification

In accordance with the Company's amended and restated memorandum and articles of association, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving in such capacity. There have been no claims to date, and the Company has a directors and officers liability insurance policy that may enable it to recover a portion of any amounts paid for future claims.

Presage License Agreement

As discussed in *Note 2. License Agreements*, we are party to a license agreement with Presage under which we may be required to make future payments upon the achievement of certain development, regulatory and commercial milestones, as well as potential future royalties based upon net sales. As of June 30, 2023, we had not accrued any amounts for potential future payments as achievement of the milestones had not been met.

Note 9. Leases

In July 2020, we entered into a lease agreement (the "Initial Lease Agreement") for approximately 32,800 square feet of office space in San Diego, California. The Lease Agreement was scheduled to expire in March 2028 but was extended by 20 months to November 2029 in accordance with the amended lease agreement we entered into in January 2022 (the "Amended Lease Agreement"). The Initial and Amended Lease Agreements are collectively referred to as the "Lease Agreements". The Lease Agreements contain rent escalations over the lease term. We have accounted for the Lease Agreements as operating leases. The Lease Agreements contain an option to renew and extend the lease term, which is not included in the determination of the ROU asset and operating lease liability, as it was not reasonably certain to be exercised. Upon commencement of the Amended Lease Agreement, to extend the lease term, we recognized an additional operating lease ROU asset and a corresponding operating lease liability. The Lease Agreements include variable non-lease components (e.g., common area maintenance, maintenance, etc.) that are not included in the ROU asset and operating lease liability and are reflected as an expense in the period incurred as a component of the lease cost.

The Amended Lease Agreements also provides for an additional 12,300 square feet of office space adjacent to our current office in San Diego. Upon taking control of the additional office space on July 1, 2022, we recognized operating lease ROU assets obtained in exchange for operating lease liabilities of \$4.3 million.

The total operating lease costs for the Lease Agreements were as follows for the periods presented (in thousands):

	Years Ended June 30,	
	2023	2022
Operating lease cost	\$ 2,434	\$ 1,583
Variable lease costs	49	61
Total lease costs included in general and administrative expenses	<u>\$ 2,483</u>	<u>\$ 1,644</u>

Supplemental cash flow information related to our operating leases was as follows for the periods presented (in thousands):

	Years Ended June 30,	
	2023	2022
Operating cash flows from operating leases	\$ 2,267	\$ 1,519

The following is a schedule of the future minimum rental payments for our operating leases, reconciled to the lease liability as of June 30, 2023 (in thousands):

	June 30, 2023
Years ending June 30,	
2024	\$ 2,335
2025	1,913
2026	2,477
2027	2,551
2028	2,715
Thereafter	<u>4,385</u>
Total lease payments	16,376
Less: Present value discount	<u>(3,648)</u>
Total operating lease liability	<u>\$ 12,728</u>
Balance Sheet Classification - Operating Leases	
Operating lease liability	\$ 1,428
Operating lease liability, long-term	11,300
Total operating lease liability	<u>\$ 12,728</u>
Other Balance Sheet Information - Operating Leases	
Weighted-Average remaining lease term (in years)	6.4
Weighted-Average discount rate	7.50%

Note 10. Income Taxes

Pre-tax loss consists of the following jurisdictions (in thousands):

	Years Ended June 30,	
	2023	2022
Domestic	\$ (31,838)	\$ (54,454)
Foreign	—	—
Pre-tax loss	<u>\$ (31,838)</u>	<u>\$ (54,454)</u>

The reconciliation of income tax computed at the U.S. federal statutory tax rates to income tax expense is as follows (in thousands):

	Years Ended June 30,			
	2023		2022	
	\$	%	\$	%
Tax benefit at U.S. statutory rates	\$ 6,689	21%	\$ 11,435	21%
State tax	187	—%	191	—%
Warrant liability costs	337	1%	4,358	8%
Equity compensation	(114)	—%	(71)	—%
Change in valuation allowance	(7,020)	(22)%	(15,473)	(28)%
Other	(79)	—%	(440)	(1)%
	<u>\$ —</u>	<u>—%</u>	<u>\$ —</u>	<u>—%</u>

Deferred tax liabilities and assets are comprised of the following (in thousands):

	June 30,	
	2023	2022
Deferred tax assets (liabilities):		
Deferred revenue	\$ 14,068	\$ 20,362
Fixed and intangible assets	10,681	13,283
Capitalization of R&D costs	10,320	—
Share-based payments	5,149	4,869
Tax losses carried forward	34,514	29,581
Compensation accruals	1,247	927
Consultant and other accruals	48	25
Right-of-use assets	(2,597)	(1,932)
Lease liabilities	2,761	2,057
Charitable contributions	8	7
Total deferred tax assets	76,199	69,179
Valuation allowance for deferred tax assets	(76,199)	(69,179)
Net deferred tax assets and liabilities	<u>\$ —</u>	<u>\$ —</u>

We evaluate the recoverability of the deferred tax assets and the amount of the required valuation allowance. Due to the uncertainty surrounding the realization of the tax deductions in future tax returns, we have recorded a valuation allowance against our net deferred tax assets as of June 30, 2023 and 2022. At such time as it is determined that it is more likely than not that the deferred tax assets will be realized, the valuation allowance would be reduced.

We had federal and state net operating loss carryforwards of approximately \$156.0 million and \$30.0 million as of June 30, 2023. The federal net operating loss will carry forward indefinitely subject to an 80% taxable income limitation. The state net operating loss carryforwards will begin to expire in 2030 unless previously utilized.

Our ability to utilize our net operating loss carryforwards may be substantially limited due to ownership changes that have occurred or that could occur in the future under Section 382 of the Internal Revenue Code and similar state laws. Through December 31, 2021, we completed a study to analyze whether one or more ownership changes had occurred and determined that two such ownership changes did occur. Although we did not conduct a formal study in 2023, we believe no significant ownership changes occurred subsequent to 2022. While the ownership changes do limit the amount of net operating loss we are able to use each year, all of our net operating losses are expected to be available for utilization prior to expiring.

None of our prior income tax returns have been selected for examination by a major taxing jurisdiction; however, the statutes of limitations for various filings remain open. The oldest filings subject to potential examination for federal and state purposes are 2020 and 2019, respectively. If we utilize a net operating loss related to a closed tax year, the tax year in which the loss was incurred is subject to adjustment up to the amount of the net operating loss.

We have not reduced any tax benefit on our consolidated financial statements due to uncertain tax positions as of June 30, 2023 and we are not aware of any circumstance that would significantly change this result through the end of fiscal year 2024. To the extent we incur income-tax related penalties or interest, we will recognize them as additional income tax expense.

Note 11. Subsequent Events

KKC License, Development and Commercialization Agreement

On July 14, 2023, we entered into a Termination Agreement (the “Termination Agreement”) with KKC to mutually terminate the Original Agreement, effective July 14, 2023, and all other related agreements between the parties. Pursuant to the Termination Agreement:

- we regained full, global rights to develop, manufacture and commercialize ME-401, subject to KKC’s limited rights to use ME-401 for “compassionate use” (as more specifically defined in the Termination Agreement) in certain expanded access programs for the existing patients who have been enrolled in Japanese clinical trials sponsored by KKC until November 30, 2027, and for which KKC is fully liable;
- each party released the other party from any and all claims, demands, etc. arising from the Original Agreement, excluding certain surviving claims; and
- we are obligated to deliver a discrete quantity of materials to facilitate KKC’s activities.

Consent Solicitation

In July 2023, Anson Advisors Inc. and Cable Car Capital LLC initiated a consent solicitation to seek the consent of our stockholders holding at least a majority of our outstanding shares of common stock to, among other things, remove and replace all members of our Board of Directors for cause (the “Consent Solicitation”). On September 18, 2023, we filed our definitive consent revocation statement urging stockholders to revoke their consents and reject the Consent Solicitation.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. As of the end of the period covered by this Annual Report, or June 30, 2023, our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of June 30, 2023. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework. Based on this assessment, our management concluded that, as of June 30, 2023, our internal control over financial reporting was effective based on those criteria.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to the rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

Remediation of Previously Disclosed Material Weakness

As disclosed in Item 9A in our Annual Report on Form 10-K for the year ended June 30, 2022, our management previously identified a material weakness in our internal control due to the inadequate design and implementation of controls to evaluate and monitor the accounting for revenue recognition related to license agreements.

During 2023, our management, with the oversight of the Audit Committee of our Board of Directors, engaged in efforts to remediate the material weaknesses identified and previously disclosed. We completed these remediation measures in the quarter ended June 30, 2023.

Remediation efforts that were implemented during 2023 included the following:

- additional review of the contractual provisions of the license agreements to confirm appropriate understanding of the terms as well as monitoring changes to the KKC agreement and our assumptions related to performance obligations;
- the implementation of a control designed to evaluate and monitor the estimated consideration to be received under license agreements;
- increased the robustness over the analysis and reconciliation of deferred revenue balances, and enhanced the review of our revenue recognition models.

Changes in Internal Control over Financial Reporting

There were no changes to our internal control over financial reporting (as defined in Rules 13a-15(f) and 15-d-15(f) under the Exchange Act) that occurred during the quarter ended June 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Internal Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Code of Ethics

We have adopted a Code of Business and Ethics policy that applies to our directors and employees (including our principal executive officer and our principal financial officer), and have posted the text of our policy on our website (www.meipharma.com). In addition, we intend to promptly disclose (i) the nature of any amendment to the policy that applies to our principal executive officer and principal financial officer and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver on our website in the future. Except as expressly stated herein, information contained on our website is not incorporated by reference herein and shall not be deemed a part of this Annual Report on Form 10-K.

The other information required by this item is incorporated herein by reference to our proxy statement for the fiscal year ended June 30, 2023 (the “Proxy Statement”).

Item 11. Executive Compensation

The information required by this item is incorporated by reference to the Proxy Statement.

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

The information required by this item is incorporated by reference to the Proxy Statement.

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

The information required by this item is incorporated by reference to the Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference to the Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) 1. Consolidated Financial Statements

Reference is made to the Consolidated Financial Statements under *Item 8* in Part II hereof.

2. Financial Statement Schedules

The Financial Statement Schedules have been omitted either because they are not required or because the information has been included in the consolidated financial statements or the notes thereto included in this Annual Report on Form 10-K.

3. Exhibits

Exhibit Index

- 2.1 Agreement and Plan of Merger by and among the Company, Merger Sub and Infinity, dated February 22, 2023 (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed on February 23, 2023 (File No. 000-50484)).
- 3.1 Certificate of Amendment of the Amended and Restated Certificate of Incorporation of MEI Pharma, Inc., filed with the Delaware Secretary of State on April 14, 2023 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on February 23, 2023 (File No. 000-50484)).
- 3.2 Fifth Amended and Restated Bylaws of MEI Pharma, Inc. effective as of February 23, 2023 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on February 23, 2023 (file No. 000-50484)).
- 3.5 Certificate of Designation of Series A Convertible Preferred Stock of Marshall Edwards, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on May 11, 2011 (File No. 000-50484)).
- 3.6 Certificate of Designation of Series B Preferred Stock of Marshall Edwards, Inc. (incorporated by reference to Exhibit 4 to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 18, 2011 (File No. 000-50484)).
- 3.7 Fifth Amended and Restated By-Laws of MEI Pharma, Inc., effective as of February 22, 2023, (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on February 23, 2023 (File No. 000-50484)).
- 4.1 Specimen Stock Certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 filed on October 31, 2003 (Reg. No. 333-109129)).
- 4.2 Form of Warrant (incorporated by reference to Exhibit B to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 16, 2018 (File No. 000-50484)).
- 4.3 Description of Capital Stock of MEI Pharma, Inc. (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K filed on September 9, 2020 (File No. 000-50484)).
- 4.4* Description of MEI Common Stock
- 10.1 Employment letter dated April 23, 2010, between Marshall Edwards, Inc. and Daniel Gold (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 26, 2010 (File No. 000-50484)).
- 10.2 Employment letter dated March 6, 2014, between MEI Pharma, Inc. and David M. Urso (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 8, 2014 (File No. 000-50484)).
- 10.3 Amendment No. 1, dated July 12, 2018, to the Employment Letter dated March 6, 2014, between MEI Pharma, Inc. and David M. Urso. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 16, 2018 (File No. 000-50484)).
- 10.4 Employment letter dated February 1, 2017, between MEI Pharma, Inc. and Brian G. Drazba (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 3, 2017 (File No. 000-50484)).
- 10.5 Employment letter dated February 17, 2016, between MEI Pharma, Inc. and Richard G. Ghalie (incorporated by reference to Exhibit 10.5 to the Registrant's Annual Report on Form 10-K filed on September 2, 2021 (File No. 000-50484)).
- 10.6 Amendment 2021-1 dated April 29, 2021, to the Employment letter dated February 17, 2016, between MEI Pharma, Inc. and Richard G. Ghalie (incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K filed on September 2, 2021 (File No. 000-50484)).

- 10.7 [Form of Indemnification Agreement \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 29, 2011 \(File No. 000-50484\)\).](#)
- 10.8** [License Agreement, dated as of September 5, 2017, by and between MEI Pharma, Inc. and Presage Biosciences, Inc. \(incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 8, 2017 \(File No. 000-50484\)\).](#)
- 10.9 [At-The-Market Equity Offering Sales Agreement, dated November 10, 2020 between MEI Pharma, Inc., Credit Suisse Securities \(USA\) LLC, and Stifel, Nicolaus & Company, Inc. \(incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed on November 10, 2020 \(File No. 000-50484\)\).](#)
- 10.10 [Securities Purchase Agreement, dated May 11, 2018, between MEI Pharma, Inc. and the purchasers identified in Exhibit A therein \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 16, 2018 \(File No. 000-50484\)\).](#)
- 10.11** [License, Development and Commercialization Agreement, dated as of October 31, 2018, by and between the Company and Kyowa Hakko Kirin Co., Ltd., now known as Kyowa Kirin Company \(incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on February 7, 2019 \(File No. 000-50484\)\).](#)
- 10.12*** [License, Development and Commercialization Agreement, dated as of April 13, 2020, by and between the Company and Kyowa Kirin Co., Ltd. \(formerly known as Kyowa Hakko Kirin Co., Ltd.\) \(incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K filed on September 2, 2021 \(File No. 000-50484\)\).](#)
- 10.13 [Transition and Retirement Agreement between Brian G. Drazba and MEI Pharma, Inc., dated as of July 7, 2022 \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 23, 2021 \(File No. 000-50484\)\).](#)
- 10.14 [Letter Agreement between Brian G. Drazba and MEI Pharma, Inc., dated as of July 7, 2022 \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 7, 2022 \(File No. 000-50484\)\).](#)
- 10.15 [CEO Employment Agreement between MEI Pharma, Inc. and David Urso, dated June 2, 2023 \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on June 2, 2023 \(File No. 000-50484\)\).](#)
- 10.16 [Employee Proprietary Information and Inventions Agreement between MEI Pharma, Inc. and Jay File, dated June 9, 2023 \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on June 13, 2023 \(File No. 000-50484\)\).](#)
- 10.17 [Employment Agreement between MEI Pharma, Inc. and Jay File, dated June 9, 2023 \(incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on June 13, 2023 \(File No. 000-50484\)\).](#)
- 10.18 [Amended and Restated MEI Pharma, Inc. 2021 Inducement Grant Equity Compensation Plan \(incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on June 13, 2023 \(File No. 000-50484\)\).](#)
- 10.19 [Termination Agreement, by and between MEI Pharma, Inc. and Kyowa Kirin Co., Ltd. \(formerly known as Kyowa Hakko Kirin Co., Ltd.\) dated as of July 14, 2023 \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 19, 2023 \(File No. 000-50484\)\).](#)
- 10.20 [Termination Letter from MEI Pharma, Inc. to Infinity Pharmaceuticals, Inc., dated July 23, 2023 \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 24, 2023 \(File No. 000-50484\)\).](#)
- 10.21 [Separation and Release Agreement between MEI Pharma, Inc. and Brian Drazba, dated June 16, 2023 \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 27, 2023 \(File No. 000-50484\)\).](#)
- 10.22* [Form of Warrant](#)
- 23.1* [Consent of Independent Registered Public Accounting Firm](#)
- 31.1* [Certification of Chief Executive Officer pursuant to Rule 13a-14\(A\) promulgated under the Securities Exchange Act of 1934](#)
- 31.2* [Certification of Chief Financial Officer pursuant to Rule 13a-14\(A\) promulgated under the Securities Exchange Act of 1934](#)
- 32.1* [Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14\(B\) promulgated under the Securities Exchange Act of 1934](#)
- 101.INS [Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document*](#)
- 101.SCH [Inline XBRL Taxonomy Extension Schema Document*](#)
- 101.CAL [Inline XBRL Taxonomy Extension Calculation Linkbase Document*](#)
- 101.DEF [Inline XBRL Taxonomy Extension Definition Linkbase Document*](#)
- 101.LAB [Inline XBRL Taxonomy Extension Label Linkbase Document*](#)

101.PRE Inline XBRL Taxonomy Extension Presentation Linkbase Document *
104 Cover Page Interactive Data File (embedded within the Inline XBRL document)*

- (*) Filed herewith.
- (**) Portions of this exhibit have been redacted pursuant to a confidential treatment request filed with the Securities and Exchange Commission.
- (***) Portions of this exhibit have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, on September 26, 2023.

MEI PHARMA, INC.
A Delaware Corporation

By: /s/ David M. Urso
David M. Urso
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities indicated on September 26, 2023.

	<u>Signatures</u>	<u>Title</u>
By:	<u>/s/ David M. Urso</u> David M. Urso	President, Chief Executive Officer and Director (Principal Executive Officer)
By:	<u>/s/ Justin J. File</u> Justin J. File	Secretary, Chief Financial Officer (Principal Financial and Accounting Officer)
By:	<u>/s/ Charles V. Baltic III</u> Charles V. Baltic	Chairman
By:	<u>/s/ Thomas C. Reynolds</u> Thomas C. Reynolds	Director
By:	<u>/s/ Nicholas R. Glover</u> Nicholas R. Glover	Director
By:	<u>/s/ Sujay R. Kango</u> Sujay Kango	Director
By:	<u>/s/ Frederick W. Driscoll</u> Frederick W. Driscoll	Director
By:	<u>/s/ Tamar D. Howson</u> Tamar D. Howson	Director
By:	<u>/s/ Daniel P. Gold</u> Daniel P. Gold	Director

