NOTICE OF ANNUAL MEETING OF STOCKHOLDERS

To Be Held on May 14, 2024

Dear Stockholders of Capricor Therapeutics, Inc.:

You are cordially invited to attend the Annual Meeting of Stockholders (the "***Annual Meeting***") of Capricor Therapeutics, Inc., a Delaware corporation (the "***Company***"), which will be held on May 14, 2024 at 10:00 a.m. (PDT), or any adjournment or postponement thereof. The Annual Meeting will be held at the Company's principal executive office located at 10865 Road to the Cure, Suite 150, San Diego, California 92121.

The Annual Meeting will be held for the following purposes, which are more fully described in the accompanying proxy statement:

1. To elect the nine (9) nominees named in this proxy statement to the Company's board of directors to serve for a one-year term expiring at our 2025 Annual Meeting of Stockholders;
2. To ratify the appointment of Rose, Snyder & Jacobs LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2024;
3. To approve, by non-binding advisory vote, the resolution approving named executive officer compensation;
4. To approve an amendment in the form set forth on Annex A to this proxy statement (the "***Charter Amendment***") to the Company's Certificate of Incorporation, as amended from time to time (the "***Certificate of Incorporation***") to increase the number of authorized shares of our common stock from 50,000,000 to 100,000,000; and
5. To transact such other business as may properly come before the Annual Meeting or any adjournment or postponement thereof.

The Company's board of directors has set the Record Date (as defined below) as March 18, 2024. Only stockholders that owned Capricor Therapeutics, Inc. common stock at the close of business on that day are entitled to notice of and may vote at the Annual Meeting or any adjournments or postponements thereof.

Important Notice Regarding the Availability of Proxy Materials for the Annual Meeting to be Held on May 14, 2024:
The proxy statement and the enclosed proxy card are available at
https://www.capricor.com/investors/sec-filings

Under rules issued by the Securities and Exchange Commission, we are providing access to our proxy materials both by sending you this full set of proxy materials and by notifying you of the availability of our proxy materials on the Internet.

You may vote your shares at the Annual Meeting only if you are present in person or if you are represented by proxy. All stockholders are invited to attend the Annual Meeting in person. Whether or not you plan to attend the Annual Meeting in person, please complete, date and sign the enclosed proxy and return it in the enclosed envelope as promptly as possible. We urge you to carefully read this entire Proxy Statement, including the documents that we refer to in this Proxy Statement. If you attend the Annual Meeting, you may withdraw the proxy and vote in person. If you have any questions regarding the completion of the enclosed proxy or would like directions to the Annual Meeting, please call (858) 727-1755.

We hope that you will be able to participate in the Annual Meeting. Thank you for your continued support.

By Order of the Board of Directors,

CAPRICOR THERAPEUTICS, INC.

/s/ Linda Marbán, Ph.D.
Linda Marbán, Ph.D.
Chief Executive Officer and a Director

San Diego, California
April 1, 2024

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PROXY STATEMENT
FOR THE 2024 ANNUAL MEETING OF THE STOCKHOLDERS
TO BE HELD ON MAY 14, 2024

COMMONLY ASKED QUESTIONS AND ANSWERS ABOUT THE ANNUAL MEETING

Why am I receiving these materials?

We have sent you these proxy materials because the board of directors (the "***Board***") of Capricor Therapeutics, Inc. (sometimes referred to as "***we***", "***us***", or the "***Company***") is soliciting your proxy to vote at the 2024 Annual Meeting of Stockholders (the "***Annual Meeting***"), including at any adjournments or postponements of the Annual Meeting. You are invited to attend the Annual Meeting in person to vote on the proposals described in this proxy statement.

We intend to mail the proxy solicitation materials, combined with the Annual Report on Form 10-K for our fiscal year ended December 31, 2023, including financial statements, to stockholders on or about April 3, 2024.

How do I attend the Annual Meeting?

The Annual Meeting will be held on May 14, 2024, at 10:00 a.m. PDT. You may attend in person, at our principal executive offices located at 10865 Road to the Cure, Suite 150, San Diego, California 92121. Information on how to vote in person at the Annual Meeting is discussed below.

Attending in Person: You will need to have a government-issued photo identification along with either your Notice and Access Card or proof of ownership of our shares of common stock as of the Record Date in order to enter the Annual Meeting. Proof of ownership may be any of the following:

A brokerage statement or letter from a bank or broker indicating ownership on the Record Date;
A printout of the proxy distribution email (if you received your materials electronically); or
A voting instruction form received from your bank, broker or nominee.

You are also encouraged to take health and safety considerations into account in determining whether to attend the Annual Meeting in person, and to comply with any laws, executive orders or governmental guidelines in effect in the City of San Diego, the County of San Diego, the State of California, the United States of America, and stockholders' jurisdictions of residence.

Who can vote at the Annual Meeting?

Only stockholders of record at the close of business on March 18, 2024 (the "***Record Date***") will be entitled to vote at the Annual Meeting. On the Record Date, there were 31,502,972 shares of our common stock outstanding and entitled to vote. Stockholders will be entitled to one (1) vote on each matter to be voted on for each share of common stock owned as of the close of business on the Record Date. There is no cumulative voting. No other securities are entitled to be voted at the Annual Meeting.

Stockholder of Record: Shares Registered in Your Name

If at the close of business on the Record Date, your shares were registered directly in your name with our transfer agent, Equiniti Trust Company, LLC, then you are a stockholder of record. As a stockholder of record, you may vote in person at the Annual Meeting or vote by proxy. Whether or not you plan to attend the Annual Meeting in person, we urge you to vote by proxy as instructed below to ensure your vote is counted.

Beneficial Owner: Shares Registered in the Name of a Broker, Bank or Other Agent

If at the close of business on the Record Date your shares were held, not in your name, but rather in an account at a brokerage firm, bank, dealer or other similar organization, then you are the beneficial owner of shares held in "street name" and the Notice is being forwarded to you by that organization. The organization holding your account is considered to be the stockholder of record for purposes of voting at the Annual Meeting. As a beneficial owner, you have the right to direct your broker, bank or other agent regarding how to vote the shares in your account. You are also invited to attend the

Annual Meeting in person. However, since you are not the stockholder of record, you may not vote your shares in person at the Annual Meeting unless you request and obtain a valid proxy from your broker, bank or other agent.

What am I voting on?

There are four (4) matters scheduled for a vote:

1. Election of nine (9) nominees named in this proxy statement to the Board;

2. Ratification of the Audit Committee's selection of Rose, Snyder & Jacobs LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2024;

3. To approve a non-binding resolution on our named executive officer compensation; and

4. To approve an amendment to the Certificate of Incorporation to increase the number of authorized shares of our common stock from 50,000,000 to 100,000,000.

What if another matter is properly brought before the Annual Meeting?

The Board knows of no other matters that will be presented for consideration at the Annual Meeting. If any other matters are properly brought before the Annual Meeting, it is the intention of the persons named in the accompanying proxy to vote on those matters in accordance with their best judgment.

What is the Board's voting recommendation?

The Board recommends that you vote your shares:

- "For" the election of each of the nine (9) nominees named in this proxy statement to the Board;

- "For" the ratification of the Audit Committee's selection of Rose, Snyder & Jacobs LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2024;

- "For" the approval, on a non-binding basis, of the Company's named executive officer compensation; and

- "For" the approval of an amendment to the Certificate of Incorporation to increase the number of authorized shares of our common stock from 50,000,000 to 100,000,000.

How do I vote?

With respect to the election of directors, you may either vote "For" all the nominees to the Board or you may "Withhold" your vote for any nominee you specify. For the ratification of the Audit Committee's selection of Rose, Snyder & Jacobs LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2024, for the approval of executive officer compensation, and for the approval of an amendment to the Certificate of Incorporation to increase the number of authorized shares of our common stock from 50,000,000 to 100,000,000, you may vote "For" or "Against" or abstain from voting. The procedures for voting are fairly simple and depend upon whether your shares are registered in your name or are held by a bank, broker or other agent.

Stockholder of Record: Shares Registered in Your Name

If you are a stockholder of record, you may vote in person at the Annual Meeting or vote by proxy. Whether or not you plan to attend the Annual Meeting in person, we urge you to vote by proxy to ensure your vote is counted. You may still attend the Annual Meeting and vote in person even if you have already voted by proxy.

- To vote in person, come to the Annual Meeting and we will give you a ballot when you arrive.

- To vote using the proxy card, simply complete, sign and date the proxy card and return it promptly in the envelope provided. If you return your signed proxy card to us before the Annual Meeting, we will vote your shares as you direct.

Beneficial Owner: Shares Registered in the Name of Broker, Bank or Other Agent

If you are a beneficial owner of shares registered in the name of your broker, bank or other agent, you should have received a notice containing voting instructions from that organization rather than from us. Simply follow the voting instructions in the notice to ensure that your vote is counted. To vote in person at the Annual Meeting, you must obtain a valid proxy from your broker, bank or other agent. Follow the instructions from your broker, bank or other agent included with these proxy materials, or contact your broker, bank or other agent to request a proxy form.

How many votes do I have?

On each matter to be voted upon, you have one (1) vote for each share of common stock you own as of the close of business on March 18, 2024, the Record Date.

What if I return a proxy card or otherwise vote but do not make specific choices?

If you return a signed and dated proxy card without marking any voting selections, your shares will be voted in accordance with the recommendations of the Board.

Who is paying for this proxy solicitation?

We will pay for the entire cost of soliciting proxies. In addition to these proxy materials, our directors and employees may also solicit proxies in person, by mail, by telephone, by email or by other means of communication. Directors and employees will not be paid any additional compensation for soliciting proxies. We may also reimburse brokerage firms, banks and other agents for the cost of forwarding proxy materials to beneficial owners.

What does it mean if I receive more than one Notice?

If you receive more than one Notice, your shares may be registered in more than one name or in different accounts. Please follow the voting instructions on each Notice to ensure that all of your shares are voted.

Can I change my vote after submitting my proxy?

Yes. You can revoke your proxy at any time before the final vote at the Annual Meeting. If you are the record holder of your shares, you may revoke your proxy in any one of the following ways:

- You may submit another properly completed proxy card with a later date;
- You may send a timely written notice that you are revoking your proxy to our Corporate Secretary at 10865 Road to the Cure, Suite 150, San Diego, California 92121; or
- You may attend the Annual Meeting and vote in person. Simply attending the Annual Meeting will not, by itself, revoke your proxy.

Your most current proxy card is the one that is counted.

If your shares are held by your broker, bank or other agent, you should follow the instructions provided by your broker, bank or other agent.

How are votes counted?

Votes will be counted by the inspector of election appointed for the Annual Meeting, who will separately count, for Proposal No. 1, “For,” “Withhold” and broker non-votes; for Proposal No. 2, “For,” “Against” and abstentions; for Proposal No. 3, “For,” “Against,” abstentions and broker non-votes; and for Proposal No. 4, “For,” “Against” and abstentions.

What are "broker non-votes"?

Broker non-votes occur when a beneficial owner of shares held in "street name" does not give instructions to the broker, bank or other agent holding the shares as to how to vote on matters deemed "non-routine." Generally, if shares are held in street name, the beneficial owner of the shares is entitled to give voting instructions to the broker, bank or other agent holding the shares. If the beneficial owner does not provide voting instructions, the broker, bank or other agent can still vote the shares with respect to matters that are considered to be "routine," but not with respect to "non-routine" matters. Under the rules and interpretations of the New York Stock Exchange, which generally apply to all brokers, banks or other nominees, "non-routine" matters are matters that may substantially affect the rights or privileges of stockholders, such as mergers, stockholder proposals, elections of directors (even if not contested), amendments to equity plans, and executive compensation, including advisory stockholder votes on executive compensation and on the frequency of stockholder votes on executive compensation. We believe that the ratification of the selection of the independent registered public accounting firm and the approval of an amendment to the Certificate of Incorporation to increase the number of authorized shares of our common stock from 50,000,000 to 100,000,000 will generally be considered to be "routine" matters for which brokers, banks or other nominees generally have discretionary voting power. The other proposals are considered non-routine matters.

Broker non-votes will be counted for the purpose of determining whether a quorum is present at the Annual Meeting.

How many votes are needed to approve each proposal?

- Directors are elected by a plurality of the votes of the shares present in person or represented by proxy at the Annual Meeting and entitled to vote for directors. Therefore, for the election of directors, the nine (9) nominees receiving the most "For" votes (from the holders of the votes of the shares present in person or represented by proxy and entitled to vote for directors) will be elected. Only votes "For" or "Withheld" will affect the outcome. Broker non-votes will have no effect.
- To be approved, Proposal No. 2, the ratification of the Audit Committee's selection of Rose, Snyder & Jacobs LLP as our independent registered public accounting firm for our fiscal year ending December 31, 2024, requires the affirmative vote of a majority of the votes cast on the proposal, meaning that the proposal must receive more votes "For" the proposal than votes "Against" the proposal. Abstentions will have no effect. Brokers generally have discretionary authority to vote shares on this proposal. Therefore, we do not expect any broker non-votes on Proposal No. 2.
- To be approved, Proposal No. 3, the advisory approval of the compensation of our named executive officers, requires the affirmative vote of a majority of the votes cast on the proposal, meaning that the proposal must receive more votes "For" the proposal than votes "Against" the proposal. Abstentions and broker non-votes will have no effect. Although the advisory vote on Proposal No. 3 is non-binding, the Board will review the results of the votes and will consider the results in making a determination concerning future executive compensation.
- To be approved, Proposal No. 4, the approval of an amendment to the Certificate of Incorporation to increase the number of authorized shares of our common stock from 50,000,000 to 100,000,000, requires the affirmative vote of a majority of the votes cast on the proposal, meaning that the proposal must receive more votes "For" the proposal than votes "Against" the proposal. Abstentions will have no effect. Brokers generally have discretionary authority to vote shares on this proposal. Therefore, we do not expect any broker non-votes on Proposal No. 4.

What is the quorum requirement?

A quorum of stockholders is necessary to hold a valid meeting. A quorum will be present if stockholders holding a majority of the voting power of the outstanding shares entitled to vote on a matter are present at the Annual Meeting in person or represented by proxy.

Your shares will be counted towards the quorum only if you submit a valid proxy (or one is submitted on your behalf by your broker, bank or other agent) or if you vote in person at the Annual Meeting. Abstentions and broker non-votes will be counted towards the quorum requirement. If there is no quorum, the holders of a majority of shares present at the Annual Meeting in person or represented by proxy may adjourn the Annual Meeting to another date.

How can I find out the results of the voting at the Annual Meeting?

Preliminary voting results will be announced at the Annual Meeting. In addition, final voting results will be published in a Current Report on Form 8-K that we expect to file with the Securities and Exchange Commission (the "***SEC***") within four (4) business days after the Annual Meeting. If final voting results are not available to us in time to file a Form 8-K with the SEC within four (4) business days after the Annual Meeting, we intend to file a Form 8-K to publish preliminary results and, within four (4) business days after the final results are known to us, file an additional Form 8-K to publish the final results.

I also have received a copy of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023. Is that a part of the proxy materials?

We filed our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, with the SEC on March 11, 2024. A copy of our Annual Report accompanies this proxy statement. This document constitutes our Annual Report to Stockholders, and is being made available to all stockholders entitled to receive notice of and to vote at the Annual Meeting. Except as otherwise stated, the Annual Report is not incorporated into this proxy statement and should not be considered proxy solicitation material.

When are stockholder proposals due for next year's annual meeting?

Stockholders may submit proposals on matters appropriate for stockholder action at the 2025 Annual Meeting of Stockholders consistent with Rule 14a-8 promulgated under the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"). To be timely and considered for inclusion in proxy materials for our 2025 Annual Meeting of Stockholders, a stockholder proposal must be submitted in writing no later than November 30, 2024 to our Corporate Secretary at 10865 Road to the Cure, Suite 150, San Diego, California 92121. However, if the date of the 2025 Annual Meeting of Stockholders is convened more than 30 days before, or delayed by more than 30 days after, May 14, 2025, to be considered for inclusion in proxy materials for our 2025 Annual Meeting of Stockholders, a stockholder proposal must be submitted in writing to our Corporate Secretary at 10865 Road to the Cure, Suite 150, San Diego, California 92121 a reasonable time before we begin to print and send our proxy materials for our 2025 Annual Meeting of Stockholders. If you would like to submit a matter for consideration at our 2025 Annual Meeting of Stockholders (including any stockholder proposal not submitted under Rule 14a-8 or any director nomination) that will not be included in the proxy statement for that annual meeting, it must be received by our Corporate Secretary a reasonable period of time prior to the 2025 Annual Meeting of Stockholders. Please review our Bylaws, which contain requirements regarding advance notice of stockholder proposals. You may view our Bylaws by visiting the SEC's Internet website at www.sec.gov. In addition to satisfying the foregoing requirements under our Bylaws, to comply with the universal proxy rules stockholders who intend to solicit proxies in support of director nominees other than management's nominees must provide notice that sets forth the information required by Rule 14a-19 under the Exchange Act no later than March 15, 2025.

INFORMATION REGARDING THE BOARD OF DIRECTORS AND CORPORATE GOVERNANCE

The following table sets forth each member of our Board:

Name	Positions
Linda Marbán, Ph.D.	President, Chief Executive Officer and Director
Frank Litvack, M.D.	Executive Chairman and Director
Earl M. (Duke) Collier Jr., J.D.	Director
David B. Musket	Director
George W. Dunbar Jr., M.B.A.	Director
Karimah Es Sabar	Director
Paul Auwaerter, M.D., M.B.A.	Director
Philip Gotwals, Ph.D.	Director
Michael Kelliher	Director

We believe that in order for our Board to effectively guide us through our continued growth as a development-stage biopharmaceutical company, it should be composed of individuals with sophistication and experience in the many disciplines that impact our business. In order to best serve our stockholders, we seek to have a Board, as a whole, that is competent in key corporate disciplines, including accounting and financial acumen, business judgement, governance, leadership, risk management, social responsibility and reputational issues, strategy and strategic planning. Additionally, we desire that the Board have specific knowledge related to our industry, such as expertise in healthcare, medical technology, and manufacturing. While we do not have a formal policy on diversity, when considering the selection of director nominees, the Nominating and Governance Committee considers individuals with diverse backgrounds, viewpoints, accomplishments, cultural backgrounds and professional expertise, among other factors. Further, our Board is committed to actively seeking highly qualified women and individuals from underrepresented minority groups to include in the pool from which new candidates are selected. Of our seven directors, two directors self-identify as female and one director self-identifies as a racial or ethnic minority.

PROPOSAL NO. 1:

ELECTION OF DIRECTORS

Our Board recommends that the nominees below be elected as member of the Board at the Annual Meeting:

Name	Age*	Positions Held	Director of Company Since
Linda Marbán, Ph.D.	60	President, Chief Executive Officer and Director	2013
Frank Litvack, M.D.	68	Executive Chairman and Director	2013
Earl M. (Duke) Collier, Jr., J.D.	76	Director	2013
David B. Musket	66	Director	2013
George W. Dunbar Jr., M.B.A.	77	Director	2013
Karimah Es Sabar	66	Director	2021
Paul Auwaerter, M.D., M.B.A.	62	Director	2023
Philip Gotwals, Ph.D.	61	Director	2023
Michael Kelliher	47	Director	2023

*Ages as of March 18, 2024.

The Nominating and Corporate Governance Committee recommended, and the Board approved, each of the nominees for election to the Board at the 2024 Annual Meeting of Stockholders. There are no family relationships between or among any of our executive officers, directors or nominees for director.

Directors are elected by a plurality of the votes of the shares present in person or represented by proxy and entitled to vote for directors. The nine (9) nominees receiving the highest number of affirmative votes will be elected. Shares represented by executed proxies will be voted, if authority to do so is not withheld, for the election of the nine (9) nominees named below. Broker non-votes will have no effect on whether any nominee is elected.

If elected by our stockholders, each nominee will serve for a one-year term expiring at our 2025 Annual Meeting of Stockholders. Each director will hold office until his or her successor has been elected and qualified or until the director's earlier resignation, removal or disqualification. If any nominee becomes unavailable for election as a result of an unexpected occurrence, your shares will be voted for the election of a substitute nominee proposed by the Board. Each person nominated for election has agreed to serve if elected. Our management has no reason to believe that any nominee will be unable to serve.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT YOU VOTE "FOR" EACH NAMED NOMINEE.

We look to our directors to lead us through our continued growth as a development-stage public biopharmaceutical company. Our directors bring their leadership experience from a variety of life science and other companies and professional backgrounds which we require to continue to grow and bring value to our stockholders.

Director Nominees

The Nominating and Corporate Governance Committee seeks to assemble a Board that, as a whole, possesses the appropriate balance of professional and industry knowledge, financial expertise and high-level management experience necessary to oversee and direct our business. The brief biographies below include information, as of the date of this proxy statement, regarding the specific and particular experience, qualifications, attributes or skills of each nominee that led the Nominating and Corporate Governance Committee to recommend that person as a nominee, and for the Board as a whole to approve the nomination of that person to the Board.

Linda Marbán, Ph.D. Dr. Marbán is currently serving as our Chief Executive Officer, and has served in that capacity and on the Board since November 2013. As co-founder of Capricor, Inc., our wholly-owned subsidiary, Dr. Marbán has been with Capricor, Inc. since 2005 and became its Chief Executive Officer in 2010. Dr. Marbán has been in the biotechnology field for more than 20 years and brings extensive experience across research, product development and business development to the Company. From 2003-2009, Dr. Marbán held various senior roles at Excigen, Inc., a gene therapy biotechnology company, where she was responsible for operations and business development and where she

oversaw the development of a biologic pacemaker for the heart. Prior to Excigen, Dr. Marbán worked in academic science, first at the Cleveland Clinic Foundation working on the development of contractile dysfunction in heart failure due to myocarditis, followed by a postdoctoral fellowship at Johns Hopkins University. While at Johns Hopkins, she advanced to the rank of Research Assistant Professor in the Department of Pediatrics, specializing in the mechanism of the biophysical properties of cardiac muscle. Her tenure at Johns Hopkins ran from 2000 to 2003. Dr. Marbán earned a Ph.D. from Case Western Reserve University in cardiac physiology and her Bachelor of Science from the University of Maryland.

Dr. Linda Marbán was selected to serve as a member of the Board in part due to her wealth of knowledge in research and development, especially for the treatment of cardiovascular diseases, her experience in early-stage life sciences companies spanning over a decade, as well as her business development expertise.

Frank Litvack, M.D., FACC. Dr. Litvack joined the Capricor, Inc. board in 2012 and since November 2013 has been serving as the Company's Executive Chairman. Dr. Litvack is a native of Canada. He completed medical school and residency at McGill University in Montreal and a Cardiovascular Fellowship at Cedars-Sinai Medical Center in Los Angeles, where he subsequently became co-director of the Cardiovascular Intervention Center and Professor of Medicine at UCLA. There he led a prominent clinical and research program known for its excellence in innovation, care, and leadership in Translational Medicine. Dr. Litvack was board-certified in Internal Medicine, Cardiovascular Diseases, and Interventional Cardiology. He has published more than one hundred research articles and chapters and is the recipient of several awards, including an American Heart Association Young Investigator Award, the Leon Goldman Medical Excellence Award for contributions to the field of biomedical optics, and the United States Space Technology and Space Foundation Hall of Fame for pioneering work with the excimer laser. Dr. Litvack left full-time practice and academics in 2000 to concentrate on entrepreneurial activities. Dr. Litvack has founded and operated several healthcare ventures, both as chairman and/or chief executive officer, including Progressive Angioplasty Systems Inc., a medical device company that was acquired by United States Surgical Corp. in 1998; Savacor, Inc., a medical device company that was acquired by St. Jude Medical in 2005; and Conor Medsystems, Inc., a publicly-traded medical device company that was acquired by Johnson & Johnson in 2007. He presently sits on the boards of several early-stage healthcare companies, including Credence MedSystems, a drug delivery company; V Wave Medical, a heart failure company; and as Director of Levation Pharma, a specialty pharmaceutical company in the area of facial aesthetics which he co-founded. Additionally, he was a Board Member of MedAvail Inc., a pharmacy technology company. Dr. Litvack was a former director of Nile Therapeutics, Inc. (predecessor entity to the Company) from 2009 to 2012. Dr. Litvack was formerly a Member of the Management Company of Pura Vida Investments, LLC, a healthcare hedge fund. Since 2023, he is the Managing Member of Wilhareka Partners LLC. He is serving as a Director on the board of Cardiovascular Research Foundation, a non-profit research and education entity and on the Advisory Board of the Tannenbaum Open Science Institute at McGill University.

Dr. Frank Litvack, our Executive Chairman, was selected to serve as a member of the Board in part due to his wealth of business-building experience and medical expertise that anchors our activities in sound scientific research and solid business planning and practices. Additionally, as an accomplished veteran of the healthcare industry who has orchestrated the founding, development, financing and sale of several medical technology companies, we believe that Dr. Litvack provides invaluable knowledge and leadership to the Company.

Earl M. (Duke) Collier Jr. Mr. Collier has been a member of the Capricor, Inc. board since 2011 and became a member of the Company's Board in November 2013. He is a member of the Company's Compensation Committee and Chairman of the Nominating and Corporate Governance Committee. From 2010-2014, he served as the Chief Executive Officer of 480 Biomedical, a medical device company developing products used in the treatment of peripheral artery disease, and the executive chairman of Arsenal Medical, Inc., a medical device company. Mr. Collier was formerly Executive Vice President at Genzyme Corporation, a biotechnology company acquired by Sanofi for $20.1 billion in 2011. Mr. Collier also served as President of Vitas Healthcare, a hospice provider, as a partner at the Washington, DC-based law firm of Hogan and Hartson, and as Deputy Administrator of the Health Care Finance Administration (now CMS) in the U.S. Department of Health & Human Services. He is Chair Emeritus of the Innovation Advisory Board of Mass General Brigham. Additionally, he is a member of the board of the Boston Athenaeum. Previously, Mr. Collier served as a director of publicly-traded Decode Genetics Inc. (DGI Resolution, Inc.), a biopharmaceutical company; GenSight, a gene therapy company in Paris that trades on the French Euronext exchange; and Tesaro, Inc., a publicly-traded biopharmaceutical company. Mr. Collier earned a Bachelor of Arts degree at Yale University and received a law degree from the University of Virginia Law School.

Mr. Collier was selected to serve as a member of the Board in part due to his significant experience with early stage private and public companies and depth of knowledge in building stockholder value, growing a company from inception and navigating significant corporate transactions and the public company process. Additionally, Mr. Collier has extensive experience in the pharmaceutical industry, allowing him to contribute significant operational experience.

David B. Musket. Mr. Musket has been a member of the Capricor, Inc. board since 2012 and a member of the Company's Board since November 2013. He is Chairman of the Company's Audit and Compensation Committees. Mr. Musket has vast experience in strategic finance and has been following developments in the pharmaceutical and medical device industries for over 30 years. Mr. Musket began his investment career as an equities research analyst at Goldman Sachs & Co. following the pharmaceutical industry. From 1991 through 2016 he served as President of Musket Research Associates, a registered broker/dealer focused exclusively on venture banking transactions for emerging healthcare companies. In 1996 he co-founded ProMed Management, a healthcare-focused investment management company that he continues to run today. He has served on the boards of several private and public companies throughout his career. From 1999 to 2007, Mr. Musket served on the board of directors of publicly-traded Conor MedSystems, Inc. a medical device company sold to Johnson & Johnson in 2007 for $1.4 billion. Mr. Musket holds a Bachelor of Arts degree in Biology and Psychology from Boston College.

Mr. Musket was selected to serve as a member of the Board in part due to his venture capital and investment banking backgrounds and expertise in financing and growing early-stage biopharmaceutical companies. Additionally, Mr. Musket has significant experience with early stage private and public companies and brings a depth of knowledge in building stockholder value, growing a company from inception and navigating significant corporate transactions and the public company process.

George W. Dunbar Jr. Mr. Dunbar has been a member of the Capricor, Inc. board since 2012 and a member of the Company's Board since November 2013. He is a member of the Company's Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee. He is Managing Partner of The Dunbar Group, LLC, and provides advisory services to healthcare and life science investors and companies who recognize they need short-term or interim industry expertise as they grow in order to be capital efficient. Mr. Dunbar has extensive healthcare and life sciences operating experience and has served as a director or chief executive officer with private and public life science companies specializing in diagnostics, specialty pharma, cell therapy and biologics, two as chief executive officer, where he led initial public offerings. He served as chief executive officer of ISTO Technologies and ISTO Biologics, two private orthobiologics companies acquired by Thompson Street Capital Partners. Prior to ISTO, Mr. Dunbar served as a Venture Partner with Arboretum Ventures, a leading healthcare venture capital firm. Mr. Dunbar is currently a board member of Progenitor Life Sciences, a private next-generation immunotherapy development company, and Executive Chairman of Akadeum Life Sciences, a private next-generation sample prep/separations tools company with a focus on cell and gene therapy. Mr. Dunbar attended Auburn University where he graduated with a Bachelor of Science degree in Electrical Engineering and later received his M.B.A. He served on the Harbert College of Business M.B.A. Advisory Board and is an advisor with Life Science Tennessee and to Vanderbilt University's Center for Technology Transfer and Commercialization.

Mr. Dunbar was selected to serve as a member of the Board in part due to his significant experience with early stage private and public companies and depth of knowledge in building stockholder value, growing a company from inception and navigating significant corporate transactions and the public company process. Additionally, Mr. Dunbar has extensive experience in the pharmaceutical industry, allowing him to contribute significant operational experience.

Karimah Es Sabar. Ms. Es Sabar joined the Company's Board in July 2021 and is a member of the Audit Committee and Nominating and Corporate Governance Committees. Since 2016 she has been the CEO and General Partner at Quark Venture LP, a venture capital investment firm, leading their global health sciences enterprise. Prior to Quark Venture, Ms. Es Sabar was President and CEO at the Centre for Drug Research and Development (CDRD), Canada's national drug development and commercialization center, responsible for developing and executing on the overall strategic direction. Ms. Es Sabar has held senior management positions with multinational pharmaceutical companies, most notably as Director International Division, and later Global Head Marketing and Business Development at Pasteur Merieux Connaught (Sanofi Pasteur) based in Toronto. She holds degrees in Neurochemistry from the Institute of Psychiatry, University of London, in Biochemistry and Chemistry from the University of Salford Manchester, and an Executive Certificate in Management and Leadership from the MIT Sloan School of Management. Ms. Es Sabar is also the Chair of the Health Biosciences Economic Strategy Table (Government of Canada) and she serves on the board of directors of several biosciences companies.

Ms. Es Sabar was selected to serve as a member of the Board in part due to her significant experience with early stage private and public companies and brings a depth of knowledge in building stockholder value, growing a company from inception and navigating significant corporate transactions and the public company process. Additionally, Ms. Es Sabar has expertise in the innovation ecosystem and has extensive experience in the pharmaceutical industry, allowing her to contribute significant operational experience.

Paul G. Auwaerter, M.D., M.B.A., FIDSA. Dr. Paul Auwaerter joined the Company's Board in July 2023. Dr. Auwaerter was first identified as a candidate for director by Louis Manzo, a former Capricor board member. Since 2013, Dr. Auwaerter has been the Sherrilyn and Ken Fisher Professor of Medicine at the Johns Hopkins University School of Medicine, serving as the Clinical Director for the Division of Infectious Diseases and Director of the Sherrilyn and Ken Fisher Center for Environmental Infectious Diseases. Dr. Auwaerter has served since 2003 as the Executive Director and Chief Medical Officer of the Johns Hopkins Point of Care-Information Technology (POC-IT) Center, producing the Johns Hopkins ABX (Antibiotic), JH HIV, JH Osler, JH Psychiatry and JH Diabetes Guides. Dr. Auwaerter has also served as Editor-in-Chief of the ABX Guide since 2017. Dr. Auwaerter's research and clinical interests include improving the diagnosis and care for patients with infectious diseases, specifically Lyme disease, respiratory infections, surgical infections, prosthetic joint infections, Epstein-Barr virus, and fever of unknown origin. He has served as Chair of the Infectious Diseases Society of America Foundation and has been on the Board of Directors of the American Lyme Disease Foundation since 2018. He is a Past President of the Infectious Diseases Society of America (IDSA), the largest professional society worldwide related to infectious diseases, serving from 2017 to 2018. Dr. Auwaerter has been a member of the Board of Directors of the Baltimore Area Council of the Boy Scouts of America and has been awarded the National Distinguished Eagle Scout award. Dr. Auwaerter holds undergraduate and medical degrees from Columbia University and subsequent training in medicine and infectious diseases at Johns Hopkins, where he has been employed since 1988; he also trained in the virology and immunology laboratory of Dr. Diane Griffin.

Dr. Paul Auwaerter was selected to serve as a member of the Board in part due to his extensive medical background, including expertise in infectious diseases.

Philip J. Gotwals, Ph.D. Dr. Philip Gotwals joined the Company's Board in July 2023. Dr. Gotwals was first identified as a candidate for director by a third-party search firm. Dr. Gotwals has experience in drug development, research, corporate strategy and business development with a career spanning nearly 30 years in the biotechnology industry. Dr. Gotwals has been a Partner at RedSky Partners, LLC, which provides advisory services to the biotechnology industry in the areas of corporate strategy and business development since 2023. Previously, Dr. Gotwals served as the Global Head, Vice President of Business Development and Licensing at Novartis Institutes for Biomedical Research (NIBR) from 2019 to 2023, where he oversaw business development efforts for all disease areas and technology platforms. Prior to that, Dr. Gotwals was Global Head of Search and Evaluation of NIBR from 2017 to 2019. Dr. Gotwals also served as Executive Director, Immuno-Oncology, at NIBR from 2009 to 2017. Under Dr. Gotwals' leadership, NIBR business development and licensing executed over 50 major strategic transactions which included licensing deals, collaborations, acquisitions and new company creations. These transactions led to significant corporate evolution and growth. During his 13 years at NIBR, Dr. Gotwals was instrumental in building the company's immuno-oncology strategic research area and spearheading the collaboration with the University of Pennsylvania to develop chimeric antigen receptor (CAR) T-cell therapies. Prior to NIBR, he was Vice President of Program Management at Altus Pharmaceuticals from 2006 to 2009, where he was responsible for all product development project management activities. Prior to Altus, he was Senior Director of Program and Alliance Management at Biogen, from 1994 to 2006, where he oversaw leadership of internal and allied early product development teams in the autoimmune, neurology and oncology therapeutic areas. Dr. Gotwals has a B.A. in Biology from Amherst College, holds a Ph.D. in Genetics from the University of California at Berkeley, completed postdoctoral research at the Massachusetts Institute of Technology, business training at Harvard Business School and has published extensively in the area of integrin biology.

Dr. Gotwals was selected to serve as a member of the Board in part due to his significant experience with early stage private and public companies and brings a depth of knowledge in building stockholder value, growing a company from inception and navigating significant corporate transactions and the public company process. Additionally, Dr. Gotwals has extensive experience in the pharmaceutical industry, allowing him to contribute significant operational experience.

Michael Kelliher. Michael Kelliher joined the Company's Board in September 2023. Mr. Kelliher was first identified as a candidate for director by a third-party search firm. Mr. Kelliher is an experienced business development and finance professional with expertise in corporate strategy, mergers and acquisitions, strategic partnerships and licensing,

with a career spanning more than 20 years with leading biotechnology and global pharmaceutical companies. He recently joined Ardelyx, a company focused on discovering, developing and commercializing first-in-class targeted therapies that advance patient care, as Executive Vice President of Corporate Development and Strategy. There, he has responsibility for strategy, business development, and M&A. Prior to Ardelyx, Mr. Kelliher served as Group Vice President, M&A and Business Development, at Horizon Therapeutics (now Amgen), a global biotechnology company focused on researching, developing and commercializing medicines for rare, autoimmune and severe inflammatory diseases. During Mr. Kelliher's 9-year tenure at Horizon, he led an aggressive growth and expansion agenda through acquisitions, development collaborations and other transactions. He was instrumental in transforming Horizon into a $28.0 billion innovation-driven biotech company. Prior to his time at Horizon, from 2009 to 2014, Mr. Kelliher held progressive financial roles at Elan Corporation (now Perrigo Company), a leading global pharmaceutical company where he oversaw strategic partnerships and collaborations and advised its Board of Directors and senior leadership on investments, business development, product commercialization and asset monetization. Mr. Kelliher began his career in banking, public accounting and corporate finance and holds a Bachelor of Commerce degree from the University College Cork (Ireland). He is also an Associated Chartered Accountant.

Mr. Kelliher was selected to serve as a member of the Board in part due to his significant experience with early stage private and public companies and brings a depth of knowledge in building stockholder value, growing a company from inception and navigating significant corporate transactions and the public company process. Additionally, Mr. Kelliher has extensive experience in the pharmaceutical industry, allowing him to contribute significant operational experience.

Independence of the Board of Directors

Pursuant to the independence rules of The Nasdaq Stock Market LLC ("***Nasdaq***"), a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the board of directors. The Board consults with our counsel to ensure that the Board's determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and us, our senior management and our independent auditors, the Board has affirmatively determined that the following eight directors are independent directors within the meaning of the applicable Nasdaq listing standards: Dr. Frank Litvack, Mr. Earl Collier, Mr. David Musket, Mr. George Dunbar, Ms. Es Sabar, Dr. Paul Auwaerter, Dr. Philip Gotwals and Mr. Michael Kelliher. The Board also determined that Mr. Louis Manzo, who served as a director during fiscal year 2023 prior to his resignation, effective July 11, 2023, was independent within the meaning of the applicable Nasdaq listing standards. In making this determination, the Board found that none of these directors had a material or other disqualifying relationship with us. In addition to transactions required to be disclosed under SEC rules, the Board considered certain other relationships in making its independence determinations, and determined in each case that such other relationships did not impair the director's ability to exercise independent judgment on our behalf. Each of our standing Board committees entirely consist of, and throughout fiscal year 2023 consisted of, independent directors.

Dr. Linda Marbán, our President and Chief Executive Officer, is not an independent director by virtue of her employment with the Company.

Board Meetings and Committees

During the last fiscal year, the Board met ten (10) times and took action by unanimous written consent ten (10) times. All directors, except Dr. Philip Gotwals attended at least 75% of the aggregate number of meetings of the Board and of the committees on which they served that were held during the portion of the last fiscal year for which they were directors or committee members, respectively.

It is our policy to invite directors and nominees for director to attend the Annual Meeting of Stockholders either in person or by telephone. Dr. Linda Marbán attended the 2023 Annual Meeting of Stockholders.

As required under applicable Nasdaq listing standards, our independent directors periodically meet in executive session at which only they are present.

The Board has three primary committees: an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Each committee operates pursuant to a written charter, which are available in the Corporate Governance section of our website at www.capricor.com. The information contained on, or that can be accessed through, our website is not incorporated by reference and is not a part of this proxy statement.

The following table provides membership and meeting information for 2023 for each of these committees of the Board:

Name	Audit	Compensation	Nominating and Corporate Governance
Linda Marbán, Ph.D.	—	—	—
Frank Litvack, M.D.	—	—	—
Earl M. (Duke) Collier Jr., J.D.	—	X	X *
David B. Musket	X *	X *	—
George W. Dunbar Jr., M.B.A.	X	X	X
Karimah Es Sabar	X	—	X
Paul Auwaerter, M.D., M.B.A.	—	—	—
Philip Gotwals, Ph.D.	—	—	—
Michael Kelliher	—	—	—
Total meetings held in 2023	4	3	1
Total actions by unanimous written consent in 2023	1	3	—

*Committee Chairperson

Below is a description of each primary committee of the Board. Each of these committees has authority to engage legal counsel or other experts or consultants, as it deems appropriate to carry out its responsibilities. The Board has determined that each member of each of these committees meets the applicable Nasdaq listing standards and regulations regarding "independence" and that the members of the Audit Committee and Compensation Committee meet the heightened independence standards applicable to those committees under the rules promulgated by the SEC and the Nasdaq listing standards. The Board has additionally determined that each committee member is free of any relationship that would impair his or her individual exercise of independent judgment with regard to us.

Audit Committee

The current members of our Audit Committee are Mr. David Musket (Chair), Mr. George Dunbar and Ms. Karimah Es Sabar. Mr. Louis Manzo served as a member of our Audit Committee until his resignation from the Board and all Board committees, effective July 11, 2023. The Board has determined that Mr. Musket qualifies as an "audit committee financial expert," as defined by the applicable rules of the SEC.

The Audit Committee of the Board is a separately-designated standing audit committee established by the Board in accordance with Section 3(a)(58)(A) of the Exchange Act.

The Audit Committee acts on behalf of the Board in fulfilling the Board's oversight responsibilities with respect to our accounting and financial reporting processes and audits of financial statements, and also assists the Board in its oversight of the quality and integrity of our financial statements and reports and the qualifications, independence and performance of our independent registered public accounting firm. For this purpose, the Audit Committee performs several functions. A summary of the responsibilities of the Audit Committee include:

- selecting, appointing, determining the compensation of, retaining and overseeing the work of our independent registered public accounting firm and any other registered public accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for us;
- prior to engagement of any prospective registered public accounting firm, reviewing and discussing with the prospective independent registered public accounting firm a written disclosure by the prospective independent registered public accounting firm of all relationships between us, or persons in financial oversight roles, and such independent registered public accounting firm or their affiliates;
- pre-approving engagements of the independent registered public accounting firm, prior to commencement of the engagement, and the scope of and plans for the audit;

- monitoring the rotation of partners of the independent registered public accounting firm on our audit engagement team;
- reviewing with management and the independent registered public accounting firm any fraud, whether or not material, that includes management or employees who have a significant role in our internal control over financial reporting and any significant changes in internal controls or other factors that could significantly affect internal controls, including any corrective actions in regards to significant deficiencies or material weaknesses;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or other auditing matters and the confidential and anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- reviewing our compliance with applicable laws and regulations and reviewing and overseeing any policies, procedures or programs designed to monitor such compliance;
- reviewing and discussing with management and the independent registered public accounting firm the annual audited financial statements (including the related notes) and any major issues regarding accounting principles and financial statement presentation and all other matters required to be discussed under generally accepted accounting standards, the results of the independent registered public accounting firm's review of our quarterly financial information prior to public disclosure and our disclosures in our periodic reports filed with the SEC; and
- performing, at least annually, an evaluation of the performance of the Audit Committee and its members, including a review of the Audit Committee's compliance with its charter.

The Audit Committee reviews, discusses and assesses its own performance at least annually, including a review of its compliance with its charter. The Audit Committee also, at least annually, reviews and assesses its charter and recommends any proposed changes to the charter to the Board for its consideration.

Compensation Committee

The current members of our Compensation Committee are Mr. David Musket (Chair), Mr. Earl Collier and Mr. George Dunbar.

The Compensation Committee acts on behalf of the Board to discharge the Board's responsibilities relating to the compensation of our executives, including by designing, recommending to the Board for approval and evaluating our compensation plans, policies and programs. The Compensation Committee is also responsible for reviewing, discussing with management and approving our disclosures relating to executive compensation for use in our reports filed with the SEC. A summary of the responsibilities of the Compensation Committee include:

- reviewing, at least annually, our compensation philosophy;
- determining and approving (or, if the Compensation Committee deems appropriate, recommending to the Board for determination and approval) corporate goals and objectives relating to the compensation of the Chief Executive Officer, evaluating the performance of the Chief Executive Officer in light of those goals, and determining or recommending the compensation of our Chief Executive Officer, including seeking to achieve an appropriate level of risk and reward in determining the long -term incentive component of the Chief Executive Officer's compensation;
- determining and approving (or, if the Compensation Committee deems appropriate, recommending to the Board for determination and approval) the compensation for all other executive officers and senior management, taking into consideration such person's success in achieving his or her individual goals and objectives and the corporate performance goals and objectives deemed relevant to such executive officers and senior management;
- reviewing and approving (or, if it deems appropriate, making recommendations to the Board regarding) the terms of employment agreements, severance agreements, change-of-control protections and other compensatory arrangements for our executive officers and senior management;
- reviewing and approving the type and amount of compensation to be paid or awarded to non-employee directors;
- reviewing and approving the adoption, amendment and termination of our stock option plans, stock appreciation rights plans, pension and welfare benefit plans, incentive plans, stock bonus plans, stock purchase plans, bonus plans, deferred compensation plans and similar programs, as applicable, and

administering all such plans, setting performance targets, selecting participants, approving grants and awards and exercising such other power and authority as may be permitted or required under such plans;

- establishing and reviewing policies concerning perquisite benefits;
- reviewing our incentive compensation arrangements to determine whether such arrangements encourage excessive risk-taking, and reviewing and discussing the relationship between our risk management policies and practices and compensation, and evaluating compensation policies and practices that could mitigate any such risk, at least annually;
- reviewing and recommending to the Board for approval the frequency with which we conduct a vote on executive compensation, taking into account the results of the most recent stockholder advisory vote on the frequency of the vote on executive compensation, and reviewing and approving the proposals and frequency of the vote on executive compensation to be included in our annual meeting proxy statements, when necessary;
- periodically reviewing the need for a Company policy regarding compensation paid to the Company's executive officers in excess of limits deductible under Section 162(m) of the Internal Revenue Code of 1986, as amended, when applicable;
- determining the Company's policy with respect to change of control or parachute payments;
- managing and reviewing executive officer indemnification and insurance matters; and
- evaluating the Committee's own performance and reviewing and assessing the Compensation Committee Charter.

The Compensation Committee holds regular or special meetings as its members deem necessary or appropriate. The Compensation Committee, through the chairperson of the Compensation Committee, reports all material activities of the Compensation Committee to the Board from time to time, or whenever so requested by the Board. The charter of the Compensation Committee grants the Compensation Committee authority to select, retain and obtain, at our expense, advice and assistance from internal and external legal, accounting or other advisors and consultants and other external resources that the Compensation Committee considers necessary or appropriate in the performance of its duties. In particular, the Compensation Committee has the sole authority to retain and terminate any compensation consultants to assist in its evaluation of director, chief executive officer or senior executive compensation, including sole authority to approve the consultant's reasonable fees and other retention terms. The Compensation Committee is directly responsible for the appointment, compensation and oversight of the work of any internal or external legal, accounting or other advisors and consultants retained by the Compensation Committee. The Compensation Committee may select an internal or external legal, accounting or other advisor or consultant only after considering the independence of such internal or external legal, accounting or other advisor or consultant using factors established by law and the rules and regulations of the SEC and Nasdaq.

Under its charter, the Compensation Committee may form, and delegate authority to, one or more subcommittees as appropriate.

Nominating and Corporate Governance Committee

The current members of our Nominating and Corporate Governance Committee are Mr. Earl Collier (Chair), Mr. George Dunbar, and Ms. Karimah Es Sabar.

The Nominating and Corporate Governance Committee acts on behalf of the Board to fulfill the Board's responsibilities in overseeing all aspects of our nominating and corporate governance functions. A summary of the responsibilities of the Nominating and Corporate Governance Committee include:

- determining the minimum qualifications, qualities, skills and other expertise required for service on the Board;
- identifying, reviewing and evaluating candidates to serve on the Board, including prior to each annual meeting of stockholders at which directors are to be elected, recommending to the Board for nomination such candidates as the Nominating and Corporate Governance Committee has found to be well qualified and willing and available to serve, and after a vacancy arises on the Board or a director advises the Board of his or her intention to resign, recommending to a prospective member for appointment to the Board;
- developing and recommending to the Board for approval standards for determining whether a director has a relationship with the Company that would impair his or her independence;

- evaluating the performance of the members of the committees of the Board, reviewing the composition of such committees and recommending to the Board annually the chairmanship and membership of each committee;
- considering and recommending the removal of a director for cause, in accordance with the applicable provisions of the Company's Certificate of Incorporation and Bylaws;
- overseeing the Board in its annual review of its performance and making appropriate recommendations to improve performance;
- developing and recommending to the Board such policies and procedures with respect to the nomination of directors or other corporate governance matters as may be required to be disclosed pursuant to any rules promulgated by the SEC or otherwise considered to be desirable and appropriate;
- developing and reviewing corporate governance principles to be applicable to the Company and periodically reviewing Company policy statements to determine their adherence to the Company's Code of Business Conduct and Ethics;
- overseeing and reviewing the processes and procedures used by the Company to provide information to the Board and its committees;
- developing and recommending to the Board plans for succession to the offices of the Company's Chief Executive Officer and other executive officers and making recommendations to the Board with respect to the selection of appropriate individuals to succeed to these positions; and
- reviewing and reassessing its Charter at least annually and submitting any recommended changes to the Board for its consideration.

It is the responsibility of the Nominating and Corporate Governance Committee to periodically, and at least annually, review, discuss and assess the performance of the Board and committees of the Board. In fulfilling this responsibility, the Nominating and Corporate Governance Committee seeks input from senior management, the full Board and others. In assessing the Board, the Nominating and Corporate Governance Committee evaluates the overall composition of the Board, the Board's contribution as a whole and its effectiveness in serving our best interests and the best interests of our stockholders.

The Nominating and Corporate Governance Committee believes that candidates for director should have certain minimum qualifications, including having the ability to read and understand basic financial statements, being over 21 years of age and having the highest personal integrity and ethics. The Nominating and Corporate Governance Committee also considers such factors as possessing relevant expertise upon which to be able to offer advice and guidance to management, having sufficient time to devote to our affairs, demonstrated excellence in his or her field, having the ability to exercise sound business judgment and having the commitment to rigorously represent the long-term interests of our stockholders. However, the Nominating and Corporate Governance Committee retains the right to modify these qualifications from time to time. Candidates for director nominees are reviewed in the context of the current composition of the Board, our operating requirements and the long-term interests of our stockholders.

In conducting this assessment, the Nominating and Corporate Governance Committee considers such factors as it deems appropriate given the current needs of the Board and us, to maintain a balance of knowledge, experience and capability, as well as diversity. The Nominating and Corporate Governance Committee views diversity broadly to include diversity of experience, skills and viewpoint, as well as traditional diversity concepts such as race or gender, and sexual orientation. In the case of new director candidates, if applicable, the Nominating and Corporate Governance Committee also determines whether the nominee is independent for Nasdaq purposes, which determination is based upon applicable Nasdaq listing standards, applicable SEC rules and regulations and the advice of counsel, if necessary. The Nominating and Corporate Governance Committee conducts any appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of the Board. The Nominating and Corporate Governance Committee meets to discuss and consider the candidates' qualifications and then selects a nominee for recommendation to the Board by majority vote.

At least annually, the Nominating and Corporate Governance Committee will review, discuss and assess its own performance and composition and review and assess the adequacy of its charter, including its roles and responsibilities as outlined in its charter, and recommend any proposed changes to the Board for its consideration and approval.

It is the policy of the Nominating and Corporate Governance Committee to consider director candidates recommended by our stockholders in accordance with the procedures described under "When are stockholder proposals due for next year's annual meeting?" above. The Nominating and Corporate Governance Committee does not intend to

alter the manner in which it evaluates candidates, including the minimum criteria set forth above, based on whether or not the candidate was recommended by a stockholder.

Board Diversity

In accordance with Nasdaq's board diversity listing standards, the below disclosure includes aggregated statistical information about the members of our Board as voluntarily identified to us by each of our directors.

Board Diversity Matrix (as of March 18, 2024)

Total Number of Directors:	**9**			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	2	7	—	—
Part II: Demographic Background				
African American or Black	1	—	—	—
Alaskan Native or Native American	—	—	—	—
Asian	—	—	—	—
Hispanic or Latinx	—	—	—	—
Native Hawaiian or Pacific Islander	—	—	—	—
White	1	7	—	—
Two or More Races or Ethnicities	—	—	—	—
LGBTQ+			—	
Did Not Disclose Demographic Background			—	

Board Leadership Structure

The Board may choose to combine or separate the positions of Executive Chairman of the Board and Chief Executive Officer. While our Bylaws do not require the position of Executive Chairman of the Board and Chief Executive Officer to be separate, our Board believes that separation of these positions reinforces the independence of our Board from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of our Board as a whole. As such, Dr. Linda Marbán serves as our Chief Executive Officer and President, while Dr. Frank Litvack serves as our Executive Chairman of the Board. Our Board has concluded that our current leadership structure is appropriate at this time. However, our Board continues to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

The duties of our Executive Chairman of the Board include the following:

- Approve board of directors meeting agenda;
- Work with committee chairs on committee matters, considering strategic issues facing the Company, and with input from other directors and the Chief Executive Officer;
- Preside over board of directors' meetings;
- Attend committee meetings as appropriate;
- Coordinate effective communication between respective committee chairs and management;
- Oversee orientation for new directors;
- Oversee that the board of directors receives accurate, timely, and clear information on:
    - The Company's performance;
    - The issues, challenges, and opportunities facing the Company; and
    - Matters reserved to it for decision;
- Facilitate effective communication and constructive relationships between the board of directors and management; and
- Meet with stockholders when engagement is requested.

Hedging and Pledging Policies

As part of our Insider Trading Policy, our officers, directors, employees and consultants are prohibited from engaging in short sales of our securities and our officers, directors and employees are prohibited from engaging in hedging transactions involving our securities. Our Insider Trading Policy further prohibits officers, directors and employees from pledging securities as collateral for a loan unless pre-cleared by the compliance officer for the Insider Trading Policy.

Role of the Board in Risk Oversight

We face a variety of risks, including liquidity and operational risks. The Board and each of its committees are involved in overseeing risk associated with our business operations. The Audit Committee reviews and discusses with management and the independent registered public accounting firm our guidelines and policies with respect to risk assessment and risk management, including our major financial risk exposures and the steps taken by management to monitor and control such exposures. The Audit Committee determines and approves, prior to commencement of the audit engagement, the scope and plan for the internal audit and confers with management and the independent registered public accounting firm regarding the scope, adequacy and effectiveness of internal controls over financial reporting, including any special audit steps taken in the event of a material control deficiency. The Audit Committee also reviews with management and the independent registered public accounting firm any fraud, whether or not material, that includes management or other employees who have a significant role in our internal controls over financial reporting and any significant changes in internal controls or other factors that could significantly affect internal controls, including any corrective actions in regard to significant deficiencies or material weaknesses. Furthermore, the Audit Committee establishes procedures for the receipt, retention and treatment of complaints that we receive regarding accounting, internal accounting controls or auditing matters and the confidential and anonymous submission by our employees of concerns regarding questionable accounting or auditing matters.

It is the role of the Nominating and Corporate Governance Committee to review, discuss and assess, along with input from senior management, the performance of the Board and the committees of the Board at least annually. The Nominating and Corporate Governance Committee is responsible for developing and making recommendations to the Board for approval, and periodically reviewing with our Chief Executive Officer, the plans for succession to the offices of our Chief Executive Officer and other executive officers and the selection of appropriate individuals to succeed to executive positions.

It is the role of the Compensation Committee to review, at least annually, our compensation philosophy and to review and approve (or, if it deems appropriate, recommend to the Board for determination and approval) the compensation of our executive officers, senior management and non-employee directors, taking into consideration the individual's success in achieving his or her individual performance goals and objectives and the corporate performance goals and objectives deemed relevant to him or her, as established by the Compensation Committee, in addition to other factors. The Compensation Committee reviews and recommends to the Board for approval the frequency with which we conduct say-on-pay votes, taking into account the results of the most recent stockholder advisory vote on the frequency of such say-on-pay votes, and reviews and approves the proposals regarding the say-on-pay vote and the frequency of the say-on-pay vote to be included in each of our annual meeting proxy statements, as applicable. It is also the role of the Compensation Committee to review, at least annually, our incentive compensation arrangements to determine whether they encourage excessive risk-taking, review and discuss the relationship between our risk management policies and practices and compensation, and evaluate compensation policies and practices that could mitigate such risk.

Code of Business Conduct and Ethics

The Board has adopted a Code of Business Conduct and Ethics (the "***Code of Ethics***") that applies to all directors, officers, employees, consultants, contractors and agents, wherever they are located and whether they work for us on a full- or part-time basis. The Code of Ethics was designed to help such directors, employees and other agents to resolve ethical issues encountered in the business environment. The Code of Ethics covers topics such as conflicts of interest, compliance with laws, confidentiality of Company information, encouraging the reporting of any violations of the Code of Ethics, fair dealing and protection and use of Company assets.

A copy of the Code of Ethics, as adopted by the Board, and revised in April 2021, is available at the Corporate Governance page of our website at www.capricor.com. We may post amendments to or waivers of the provisions of the Code of Ethics, if any, made with respect to any directors and employees on that website. Please note that information

contained on, or that can be accessed through, our website is not incorporated by reference and is not a part of this proxy statement.

Stockholder Communications with the Board of Directors

Historically, we have not adopted a formal process related to stockholder communications with the Board. Nevertheless, every effort has been made to ensure that the views of our stockholders are heard by the Board or individual directors, as applicable, and that appropriate responses are provided to our stockholders in a timely manner. In order to communicate with the Board as a whole, with non-management directors or with specified individual directors, correspondence may be directed to our Corporate Secretary at 10865 Road to the Cure, Suite 150, San Diego, California 92121. Each communication will be reviewed by our Corporate Secretary to determine whether it is appropriate for presentation to the Board or such director. Communications determined by our Corporate Secretary to be appropriate for presentation to the Board or such director will be submitted to the Board or the director on a periodic basis.

INFORMATION REGARDING EXECUTIVE OFFICERS

Below is a list of the names, ages, positions, and a description of the business experience of each of our executive officers as of March 18, 2024:

Name	Age	Positions
Linda Marbán, Ph.D.	60	President, Chief Executive Officer and Director
Anthony Bergmann, M.B.A.	38	Chief Financial Officer
Karen G. Krasney, J.D.	71	Executive Vice President and General Counsel

A description of the business experience of ***Linda Marbán*** is provided above under the heading "Proposal No. 1: Election of Directors."

Anthony Bergmann, M.B.A. Mr. Bergmann has served as our Chief Financial Officer since 2018 and has been involved in the biotechnology industry for over a decade. He also serves as the Company's corporate treasurer. Mr. Bergmann joined Capricor, Inc. in 2011 and held various roles of increasing responsibility throughout his tenure. Prior to joining Capricor, Inc., Mr. Bergmann had experience in accounting, finance and operations management of companies ranging in size from start-ups to mid-size companies. Prior to Capricor, Inc., he was with the business management firm, Gettleson, Witzer, and O'Connor, in Beverly Hills, California, where he focused on accounting and finance for several production studios generating motion picture releases and worldwide revenue that exceeded $1.0 billion. The firm's clients included international foundations, actors, writers, producers and directors across the entertainment industry. While at the firm, he focused on asset management, budgeting and tax forecasting. Earlier in his career, Mr. Bergmann served in financial positions in various industries. During his time at Capricor, Mr. Bergmann coordinated the Company's reverse merger and subsequent uplisting to the Nasdaq Capital Market and has completed equity financings yielding over $100 million, to date. Mr. Bergmann oversees the Company's finance, accounting and human resource functions. Mr. Bergmann graduated from Providence College with a Bachelor of Science degree in Management and a minor in Finance. He has an M.B.A. from the University of Southern California's Marshall School of Business. He is actively involved in various venture capital and entrepreneurial associations throughout the Southern California area.

Karen G. Krasney, J.D. Ms. Krasney has served as our Executive Vice President, Secretary and General Counsel since 2012. Ms. Krasney's career spans over 40 years serving as general counsel for numerous corporations and private companies engaged in a wide variety of industries. Her extensive background and vast experience has been focused on domestic and international corporate and business law, as well as litigation. Ms. Krasney has been involved in the medical technology arena since the mid-1990s, representing several medical technology companies developing products for the treatment of cardiovascular disease. Commencing in 2002, Ms. Krasney served as legal counsel for Biosensors International Group Ltd., a multinational medical device company that developed, manufactured and sold medical devices for cardiology applications. In 2006, she accepted the position of General Counsel and Executive Vice President of Biosensors and served in that capacity until 2010. During her tenure at Biosensors Ms. Krasney, among other things, headed the legal team that facilitated the company's successful initial public offering in Singapore and was responsible for negotiating and documenting all agreements for the company worldwide, including licensing agreements with major medical device companies and agreements required for the company's international clinical trials. During her tenure at Capricor, Ms. Krasney has been responsible for overseeing all legal matters involving the Company including, business transactions, corporate governance, and intellectual property and has played an integral role in all transactional matters involving the Company. Ms. Krasney also serves as a director on the board of Cardiovascular Research Foundation, a non-profit research and education entity, and as a director for a private non-profit charitable foundation. Ms. Krasney received her Bachelor of Arts degree from the University of California, Los Angeles and her Juris Doctorate from the University of Southern California.

EXECUTIVE COMPENSATION

2023 Executive Compensation

The following summary compensation table reflects cash and non-cash compensation for the 2023 and 2022 fiscal years awarded to or earned by (i) our principal executive officer for the fiscal year ended December 31, 2023; and (ii) the two most highly-compensated individuals, other than our principal executive officer, that served as an executive officer at the end of the fiscal year ended December 31, 2023 and who received in excess of $100,000 in total compensation during such fiscal year. We refer to these individuals as our "named executive officers" or "NEOs."

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards($)[1]	All Other Compensation ($)[2]	Total ($)
Linda Marbán, Ph.D.	2023	$ 220,500	$ 50,115 [3]	$ 466,695	$ 10,005	$ 747,315
Chief Executive Officer	2022	$ 210,000	$ 63,000	$ 1,051,123	$ 9,300	$ 1,333,423
Karen Krasney, J.D.	2023	$ 362,250	$ 52,400 [4]	$ 314,047	$ 12,072	$ 740,769
Executive Vice President & General Counsel	2022	$ 345,000	$ 78,500 [5]	$ 233,911	$ 11,032	$ 668,443
Anthony Bergmann, M.B.A.	2023	$ 362,250	$ 63,350 [6]	$ 293,845	$ 11,400	$ 730,845
Chief Financial Officer	2022	$ 345,000	$ 103,500	$ 464,538	$ 10,650	$ 923,688

(1) Amounts reflect the grant date fair value of awards granted under the 2021 Equity Incentive Plan, computed pursuant to Financial Accounting Standards Board's Accounting Standards Codification 718 *"Compensation – Stock Compensation."* Assumptions used in the calculation of these amounts are included in Note 3 – "Stock Awards, Warrants and Options," of the Notes to Consolidated Financial Statements included in the Annual Report on Form 10-K as filed with the Securities and Exchange Commission on March 11, 2024. See the *"Outstanding Equity Awards at Fiscal Year-End"* table for information regarding all option awards outstanding as of December 31, 2023.

(2) Represents premiums contributed by the Company for the employee's health reimbursement account and matching contributions contributed by the Company to each NEO's account in the Company's 401(k) Plan.

(3) Dr. Marbán elected to forego a portion of her cash bonus in exchange for a stock option award. She elected to convert $26,985 of her cash bonus into stock options in lieu of receiving the cash. Pursuant to this election, she received an option award for 9,633 shares of common stock that were deemed fully vested upon the grant date of January 2, 2024.

(4) Ms. Krasney elected to forego a portion of her cash bonus in exchange for a stock option award. She elected to convert $20,000 of her cash bonus into stock options in lieu of receiving the cash. Pursuant to this election, she received an option award for 7,140 shares of common stock that were deemed fully vested upon the grant date of January 2, 2024.

(5) Ms. Krasney elected to forego a portion of her cash bonus in exchange for a stock option award. She elected to convert $25,000 of her cash bonus into stock options in lieu of receiving the cash. Pursuant to this election, she received an option award for 11,878 shares of common stock that were deemed fully vested upon the grant date of January 3, 2023.

(6) Mr. Bergmann elected to forego a portion of his cash bonus in exchange for a stock option award. He elected to convert $27,150 of his cash bonus into stock options in lieu of receiving the cash. Pursuant to this election, he received an option award for 9,692 shares of common stock that were deemed fully vested upon the grant date of January 2, 2024.

Employment Agreements and Potential Payments Upon Termination or Change in Control

Linda Marbán, Ph.D. — President and Chief Executive Officer

Dr. Linda Marbán's employment as our Chief Executive Officer is subject to the terms of that certain restated and amended employment agreement dated June 5, 2019, by and between Capricor, Inc. and Dr. Marbán. In accordance with the agreement, Dr. Marbán was initially entitled to an annual salary of $150,000. Effective January 1, 2022, Dr. Marbán's annual base salary was increased to $210,000. Dr. Marbán received a $63,000 bonus for 2022 services which was paid on March 3, 2023. Effective January 1, 2023, Dr. Marbán's annual base salary was increased to $220,500. Dr. Marbán also received a $77,100 bonus for 2023 services, of which $26,985 was converted into a fully vested option

award on January 2, 2024 and $50,115 was paid on March 4, 2024. Effective January 1, 2024, Dr. Marbán's annual base salary was increased to $229,300. Dr. Marbán's employment is at will and she has also signed an employee invention assignment, non-disclosure, non-solicitation and non-competition agreement. In the event the employment agreement is terminated during the term other than for cause, death or disability, or if Dr. Marbán resigns for good reason, she would be entitled to receive a severance payment equal to six months' salary then in effect (ignoring any decrease that forms the basis of Dr. Marbán's resignation for good reason, if applicable).

Karen Krasney, J.D. — Executive Vice President, General Counsel

Karen Krasney's employment as our Executive Vice President and General Counsel is subject to the terms of that certain employment agreement dated May 14, 2019. Under the agreement, Ms. Krasney was initially entitled to an annual salary of $300,000. Effective January 1, 2022, Ms. Krasney's annual base salary was increased to $345,000. Ms. Krasney received a $103,500 bonus for 2022 services, of which $25,000 was converted into a fully vested option award on January 3, 2023 and $78,500 was paid on March 3, 2023. Effective January 1, 2023, Ms. Krasney's annual base salary was increased to $362,250. Ms. Krasney also received a $72,400 bonus for 2023 services, of which $20,000 was converted into a fully vested option award on January 2, 2024 and $52,400 was paid on March 4, 2024. Effective January 1, 2024, Ms. Krasney's annual base salary was increased to $376,700. In addition, Ms. Krasney has signed an at-will employment, confidential information, invention assignment and arbitration agreement. In the event the employment agreement is terminated during the term other than for cause, death or disability, or if Ms. Krasney resigns for good reason, she would be entitled to receive a severance payment equal to six months' salary then in effect (ignoring any decrease that forms the basis of Ms. Krasney's resignation for good reason, if applicable).

Anthony Bergmann, M.B.A. — Chief Financial Officer

Anthony Bergmann's employment as our Chief Financial Officer is subject to the terms of that certain employment agreement dated May 14, 2019. Under the agreement, Mr. Bergmann was initially entitled to an annual salary of $200,000. Effective January 1, 2022, Mr. Bergmann's annual base salary was increased to $345,000. Mr. Bergmann also received a $103,500 bonus for 2022 services which was paid on March 3, 2023. Effective January 1, 2023, Mr. Bergmann's annual base salary was increased to $362,250. Mr. Bergmann also received a $90,500 bonus for 2023 services, of which $27,150 was converted into a fully vested option award on January 2, 2024 and $63,350 was paid on March 4, 2024. Effective January 1, 2024, Mr. Bergmann's annual base salary was increased to $376,700. In addition, Mr. Bergmann has signed an at-will employment, confidential information, invention assignment and arbitration agreement. In the event the employment agreement is terminated during the term other than for cause, death or disability, or if Mr. Bergmann resigns for good reason, he would be entitled to receive a severance payment equal to six months' salary then in effect (ignoring any decrease that forms the basis of Mr. Bergmann's resignation for good reason, if applicable).

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning unexercised stock options held by the named executive officers at December 31, 2023:

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price ($)	Option Expiration Date	
Linda Marbán, Ph.D.	25,000	—	—	1.39	03/03/2025	(1)(12)
	19,999	—	—	1.39	01/03/2027	(2)(12)
	9,998	—	—	1.39	01/02/2028	(3)(12)
	25,000	—	—	1.39	08/08/2029	(4)(12)
	353,096	15,353	—	1.39	02/12/2030	(5)(13)
	334,463	124,230	—	3.74	01/04/2031	(6)(13)
	181,043	196,787	—	3.18	01/03/2032	(7)(14)
	30,937	104,063	—	3.85	01/03/2033	(8)(14)
Karen Krasney, J.D.	3,000	—	—	1.39	03/03/2025	(1)(12)
	5,000	—	—	1.39	06/02/2026	(9)(12)
	2,500	—	—	1.39	01/03/2027	(2)(12)
	3,500	—	—	1.39	01/02/2028	(10)(12)
	14,000	—	—	1.39	08/08/2029	(11)(12)
	100,536	4,372	—	1.39	02/12/2030	(5)(13)
	69,776	25,917	—	3.74	01/04/2031	(6)(13)
	40,288	43,792	—	3.18	01/03/2032	(7)(14)
	30,211	61,667	—	3.85	01/03/2033	(8)(14)
Anthony Bergmann, M.B.A.	2,500	—	—	1.39	03/03/2025	(1)(12)
	3,000	—	—	1.39	06/02/2026	(9)(12)
	3,500	—	—	1.39	01/03/2027	(2)(12)
	5,000	—	—	1.39	01/02/2028	(10)(12)
	14,000	—	—	1.39	08/08/2029	(11)(12)
	115,002	5,001	—	1.39	02/12/2030	(5)(13)
	69,776	25,917	—	3.74	01/04/2031	(6)(13)
	80,011	86,969	—	3.18	01/03/2032	(7)(14)
	19,479	65,521	—	3.85	01/03/2033	(8)(14)

(1) Vesting schedule is as follows: The shares of common stock subject to this option vest 1/48th per month commencing April 1, 2015. This option became fully vested on March 1, 2019.

(2) Vesting schedule is as follows: The shares of common stock subject to this option vest 1/48th per month commencing February 1, 2017. This option became fully vested on January 1, 2021.

(3) Vesting schedule is as follows: 3,351 of the shares of common stock subject to this option vest 1/12th per month commencing February 1, 2018, with the last 1/12th vesting on December 31, 2018. 6,647 of the shares of common stock subject to this option vest 1/48th per month commencing on February 1, 2018. This option became fully vested on January 1, 2022.

(4) Vesting schedule is as follows: 20% of the shares of common stock subject to this option vested immediately, with the remainder vesting monthly over 48 months commencing September 1, 2019.

(5) Vesting schedule is as follows: The shares of common stock subject to this option vest 1/48th per month commencing March 1, 2020.

(6) Vesting schedule is as follows: The shares of common stock subject to this option vest 1/48th per month commencing February 1, 2021.

(7) Vesting schedule is as follows: The shares of common stock subject to this option vest 1/48th per month commencing February 1, 2022.

(8) Vesting schedule is as follows: The shares of common stock subject to this option vest 1/48th per month commencing February 1, 2023.
(9) Vesting schedule is as follows: The shares of common stock subject to this option vest 1/48th per month commencing July 1, 2016. This option became fully vested on June 1, 2020.
(10) Vesting schedule is as follows: The shares of common stock subject to this option vest 1/48th per month commencing February 1, 2018. This option became fully vested on January 1, 2022.
(11) Vesting schedule is as follows: 4,666 shares of common stock subject to this option vested immediately, with the remainder vesting monthly over 48 months commencing September 1, 2019.
(12) The options issued under the 2012 Restated Equity Incentive Plan are subject to early exercise. If the option holder elects to take advantage of the early exercise feature and purchase shares prior to the vesting of such shares, the shares will be deemed restricted stock and will be subject to a repurchase option in favor of the Company if the option holder's service to the Company terminates prior to vesting.
(13) The options issued under the 2020 Equity Incentive Plan are subject to early exercise. If the option holder elects to take advantage of the early exercise feature and purchase shares prior to the vesting of such shares, the shares will be deemed restricted stock and will be subject to a repurchase option in favor of the Company if the option holder's service to the Company terminates prior to vesting.
(14) The options issued under the 2021 Equity Incentive Plan are subject to early exercise. If the option holder elects to take advantage of the early exercise feature and purchase shares prior to the vesting of such shares, the shares will be deemed restricted stock and will be subject to a repurchase option in favor of the Company if the option holder's service to the Company terminates prior to vesting.

Pay Versus-Performance Table and Discussion

The following table sets forth additional compensation information of our Principal Executive Officer ("PEO") and our non-PEO named executive officers, along with total stockholder return, and net loss results for our fiscal years ending in 2023 and 2022:

					Value of Initial Fixed $100 Investment Based On:	
Year	Summary Compensation Table Total for PEO [1]	Compensation Actually Paid to PEO [2]	Average Summary Compensation Table Total for Non-PEO NEO [1]	Average Compensation Actually Paid to Non-PEO NEO [2]	Total Stockholder Return [3]	Net Income/(Loss) [4]
2023	$ 747,315	$ 1,123,804	$ 735,807	$ 754,663	$ 167	$ (22,287,542)
2022	1,333,423	2,190,786	796,066	820,990	132	(29,019,532)

(1) Linda Marbán served as our CEO for the entirety of 2023 and 2022. The other NEOs for 2023 and 2022 were Anthony Bergmann and Karen Krasney.
(2) The SEC's rules require certain adjustment be made to the "Summary Compensation Table" totals to determine "compensation actually paid" as reported in the "Pay Versus Performance Table" above. For purposes of the equity award adjustments shown below, no equity awards were cancelled due to a failure to meet vesting conditions and no dividends or other earnings paid on stock or option awards in the covered fiscal year prior to the vesting date were not otherwise included in the total compensation for the covered fiscal year. In calculating the "compensation actually paid" amounts reflected in these columns, the fair value or change in fair value, as applicable, of the equity award adjustments included in such calculations was computed in accordance with FASB ASC Topic 718. The valuation assumptions used to calculate such fair values did not materially differ from those disclosed at the time of grant. The following tables detail the applicable adjustments that were made to the determine "compensation actually paid" (all amounts are averages for the NEOs other than the PEO).
(3) Cumulative total shareholder return ("TSR") assumes an initial investment of $100 on December 31, 2021.
(4) Net loss attributable to the Company is reflected as reported in the Company's consolidated financial statements included in our 2023 Annual Report on Form 10-K.

Compensation Actually Paid to PEO:

Year	Summary Compensation Table Total for PEO	Deduct Option Awards [(A)]	Equity Award Adjustment [(B)]	Compensation Actually Paid to PEO
2023	$ 747,315	$ 466,695	$ 843,184	$ 1,123,804
2022	1,333,423	1,051,123	1,908,486	2,190,786

(A) Represents the amounts reported in the Option Awards column in the Summary Compensation Table for the applicable year.

(B) Represents the stock award adjustments (deductions and additions) for PEO stock awards for each applicable year calculated as follows:

PEO Equity Award Adjustment:

Year	Year-End Fair Value of Outstanding and Unvested Equity Awards Granted during the Year	Change in Fair Value of Outstanding and Unvested Equity Awards	Fair Value as of Vesting Date of Equity Awards Granted and Vested in the Year	Change in Fair Value of Equity Awards Granted in Prior Years that Vested in the Year	Total Equity Award Adjustments
2023	$ 409,592	$ 328,818	$ 111,307	$ (6,533)	$ 843,184
2022	930,816	301,185	328,436	348,049	1,908,486

Average Compensation Actually Paid to Non-PEO NEO (all amounts are averages):

Year	Summary Compensation Table Total for Non-PEO NEO	Deduct Option Awards [(A)]	Equity Award Adjustment [(B)]	Compensation Actually Paid to Non-PEO NEO
2023	$ 735,807	$ 303,946	$ 322,802	$ 754,663
2022	796,066	349,225	374,149	820,990

(A) Represents the amounts reported in the Option Awards column in the Summary Compensation Table for the applicable year.

(B) Represents the stock award adjustments (deductions and additions) for Non-PEO NEO stock awards for each applicable year calculated as follows:

Average Non-PEO NEO Equity Award Adjustment:

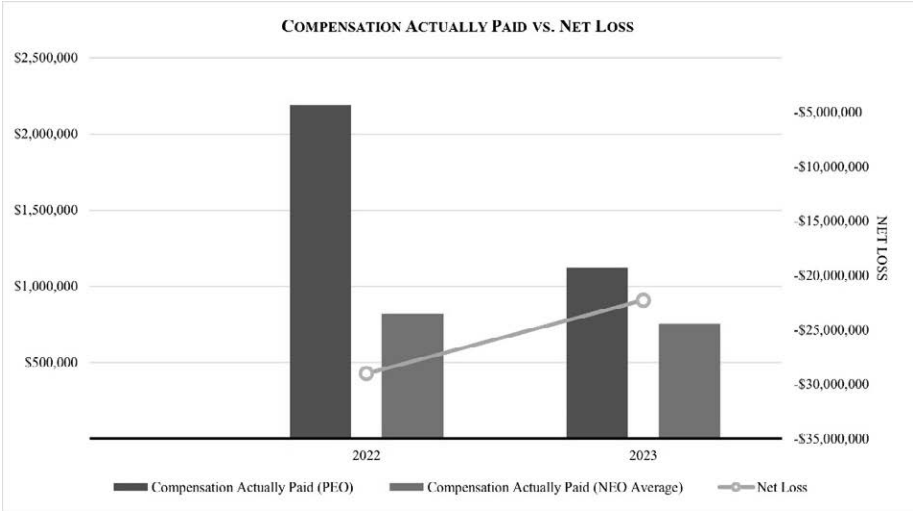
Year	Year-End Fair Value of Outstanding and Unvested Equity Awards Granted during the Year	Change in Fair Value of Outstanding and Unvested Equity Awards	Fair Value as of Vesting Date of Equity Awards Granted and Vested in the Year	Change in Fair Value of Equity Awards Granted in Prior Years that Vested in the Year	Total Equity Award Adjustments
2023	$ 250,306	$ (11,570)	$ 86,764	$ (2,698)	$ 322,802
2022	309,254	(106,570)	109,127	62,338	374,149

Pay Versus Performance Comparative Disclosure

The Company uses several measures to reward achievement of our specific annual and long-term strategic goals, however, all of those performance measures are not presented in the Pay Versus Performance Table set forth above. The Company does not specifically align the Company's performance measures with compensation that is actually paid (as calculated in accordance with Item 402(v) of Regulation S-K) for a particular year. In accordance with Item 402(v) of Regulation S-K, the Company is providing the following descriptions of the relationships between information presented in the Pay Versus Performance Table.

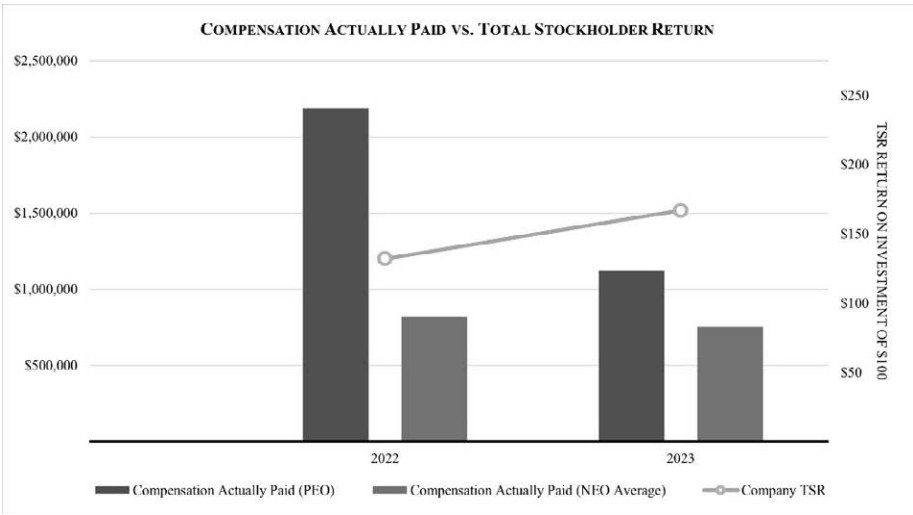
Compensation Actually Paid and Net Loss

The SEC's rules require that net loss be presented as a performance measure in the Pay Versus Performance Table above. The graph below shows the relationship between compensation actually paid to our PEO and the average of the compensation actually paid to our other NEOs and net loss attributable to the Company over the two fiscal years ending December 31, 2023, as reported in the Company consolidated financial statements.



Compensation Actually Paid and Company TSR

The SEC's rules require that TSR be presented as a performance measure in the Pay Versus Performance Table above. The graph below shows the relationship between (1) compensation actually paid to our PEO and the average of the compensation actually paid to our other NEOs and (2) our cumulative TSR, over the two fiscal years ending December 31, 2023.



Securities Authorized for Issuance Under Equity Compensation Plans

We have three equity-incentive plans that have been approved by stockholders: (i) the 2012 Restated Equity Incentive Plan; (ii) the 2020 Equity Incentive Plan (the "2020 Plan"); and (iii) the 2021 Equity Incentive Plan (the "2021 Plan"). The Company also maintains the 2012 Non-Employee Director Stock Option Plan, which has not been approved by stockholders. At this time, the Company only issues options under the 2020 Plan and 2021 Plan.

The following table sets forth additional information with respect to the shares of common stock that may be issued upon the exercise of options and other rights under our existing equity compensation plans and arrangements in effect as of December 31, 2023. The information includes the number of shares covered by, and the weighted average exercise price of, outstanding options, warrants and rights, and the number of shares remaining available for future grant, excluding the shares to be issued upon exercise of outstanding options, warrants and rights.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (A)	Weighted-average exercise price of outstanding options, warrants and rights (B)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (A))(C)
Equity compensation plans approved by security holders:			
The 2012 Restated Equity Incentive Plan[1]	282,503	$ 1.43	—
The 2020 Equity Incentive Plan	2,819,188	$ 2.72	485,588
The 2021 Equity Incentive Plan	5,125,713	$ 3.99	746,730 [2]
Total	8,227,404	$ 3.46	1,232,318

(1) The 2012 Restated Equity Incentive Plan expired in November 2022, therefore, no additional stock option awards may be granted from the 2012 Restated Equity Incentive Plan.

(2) The number of shares available for future issuance under the 2021 Plan shall automatically increase on January 1 of each year by an amount equal to 5% of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year (rounded down to the nearest whole share).

NON-EMPLOYEE DIRECTOR COMPENSATION

Compensation of Directors

The following table sets forth the compensation received by our directors in fiscal year 2023. Dr. Marbán is not listed below because she is an employee of the Company and receives no additional compensation for serving on our Board or its committees.

Name	Fees Earned or Paid in Cash	Option Awards[1][2]	All Other Compensation	Total
Frank Litvack, M.D.	—	$ 639,545	$ 120,000 [3]	$ 759,545
Earl M. (Duke) Collier Jr., J.D.	—	$ 222,369	—	$ 222,369
David B. Musket	—	$ 237,360	—	$ 237,360
George W. Dunbar Jr., M.B.A.	—	$ 211,134	—	$ 211,134
Karimah Es Sabar	—	$ 196,143	—	$ 196,143
Louis Manzo [4]	—	$ 207,378	—	$ 207,378
Paul Auwaerter, M.D., M.B.A.	—	$ 459,425	—	$ 459,425
Philip Gotwals, Ph.D.	—	$ 467,360	—	$ 467,360
Michael Kelliher	—	$ 681,375	—	$ 681,375

(1) Amounts reflect the grant date fair value of awards granted under the 2021 Equity Incentive Plan computed pursuant to Financial Accounting Standards Board's Accounting Standards Codification 718 "Compensation – Stock Compensation." Assumptions used in the calculation of these amounts are included in Note 3 – "Stock Awards, Warrants and Options" of the Notes to the Consolidated Financial Statements included in the Annual Report on Form 10-K as filed with the Securities and Exchange Commission on March 11, 2024.

(2) Options granted for the following number of shares were outstanding as of December 31, 2023: Dr. Litvack – 990,532 shares; Mr. Collier – 300,494 shares; Mr. Musket – 378,752 shares; Mr. Dunbar – 296,934 shares; Ms. Es Sabar – 183,020 shares; Mr. Manzo – 316,452 shares; Dr. Auwaerter – 115,000 shares; Dr. Gotwals – 115,000 shares; and Mr. Kelliher – 115,000 shares.

(3) Pursuant to the terms of a Consulting Agreement, dated March 24, 2014, Capricor, Inc. paid to Dr. Litvack $10,000 per month, for an aggregate of $120,000, during the year ended December 31, 2023, as consideration.

(4) Mr. Manzo resigned from the Board effective July 11, 2023.

Risk Assessment of Compensation Programs

We do not believe that our compensation programs create risks that are reasonably likely to have a material adverse effect on our Company. We believe that the combination of different types of compensation as well as the overall amount of compensation, together with our internal controls and oversight by our Board, mitigates potential risks.

Certain Relationships and Related Party Transactions

Except as reported below, there have not been transactions since January 1, 2023, in which we were a party, where the amount involved exceeded or will exceed $120,000 and in which any related party had a direct or indirect material interest.

Nippon Shinyaku Co., Ltd.

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: United States)

On January 24, 2022, Capricor entered into a Commercialization and Distribution Agreement (the "***U.S. Distribution Agreement***") with Nippon Shinyaku Co. Ltd., ("***Nippon Shinyaku***"), a Japanese corporation and a shareholder of the Company. Under the terms of the U.S. Distribution Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in the United States of CAP-1002 for the treatment of DMD.

Under the terms of the U.S. Distribution Agreement, Capricor will be responsible for the conduct of the HOPE-3 trial as well as the manufacturing of CAP-1002. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in the United States. Pursuant to the U.S Distribution Agreement, Capricor received an upfront payment of $30.0 million

in the first quarter of 2022. The first milestone payment of $10.0 million was paid in the first quarter of 2024 upon completion of the interim futility analysis of the HOPE-3 trial whereby the outcome was determined to be not futile. Additionally, there are potential milestones totaling up to $90.0 million leading up to and including the Biologics License Application approval. Further, there are various potential sales-based milestones, if commercialized, tied to the achievement of certain sales thresholds for annual net sales of CAP-1002 of up to $605.0 million. Further, pursuant to the U.S. Distribution Agreement, Capricor has the obligation to sell commercial product to Nippon Shinyaku, subject to regulatory approval, and Capricor will have the right to receive a meaningful mid-range double-digit share of product revenue.

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: Japan)

On February 10, 2023, Capricor entered into a Commercialization and Distribution Agreement (the "***Japan Distribution Agreement***") with Nippon Shinyaku. Under the terms of the Japan Distribution Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in Japan of CAP-1002 for the treatment of DMD.

Under the terms of the Japan Distribution Agreement, Capricor received an upfront payment of $12.0 million in the first quarter of 2023 and in addition, Capricor may potentially receive additional development and sales-based milestone payments of up to approximately $89.0 million, subject to foreign currency exchange rates, and a meaningful double-digit share of product revenue. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in Japan. Capricor will be responsible for the conduct of clinical development in Japan, as may be required, as well as the manufacturing of CAP-1002. Subject to regulatory approval, Capricor will sell commercial product to Nippon Shinyaku in Japan. In addition, Capricor or its designee will hold the Marketing Authorization in Japan if the product is approved in that territory.

Employment Agreements

Information regarding our executive employment agreements for certain officers is located under the caption, "Employment Agreements and Potential Payments Upon Termination or Change in Control" above.

Director and Officer Indemnification Agreements

In addition to the indemnification provisions contained in our Certificate of Incorporation and Bylaws, we generally enter into separate indemnification agreements with our directors and executive officers. These agreements require us, among other things, to indemnify the director or executive officer against specified expenses and liabilities, such as attorneys' fees, judgments, fines and settlements, paid by the individual in connection with any action, suit or proceeding arising out of the individual's status or service as our director or executive officer, other than liabilities arising from willful misconduct or conduct that is knowingly fraudulent or deliberately dishonest, and to advance expenses incurred by the individual in connection with any proceeding against the individual with respect to which the individual may be entitled to indemnification by us. We also intend to enter into these agreements with our future directors and executive officers.

Policies and Procedures for Related Party Transactions

Although we have adopted a Code of Business Conduct and Ethics, we rely on the Board to review related party transactions on an ongoing basis to prevent conflicts of interest. The Board reviews a transaction in light of the affiliations of the director, officer or employee and the affiliations of such person's immediate family. Transactions are presented to the Board for approval before they are entered into or, if this is not possible, for ratification after the transaction has occurred. If the Board finds that a conflict of interest exists, then it will determine the appropriate remedial action, if any. The Board approves or ratifies a transaction if it determines that the transaction is consistent with the best interests of the Company.

PROPOSAL NO. 2:

RATIFICATION OF THE SELECTION OF THE INDEPENDENT REGISTERED ACCOUNTING FIRM

The Audit Committee of the Board has selected Rose, Snyder & Jacobs LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2024 and has further directed that management seek stockholder ratification of the selection of the independent registered public accounting firm at the Annual Meeting. Rose, Snyder & Jacobs LLP was appointed our registered public accounting firm on January 17, 2014, and has served as our independent registered public accounting firm for each year since the year ended December 31, 2013.

Representatives of Rose, Snyder & Jacobs LLP are expected to be present at the Annual Meeting. They will have an opportunity to make a statement if they so desire and will be available to respond to appropriate questions.

Neither our Bylaws nor other governing documents or law requires stockholder ratification of the selection of Rose, Snyder & Jacobs LLP as our independent registered public accounting firm. However, the Audit Committee is submitting the selection of Rose, Snyder & Jacobs LLP to our stockholders for ratification as a matter of good corporate practice. If our stockholders fail to ratify the selection, the Audit Committee will reconsider whether or not to retain that firm. Even if the selection is ratified, the Audit Committee of the Board in its discretion may direct the appointment of different independent auditors at any time during the year if they determine that such a change would be in our best interests as well as the best interest of our stockholders.

Services provided to the Company and its subsidiaries by Rose, Snyder & Jacobs LLP for the years ended December 31, 2023 and 2022 are described below and under "Audit Committee Report."

Principal Accountant Fees and Services

In connection with the audit of the 2023 financial statements, we entered into an engagement agreement with Rose, Snyder & Jacobs LLP which sets forth the terms by which Rose, Snyder & Jacobs LLP would perform audit services for us.

The following is a summary of the approximate fees billed to us by Rose, Snyder & Jacobs LLP, our independent registered public accounting firm, for professional services rendered for the fiscal years ended December 31, 2023 and 2022 which includes Capricor, Inc. and Capricor Therapeutics, Inc.:

	Fiscal Year Ended December 31,	
Service Category	**2023**	**2022**
Audit Fees	$ 89,050	$ 86,300
Audit-Related Fees	45,250	8,000
Tax Fees	11,500	12,500
All Other Fees	1,600	4,050
Total Fees	$ 147,400	$ 110,850

In the above table, in accordance with the SEC's definitions and rules, "audit fees" are fees for professional services for the audit and review of our annual financial statements, as well as the audit and review of our financial statements included in our registration statements filed under the Securities Act and issuance of consents and for services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements, except those not required by statute or regulation; "audit-related fees" are fees for assurance and related services that were reasonably related to the performance of the audit or review of our financial statements, including attestation services that are not required by statute or regulation, due diligence and services related to acquisitions; "tax fees" are fees for tax compliance, tax advice and tax planning; and "all other fees" are fees for any services not included in the first three categories which include foreign tax research and consents necessary for applicable filings with the SEC.

Pre-Approval Policies and Procedures.

Pursuant to our Audit Committee Charter, before the independent registered public accounting firm is engaged by the Company or its subsidiaries to render audit or non-audit services, the Audit Committee pre-approves the

engagement. Audit Committee pre-approval of audit and non-audit services is not required if the engagement for the services is entered into pursuant to pre-approval policies and procedures established by the Audit Committee regarding the Company's engagement of the independent registered public accounting firm, provided the policies and procedures are detailed as to the particular service, the Audit Committee is informed of each service provided and such policies and procedures do not include delegation of the Audit Committee's responsibilities under the Exchange Act to the Company's management. The Audit Committee may delegate to one or more designated members of the Audit Committee the authority to grant pre-approvals, provided such approvals are presented to the full Audit Committee at a subsequent meeting. If the Audit Committee elects to establish pre-approval policies and procedures regarding non-audit services, the Audit Committee must be informed of each non-audit service provided by the independent registered public accounting firm. Audit Committee pre-approval of non-audit services (other than review and attest services) also is not required if such services fall within available exceptions established by the SEC. None of the services provided by our independent registered public accounting firm for fiscal 2023 or 2022 were obtained in reliance on the waiver of the pre-approval requirement afforded in SEC regulations.

The affirmative vote of a majority of the shares cast on Proposal No. 2 at the Annual Meeting will be required to ratify the selection of Rose, Snyder & Jacobs LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2024. Abstentions will have no effect on whether this proposal is approved. Under the rules of the New York Stock Exchange, brokers have discretionary authority to vote shares on this proposal. Therefore, we do not expect any broker non-votes on Proposal No. 2.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT YOU VOTE "FOR" PROPOSAL NO. 2

AUDIT COMMITTEE REPORT*

The Audit Committee has reviewed and discussed the audited financial statements for the fiscal year ended December 31, 2023, with our management. The Audit Committee has discussed with the independent registered public accounting firm the matters required to be discussed by Auditing Standard No. 1301 adopted by the Public Company Accounting Oversight Board (United States) (the "***PCAOB***") regarding "*Communications with Audit Committees*." The Audit Committee has also received the written disclosures and the letter from the independent registered public accounting firm required by applicable requirements of the PCAOB regarding the accounting firm's communications with the Audit Committee concerning independence, and has discussed with the independent registered public accounting firm the firm's independence. Based on the foregoing, the Audit Committee has recommended to the Board that the audited financial statements be included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

Respectively submitted by:
Mr. Musket
Ms. Es Sabar
Mr. Dunbar

**The material in this report is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference in any of our filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.*

PROPOSAL NO. 3:

TO APPROVE, BY NON-BINDING ADVISORY VOTE, THE RESOLUTION APPROVING NAMED EXECUTIVE OFFICER COMPENSATION

Under the Dodd-Frank Wall Street Reform and Consumer Protection Act and Section 14A of the Exchange Act, our stockholders are entitled to vote to approve, on an advisory basis, the compensation of our named executive officers as disclosed in this proxy statement in accordance with SEC rules. Consistent with the preference expressed by our stockholders at the last advisory vote on the frequency of our "say-on-pay" vote, we are conducting such vote annually. This vote is not intended to address any specific item of compensation, but rather the overall compensation of our named executive officers and the philosophy, policies and practices described in this proxy statement.

Our compensation policies are designed to align our key executives' compensation with both our business objectives and the interests of our stockholders. We also seek to provide compensation policies that attract, motivate and retain key executives who are critical to our success.

We recommend that our stockholders review the application of our compensation philosophy and the elements of compensation provided to each named executive officer as reflected in the discussion and tables included in the "2023 Executive Compensation" section of this proxy statement.

We believe our executive compensation policies are designed appropriately and are functioning as intended to produce long-term value for our stockholders. Accordingly, we are asking our stockholders to approve the overall application of our compensation policies to our named executive officers through this advisory vote.

Accordingly, the Board is asking our stockholders to indicate their support for the compensation of our named executive officers as described in this proxy statement by casting a non-binding advisory vote "FOR" the following resolution:

"RESOLVED, that the compensation paid to Capricor Therapeutics' named executive officers, as disclosed in the proxy statement for the 2024 Annual Meeting of Stockholders of Capricor Therapeutics pursuant to the compensation disclosure rules of the Securities and Exchange Commission, including the 2023 Executive Compensation, compensation tables and related narrative discussion, is hereby APPROVED on an advisory, non-binding basis."

Because the vote is advisory, it is not binding on the Board or us. Nevertheless, the views expressed by our stockholders, whether through this vote or otherwise, are important to management and the Board and, accordingly, the Board and the Compensation Committee intend to consider the results of this vote in making determinations in the future regarding executive compensation arrangements.

Advisory approval of this Proposal No. 3 requires the affirmative vote of a majority of the shares cast on Proposal No. 3 at the Annual Meeting. Abstentions and broker non-votes will have no effect on whether this proposal is approved.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT YOU VOTE "FOR" PROPOSAL NO. 3.

PROPOSAL NO. 4:

TO APPROVE AN AMENDMENT TO THE CERTIFICATE OF INCORPORATION TO INCREASE THE NUMBER OF AUTHORIZED SHARES OF OUR COMMON STOCK FROM 50,000,000 TO 100,000,000

Background of the Proposal

The Board has unanimously adopted and declared advisable, and has recommended that the Company's stockholders approve, the Charter Amendment, which would amend the Certificate of Incorporation to increase the number of authorized shares of our common stock from 50,000,000 to 100,000,000.

The following table sets forth certain information with respect to the Company's common stock as of March 18, 2024:

Common Stock	As of March 18, 2024
Shares presently authorized for issuance	50,000,000
Shares issued and outstanding	31,502,972
Shares reserved for issuance under outstanding warrants and pursuant to equity compensation plans	16,053,216
Shares presently available for issuance	2,443,812
Shares that will be available for issuance if this proposal is adopted	52,443,812

Reasons for the Charter Amendment

The Board and management believe that the limited number of currently authorized but unissued and unreserved shares of common stock may restrict the Company's ability to respond to its business needs and opportunities. The availability of additional shares of common stock for issuance will afford the Company flexibility by assuring that there will be sufficient authorized but unissued shares of common stock for business and financial purposes in the future. The additional shares may be used for various purposes without further stockholder approval. These purposes may include raising capital; providing equity incentives to employees, officers or directors; establishing strategic relationships with other companies; expanding the Company's business or product lines through the acquisition of other businesses or products; stock splits and other corporate purposes.

Except as described above, the Company currently has no plans for the use of the additional authorized shares of common stock that would become available upon stockholder approval of the Charter Amendment.

Timing and Effect

If adopted by our stockholders at the Annual Meeting, the Charter Amendment will become effective upon the filing with the Delaware Secretary of State of the Charter Amendment, which would be done as soon as practicable following the Annual Meeting.

The additional common stock to be authorized by adoption of the Charter Amendment would have rights identical to the currently outstanding common stock. A description of our common stock is contained in Exhibit 4.1 to our Annual Report on Form 10-K. Adoption of the Charter Amendment would not affect the rights of the holders of currently outstanding common stock. Effects incidental to potential dilution (such as dilution of the earnings per share and voting rights of current holders of common stock) could occur, and potential downward pressure on the market price of our common stock could occur if we elect to issue and sell common stock into the public market or otherwise.

If the Charter Amendment is approved and filed, the increased number of authorized shares of common stock will be available for issuance, from time to time, for such purposes and consideration, and on such terms, as the Board may approve, and no further vote of the stockholders of the Company will be sought, although certain issuances of shares may require stockholder approval in accordance with the requirements of Nasdaq or the General Corporation Law of the State of Delaware.

The existence of additional authorized shares of common stock could have the effect of rendering more difficult or discouraging hostile takeover attempts. For example, without further stockholder approval, the Board could adopt a

"poison pill" which would, under certain circumstances related to an acquisition of shares not approved by the Board, give certain holders the right to acquire additional shares of common stock at a low price, or the Board could strategically sell shares of common stock in a private transaction to purchasers who would oppose a takeover or favor the current Board. The Board is not aware of any existing or planned effort on the part of any party to accumulate material amounts of voting stock, or to acquire or control the Company by means of a merger, tender offer, solicitation of proxies in opposition to management or otherwise, or to change the Company's management, nor is the Board aware of any person having made any offer to acquire the voting stock or assets of the Company. Although this proposal to increase the authorized common stock has been prompted by business and financial considerations and not by the threat of any hostile takeover attempt (nor is the Board currently aware of any such attempts directed at the Company), nevertheless, stockholders should be aware that approval of this proposal could facilitate future efforts by the Company to deter or prevent changes in control of the Company, including transactions in which the stockholders might otherwise receive a premium for their shares over then current market prices.

If approved and filed, the Charter Amendment will have no effect on the number of shares of preferred stock the Company is authorized to issue.

Vote Required

The affirmative vote of a majority of the shares cast on Proposal No. 4 at the Annual Meeting will be required to approve the Charter Amendment. Abstentions will have no effect on whether this proposal is approved. Under the rules of the New York Stock Exchange, brokers have discretionary authority to vote shares on this proposal. Therefore, we do not expect any broker non-votes on Proposal No. 4.

At any time prior to the effectiveness of the filing of the Charter Amendment with the Delaware Secretary of State, notwithstanding authorization of the Charter Amendment by the stockholders of the Company, the Board may abandon the Charter Amendment without further action by the stockholders.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT YOU VOTE "FOR" PROPOSAL NO. 4.

STOCK OWNERSHIP INFORMATION

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information known to us regarding the beneficial ownership of our common stock as of March 18, 2024 by:

- each of our current directors;
- each named executive officer as defined and named in this proxy statement, and included in the Summary Compensation Table;
- all of our current directors and executive officers as a group; and
- each person known by us to beneficially own more than five percent of our common stock (based on information supplied in Schedules 13D and 13G filed with the SEC).

Except as indicated by footnote, and subject to applicable community property laws, each person identified in the table possesses sole voting and dispositive power with respect to all capital stock shown to be held by that person. The address of each named executive officer and director, unless indicated otherwise, is c/o Capricor Therapeutics, Inc., 10865 Road to the Cure, Suite 150, San Diego, California 92121.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned[1]	Percentage of Common Stock Beneficially Owned[1]
Named Executive Officers and Directors:		
Frank Litvack, M.D.[2]	897,225	2.8
Earl M. (Duke) Collier Jr., J.D.[3]	321,143	1.0
David B. Musket[4]	405,529	1.3
George W. Dunbar Jr., M.B.A.[5]	302,267	*
Karimah Es Sabar[6]	172,367	*
Paul Auwaerter, M.D., M.B.A.[7]	22,400	*
Philip Gotwals, Ph.D.[8]	17,450	*
Michael Kelliher[9]	45,370	*
Anthony Bergmann, M.B.A.[10]	372,641	1.2
Linda Marbán, Ph.D.[11]	1,326,080	4.1
Karen Krasney, J.D.[12]	334,095	1.1
Directors and executive officers as a group (11 individuals)	4,216,567	12.0
5% Stockholders:		
Highbridge Capital Management, LLC and affiliated entities[13]	5,579,398	16.3
Nippon Shinyaku Co., Ltd.[14]	4,291,844	12.8

*Represents less than 1%.

(1) We have based percentage ownership of our common stock on 31,502,972 shares of our common stock outstanding as of March 18, 2024. Beneficial ownership is determined in accordance with Rule 13d-3 under the Exchange Act and includes any shares as to which the security holder has sole or shared voting power or dispositive power, and also any shares which the security holder has the right to acquire within sixty (60) days of March 18, 2024, whether through the exercise or conversion of any stock option, convertible security, warrant or other right. The indication herein that shares are beneficially owned is not an admission on the part of the security holder that he, she or it is a direct or indirect beneficial owner of those shares.

(2) Includes (i) 133,269 shares held by Dr. Litvack; (ii) 743,565 shares issuable upon the exercise of stock options held directly by Dr. Litvack that are exercisable or will become exercisable within sixty (60) days of March 18, 2024; and (iii) 20,391 shares issuable upon the exercise of warrants held directly by Dr. Litvack which are exercisable or will become exercisable within sixty (60) days of March 18, 2024. The shares issuable upon the exercise of stock options issued to Dr. Litvack are subject to early exercise under the 2021 Plan, the 2020 Plan, and the Capricor Therapeutics, Inc. 2012 Restated Equity Incentive Plan. As of March 18, 2024, Dr. Litvack has not indicated his intent to exercise early. If the option holder elects to take advantage of the early exercise feature and purchase shares prior

to the vesting of such shares, the shares will be deemed restricted stock and will be subject to a repurchase option in favor of the Company if the option holder's service to the Company terminates prior to vesting.

(3) Includes (i) 26,856 shares held by Mr. Collier; and (ii) 294,287 shares issuable upon the exercise of stock options which are exercisable or will become exercisable within sixty (60) days of March 18, 2024. The shares issuable upon the exercise of stock options issued to Mr. Collier are subject to early exercise under the 2021 Plan, the 2020 Plan, and the Capricor Therapeutics, Inc. 2012 Restated Equity Incentive Plan. As of March 18, 2024, Mr. Collier has not indicated his intent to exercise early. If the option holder elects to take advantage of the early exercise feature and purchase shares prior to the vesting of such shares, the shares will be deemed restricted stock and will be subject to a repurchase option in favor of the Company if the option holder's service to the Company terminates prior to vesting.

(4) Includes (i) 7,096 shares held by SEP FBO David B. Musket, Pershing LLC as Custodian; (ii) 31,536 held by David B. Musket; and (iii) 366,897 shares issuable upon the exercise of stock options held directly by David B. Musket, which are exercisable or will become exercisable within sixty (60) days of March 18, 2024. The shares issuable upon the exercise of stock options issued to Mr. Musket are subject to early exercise under the 2021 Plan, the 2020 Plan, and the Capricor Therapeutics, Inc. 2012 Restated Equity Incentive Plan. As of March 18, 2024, Mr. Musket has not indicated his intent to exercise early. If the option holder elects to take advantage of the early exercise feature and purchase shares prior to the vesting of such shares, the shares will be deemed restricted stock and will be subject to a repurchase option in favor of the Company if the option holder's service to the Company terminates prior to vesting.

(5) Includes (i) 10,556 shares held by Mr. Dunbar; and (ii) 291,711 shares issuable upon the exercise of stock options that are exercisable or will become exercisable within sixty (60) days of March 18, 2024. The shares issuable upon the exercise of stock options issued to Mr. Dunbar are subject to early exercise under the 2021 Plan, the 2020 Plan, and the Capricor Therapeutics, Inc. 2012 Restated Equity Incentive Plan. As of March 18, 2024, Mr. Dunbar has not indicated his intent to exercise early. If the option holder elects to take advantage of the early exercise feature and purchase shares prior to the vesting of such shares, the shares will be deemed restricted stock and will be subject to a repurchase option in favor of the Company if the option holder's service to the Company terminates prior to vesting.

(6) Includes 172,367 shares issuable upon the exercise of stock options which are exercisable or will become exercisable within sixty (60) days of March 18, 2024. The shares issuable upon the exercise of stock options issued to Ms. Es Sabar are subject to early exercise under the 2021 Plan. As of March 18, 2024, Ms. Es Sabar has not indicated her intent to exercise early. If the option holder elects to take advantage of the early exercise feature and purchase shares prior to the vesting of such shares, the shares will be deemed restricted stock and will be subject to a repurchase option in favor of the Company if the option holder's service to the Company terminates prior to vesting.

(7) Includes 17,400 shares issuable upon the exercise of stock options which are exercisable or will become exercisable within sixty (60) days of March 18, 2024. The shares issuable upon the exercise of stock options issued to Dr. Auwaerter are subject to early exercise under the 2021 Plan. As of March 18, 2024, Dr. Auwaerter has not indicated his intent to exercise early. If the option holder elects to take advantage of the early exercise feature and purchase shares prior to the vesting of such shares, the shares will be deemed restricted stock and will be subject to a repurchase option in favor of the Company if the option holder's service to the Company terminates prior to vesting.

(8) Includes 17,450 shares issuable upon the exercise of stock options which are exercisable or will become exercisable within sixty (60) days of March 18, 2024. The shares issuable upon the exercise of stock options issued to Dr. Gotwals are subject to early exercise under the 2021 Plan. As of March 18, 2024, Dr. Gotwals has not indicated his intent to exercise early. If the option holder elects to take advantage of the early exercise feature and purchase shares prior to the vesting of such shares, the shares will be deemed restricted stock and will be subject to a repurchase option in favor of the Company if the option holder's service to the Company terminates prior to vesting.

(9) Includes 45,370 shares issuable upon the exercise of stock options which are exercisable or will become exercisable within sixty (60) days of March 18, 2024. The shares issuable upon the exercise of stock options issued to Mr. Kelliher are subject to early exercise under the 2021 Plan. As of March 18, 2024, Mr. Kelliher has not indicated his intent to exercise early. If the option holder elects to take advantage of the early exercise feature and purchase shares prior to the vesting of such shares, the shares will be deemed restricted stock and will be subject to a repurchase option in favor of the Company if the option holder's service to the Company terminates prior to vesting.

(10) Includes (i) 2,381 shares held by Mr. Bergmann and (ii) 370,260 shares issuable upon the exercise of stock options held directly by Mr. Bergmann that are exercisable or will become exercisable within sixty (60) days of March 18, 2024. The shares issuable upon the exercise of stock options issued to Mr. Bergmann are subject to early exercise under the 2021 Plan, the 2020 Plan, and the Capricor Therapeutics, Inc. 2012 Restated Equity Incentive Plan. As of March 18, 2024, Mr. Bergmann has not indicated his intent to exercise early. If the option holder elects to take advantage of the early exercise feature and purchase shares prior to the vesting of such shares, the shares will be deemed restricted stock and will be subject to a repurchase option in favor of the Company if the option holder's service to the Company terminates prior to vesting.

(11) Includes (i) 198,604 shares held by Dr. Linda Marbán; (ii) 920 shares held by Linda and Eduardo Marbán as joint tenants with rights of survivorship; and (iii) 1,126,556 shares issuable upon the exercise of stock options held directly by Dr. Linda Marbán which are exercisable or will become exercisable within sixty (60) days of March 18, 2024. Certain shares issuable upon the exercise of stock options issued to Dr. Linda Marbán are subject to early exercise under the 2021 Plan, the 2020 Plan, and the Capricor Therapeutics, Inc. 2012 Restated Equity Incentive Plan. As of March 18, 2024, Dr. Linda Marbán has not indicated her intent to exercise early. If the option holder elects to take advantage of the early exercise feature and purchase shares prior to the vesting of such shares, the shares will be deemed restricted stock and will be subject to a repurchase option in favor of the Company if the option holder's service to the Company terminates prior to vesting.

(12) Includes (i) 20,047 shares held by Ms. Krasney and (ii) 314,048 shares issuable upon the exercise of stock options held directly by Ms. Krasney that are exercisable or will become exercisable within sixty (60) days of March 18, 2024. The shares issuable upon the exercise of stock options issued to Ms. Krasney are subject to early exercise under the 2021 Plan, the 2020 Plan, and the Capricor Therapeutics, Inc. 2012 Restated Equity Incentive Plan. As of March 18, 2024, Ms. Krasney has not indicated her intent to exercise early. If the option holder elects to take advantage of the early exercise feature and purchase shares prior to the vesting of such shares, the shares will be deemed restricted stock and will be subject to a repurchase option in favor of the Company if the option holder's service to the Company terminates prior to vesting.

(13) Includes (i) 2,789,699 shares held by Highbridge Capital Management, LLC and affiliated entities; and (ii) 2,789,699 shares issuable upon the exercise of warrants held directly by Highbridge Capital Management, LLC and affiliated entities which are exercisable or will become exercisable within sixty (60) days of March 18, 2024. Highbridge Capital Management, LLC reports that it holds shared voting power and shared dispositive power with respect to all shares held by it. The address for Highbridge Capital Management, LLC is 277 Park Avenue, 23rd Floor, New York, New York 10172. Based solely on information set forth in a Schedule 13G filed with the SEC on February 7, 2024.

(14) Includes (i) 2,145,922 shares held by Nippon Shinyaku Co., Ltd.; and (ii) 2,145,922 shares issuable upon the exercise of warrants held directly by Nippon Shinyaku Co., Ltd. which are exercisable or will become exercisable within sixty (60) days of March 18, 2024. Nippon Shinyaku Co., Ltd reports that it holds sole voting power and sole dispositive power with respect to all shares held by it. The address for Nippon Shinyaku Co., Ltd. is 14, Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550, Japan. Based solely on information set forth in a Schedule 13G filed with the SEC on October 17, 2023.

Delinquent Section 16(a) Reports

None.

OTHER INFORMATION

Householding of Proxy Materials

The SEC has adopted rules that permit companies and intermediaries (e.g., brokers) to satisfy the delivery requirements for Notices and other Annual Meeting materials with respect to two or more stockholders sharing the same address by delivering a single Notice, Proxy Statement, Annual Report and other Annual Meeting materials addressed to those stockholders. This process, which is commonly referred to as "householding," potentially means extra convenience for stockholders and cost savings for companies.

This year, a number of brokers with account holders who are our stockholders will be "householding" our proxy materials. A single Notice, Proxy Statement and Annual Report will be delivered to multiple stockholders sharing an address unless contrary instructions have been received from the affected stockholders. Once you have received notice from your broker that they will be "householding" communications to your address, "householding" will continue until you are notified otherwise or until you revoke your consent. If, at any time, you no longer wish to participate in "householding" and would prefer to receive a separate Notice, Proxy Statement and Annual Report, please notify your broker or us. Direct your written request to the Company's Corporate Secretary at 10865 Road to the Cure, Suite 150, San Diego, California 92121 or contact the Company's Corporate Secretary at (858) 727-1755. Stockholders who currently receive multiple copies of the Notices, Proxy Statements, Annual Reports and other Annual Meeting materials at their addresses and would like to request "householding" of their communications should contact their broker or our Corporate Secretary in the same manner described above. In addition, we will promptly deliver, upon written or oral request to the address or telephone number above, a separate copy of the Notice, Proxy Statement, Annual Report and other Annual Meeting materials to a stockholder at a shared address to which a single copy of the documents was delivered.

Where You Can Find More Information

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any reports, statements or other information that we have filed with the SEC at the SEC's public reference room at the following location:

Public Reference Room
100 F Street, N.E.
Washington, DC 20549

Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. These SEC filings are also available to the public from commercial document retrieval services and at the Internet World Wide Web site maintained by the SEC at "http://www.sec.gov." Copies of our SEC filings are also available through our website (www.capricor.com) as soon as reasonably practicable after we electronically file the material with, or furnish it to, the SEC. The information contained on, or that can be accessed through, our website is not incorporated by reference and is not a part of this proxy statement.

The Board knows of no other matters that will be presented for consideration at the Annual Meeting. If any other matters are properly brought before the Annual Meeting, it is the intention of the persons named in the accompanying proxy to vote on such matters in accordance with their best judgment.

By Order of the Board of Directors

CAPRICOR THERAPEUTICS, INC.

/s/ Linda Marbán, Ph.D.
Linda Marbán, Ph.D.
Chief Executive Officer and a Director

ANNEX A

CERTIFICATE OF AMENDMENT
OF
CERTIFICATE OF INCORPORATION
OF
CAPRICOR THERAPEUTICS, INC.

Capricor Therapeutics, Inc. (the "**Corporation**"), a corporation organized and existing under the General Corporation Law of the State of Delaware (the "**DGCL**"), does hereby certify that:

FIRST: The name of the Corporation is Capricor Therapeutics, Inc.

SECOND: The original Certificate of Incorporation of the Corporation (formerly known as SMI Products, Inc. and Nile Therapeutics, Inc., respectively) was filed with the Secretary of State of the State of Delaware on January 26, 2007, which was amended by a Certificate of Amendment of Certificate of Incorporation thereafter filed with the Secretary of State of the State of Delaware on November 20, 2013 and a Certificate of Amendment of Certificate of Incorporation thereafter filed with the Secretary of State of the State of Delaware on June 4, 2019 (the "**Certificate of Incorporation**").

THIRD: The Board of Directors of the Corporation duly adopted resolutions setting forth proposed amendments (the "**Certificate of Amendment**") to the Certificate of Incorporation amending the Certificate of Incorporation as follows:

The Certificate of Incorporation shall be amended by deleting and substituting the text of the two paragraphs of Article Fourth thereof with the following one paragraph.

> "(a) *Authorized Capital*. The total number of shares of all classes of stock which the Corporation shall have authority to issue shall be One Hundred Five Million (105,000,000) shares, consisting of (i) One Hundred Million (100,000,000) shares of common stock, par value $0.001 per share ("Common Stock"), and (ii) Five Million (5,000,000) shares of preferred stock, par value $0.001 per share ("Preferred Stock")."

FOURTH: The Board of Directors of the Corporation declared the Certificate of Amendment to be advisable and directed that the Certificate of Amendment be submitted to the stockholders of the Corporation for consideration thereof.

FIFTH: That, pursuant to resolution of its Board of Directors of the Corporation, a meeting of stockholders of the Corporation was duly called and held upon notice in accordance with Section 222 of the Delaware General Corporation Law at which meeting the necessary number of shares as required by statute were voted in favor of the Certificate of Amendment.

SIXTH: That the foregoing Certificate of Amendment was duly adopted in accordance with the provisions of Section 222 of the Delaware General Corporation Law.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be signed by its President and Chief Executive Officer this [●] day of [●], 2024.

CAPRICOR THERAPEUTICS, INC.

_____
Linda Marbán, Ph.D.
Chief Executive Officer

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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 December 31, 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: 001-34058

CAPRICOR THERAPEUTICS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

Delaware	**88-0363465**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

10865 Road to the Cure, Suite 150, San Diego, California 92121
(Address of principal executive offices including zip code)

(858) 727-1755
(Registrant's telephone number, including area code)

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

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	CAPR	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act:
None

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☑	Smaller reporting company	☑
		Emerging growth company	☐

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 USC. 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 registrant's common stock held by non-affiliates of the registrant as of June 30, 2023 was approximately $119,715,277, based on the last reported sale of the registrant's common stock on The Nasdaq Capital Market on June 30, 2023 of $4.78 per share.

As of March 7, 2024, there were 31,399,667 shares of the registrant's common stock, par value $0.001 per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates information by reference from the definitive proxy statement for the registrant's 2024 Annual Meeting of Stockholders.

TABLE OF CONTENTS

References to "the Company," "Capricor Therapeutics," "we," "us" or "our" in this Annual Report on Form 10-K refer to Capricor Therapeutics, Inc., a Delaware corporation, and its subsidiaries, unless the context indicates otherwise. References to "Capricor" in this Annual Report on Form 10-K refer to our wholly owned subsidiary, Capricor, Inc., unless the context indicates otherwise.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "potential," "projects," "intends," "may," "will" or "should" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements about the development of our product candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates; expectation of or dates for commencement of clinical trials; timing of study or trial results; manufacturing capabilities, investigational new drug filings, similar plans or projections; the regulatory approval of our drug candidates and dates for regulatory meetings; our ability to achieve product milestones and to receive milestone payments from commercial partners; our use of clinical research centers, third-party manufacturers and other contractors; our ability to find collaborative partners for research, development and commercialization of potential products; our or a designated third-party's ability to manufacture products for clinical and commercial use; our ability to protect our patents and other intellectual property; our ability to market any of our products; our projected operating losses and ability to operate as a going concern; the impact of taxes on our business, including our ability to utilize net operating losses; our ability to compete against other companies and research institutions; the effect of potential strategic transactions on our business; acceptance of our products by doctors, patients or payors and the availability of reimbursement for our product candidates; our ability to attract and retain key personnel; the volatility of our stock price; our ability to continue as a going concern; and other risks and uncertainties detailed in the section of this Annual Report on Form 10-K entitled "Risk Factors". These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Annual Report on Form 10-K.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results and preclinical studies. Data obtained from such clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Readers are expressly advised to review and consider certain risk factors, which include risks associated with (1) our ability to successfully conduct clinical trials and preclinical studies for our product candidates, (2) our ability to obtain required regulatory approvals to develop, manufacture and market our product candidates, either on an accelerated basis or at all, (3) our ability to raise additional capital or to license our products on favorable terms, (4) our ability to execute our development plan on time and on budget, (5) our ability to identify and obtain additional product candidates, (6) our ability to raise enough capital to fund our operations, (7) our ability to protect our intellectual property rights, and (8) our compliance with legal and regulatory requirements as a public company. Although we believe that the assumptions underlying the forward-looking statements contained in this Annual Report on Form 10-K are reasonable, any of the assumptions could be inaccurate, and therefore there can be no assurance that such statements will be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation by us or any other person that the results or conditions described in such statements or our objectives and plans will be achieved. Furthermore, past performance in operations and share price is not necessarily indicative of future performance. Except to the extent required by applicable laws or rules, we do not undertake to update any forward-looking statements or to announce publicly revisions to any of our forward-looking statements, whether resulting from new information, future events or otherwise.

The following discussion should be read together with our consolidated financial statements and related consolidated notes contained in this Annual Report on Form 10-K. Results for the year ended December 31, 2023 are not necessarily indicative of results that may be attained in the future.

PART I

ITEM 1. BUSINESS

Overview

Capricor Therapeutics, Inc. is a clinical-stage biotechnology company focused on the development of transformative cell and exosome-based therapeutics for treating Duchenne muscular dystrophy ("DMD"), a rare form of muscular dystrophy which results in muscle degeneration and premature death, and other diseases with high unmet medical needs.

Technology and Platforms

Cell Therapy Platform

Our core program is focused on the development and commercialization of a cell therapy (referred to herein as CAP-1002) comprised of cardiosphere-derived cells ("CDCs"), which are a population of stromal cells isolated from donated cells of healthy human hearts currently being developed for the treatment of DMD. DMD is a rare, monogenic, X-linked muscle disease driven by the impaired production of functional dystrophin, which normally functions as a structural protein in muscle. The reduction of functional dystrophin in muscle cells leads to significant cell damage and ultimately causes muscle cell death and fibrotic replacement. CAP-1002 is designed to slow disease progression in DMD through the immunomodulatory, anti-inflammatory, and anti-fibrotic actions of CDCs, which are mediated by secreted exosomes laden with bioactive cargo. Among the cargo elements known to be bioactive in CDC-exosomes are microRNAs. Collectively, these non-coding RNA species alter gene expression in macrophages and other target cells, dialing down generalized inflammation and stimulating tissue regeneration in DMD (and in a variety of other inflammatory diseases). This mechanism of action, consistent with the changes observed in clinical studies to date in circulating inflammatory biomarkers, contrasts with that of exon-skipping oligonucleotides and gene therapy approaches that aim to restore dystrophin expression. Our CAP-1002 cell therapy program for the treatment of DMD is currently in Phase 3 clinical development in the United States, for which we expect to have top-line data available in the fourth quarter of 2024.

Exosomes Platform

Extracellular vesicles, including exosomes and microvesicles, are nano-scale, membrane-enclosed vesicles secreted by most cells and contain characteristic lipids, proteins and nucleic acids such as mRNA and microRNAs. They can signal through the binding and activation of membrane receptors or the delivery of their cargo into the cytosol of target cells. Exosomes act as messengers to regulate the functions of neighboring or distant cells and have been shown to regulate functions such as cell survival, proliferation, inflammation and tissue regeneration. Their size, low or null immunogenicity and ability to communicate in native cellular language potentially make them an exciting new class of therapeutic agents with the potential to expand our ability to address complex biological responses. Because exosomes are cell-free substances, they can be stored, handled, reconstituted and administered in similar fashion to common biopharmaceutical products such as antibodies. Aspects of our exosome pipeline have been supported through collaborations and alliances. Our collaborations and research around exosomes include the National Institutes of Health ("NIH"), the National Institute of Allergy and Infectious Diseases ("NIAID"), Johns Hopkins University ("JHU"), the Department of Defense ("DoD"), the U.S. Army Institute of Surgical Research ("USAISR"), and Cedars-Sinai Medical Center ("CSMC"). Our platform builds on advances in fundamental RNA and protein science, targeting technology and manufacturing, providing us the opportunity to potentially build a broad pipeline of new therapeutic candidates. Currently, we are developing exosome-based vaccines and therapeutics for infectious diseases, monogenic diseases and other potential indications. Our current strategy is focused on securing partners who will provide capital and additional resources to enable us to bring this program into the clinic.

Objectives and Business Strategy

We believe that our cell therapy and exosome-based platforms can be used to develop novel therapeutics to treat a broad range of diseases. We intend to leverage our technology, collaborations and resources to develop therapeutics for diseases with high unmet needs. In pursuit of this objective, we intend to focus on the following activities:

- continuing the development of our CAP-1002 program for the treatment of DMD in preparation for potential commercialization, which includes streamlining our manufacturing capabilities, furthering our commercial capabilities and securing additional partners in other markets around the world for the potential launch in the U.S., Japan and in other select territories;
- advancing our exosome technology for therapeutic development, focused on internal research, strategic partnerships and collaborations; and
- opportunistically evaluating strategic collaborations to accelerate development and commercialization timelines as well as potentially expand our pipeline within our core therapeutic areas.

Our History

Capricor, Inc., a wholly-owned subsidiary of Capricor Therapeutics, was founded in 2005 as a Delaware corporation based on the innovative work of its founder, Eduardo Marbán, M.D., Ph.D. Our core cell therapy technology was first identified in the academic laboratory of Dr. Eduardo Marbán while he was Chief of Cardiology at Johns Hopkins. Since its initial publication in 2007, CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to over 200 human subjects across several clinical trials. We began to explore the therapeutic potential of exosomes as we learned that CDCs mediate most of their therapeutic activities through the secretion of exosomes.

We have assembled a scientific advisory board with cardiology and neurology experts, including DMD specialists. Our advisors include clinicians and researchers who are experts on DMD's skeletal and cardiac aspects. Moreover, some of our advisors lead clinical units at some of the leading DMD centers in the United States and are actively involved in our drug development process and programs.

Capricor became public after the completion of a merger between Capricor and a subsidiary of Nile Therapeutics, Inc., a Delaware corporation ("Nile"), in 2013, where Capricor became a wholly-owned subsidiary of Nile and Nile formally changed its name to Capricor Therapeutics, Inc. Capricor Therapeutics was listed on the Nasdaq Capital Market shortly thereafter and currently trades under the symbol "CAPR". Capricor Therapeutics and Capricor have together raised approximately $145.0 million in equity capital (both privately and publicly) as well as approximately $90.0 million in non-dilutive funding from our partners including Nippon Shinyaku Co. Ltd., a Japanese corporation ("Nippon Shinyaku"), as well as government sources such as the NIH and the California Institute for Regenerative Medicine ("CIRM").

Core Therapeutic Areas

Duchenne muscular dystrophy (DMD): DMD is a rare, monogenic, X-linked muscle disease with mortality at a median age of approximately 30 years. There is no cure for DMD, and for the vast majority of patients, there are no satisfactory symptomatic or disease-modifying treatments. It is estimated that DMD occurs in approximately one in every 3,500 to 5,000 live male births and that the patient population is estimated to be approximately 15,000-20,000 in the United States. DMD pathophysiology is driven by the impaired production of functional dystrophin, which normally functions as a structural protein in muscle. The reduction of functional dystrophin in muscle cells leads to significant cell damage and ultimately causes muscle cell death and fibrotic replacement. Due to reduced functional dystrophin protein, affected individuals generally experience the following symptoms, although disease severity and life expectancy vary:

- muscle damage characterized by inflammation and fibrosis beginning at an early age;
- muscle weakness and progressive loss of muscle function beginning in the first few years of life;
- decline of ambulation and respiratory function after the age of seven;
- total loss of ambulation in the pre-teenage or early teenage years;
- progressive loss of upper extremity function during mid- to late-teens;
- respiratory and/or cardiac failure, resulting in death before the age of 30; and
- cardiomyopathy eventually leads to heart failure, which is currently the leading cause of death among those with DMD.

Glucocorticoid treatment, the current standard of care, has been shown to improve muscle strength temporarily, prolong the period of ambulation and slow the progression of DMD. However, glucocorticoid use is associated with well-known adverse side effects, including: severe weight gain, stunted growth, weakening of bone structure (osteoporosis) and metabolic dysfunctions, among others. Despite recent therapeutic advances, DMD represents a significant societal and economic burden. The annual cost of care for patients with DMD is very high and increases with disease progression. The economic burden includes costs associated with hospital admissions, medications, frequent doctor visits, assistive devices, as well as indirect costs related to productivity losses for caregivers and costs due to pain, anxiety, social handicap as well as end-of-life care expenses. While there are many clinical initiatives in DMD, Capricor's program is one of the very few to focus on predominantly non-ambulant patients. These boys and young men are looking to maintain their function in their arms and hands and slow the progression of cardiomyopathy. We therefore believe that DMD represents a significant market opportunity for our product candidate, CAP-1002.

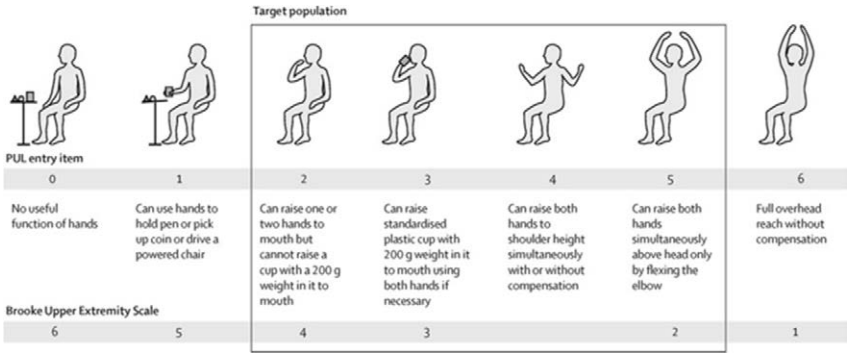
SARS-CoV-2: Coronaviruses are a large family of viruses that can cause illness in animals or humans. In humans, several known coronaviruses cause respiratory infections. These coronaviruses range from the common cold to more severe diseases such as severe acute respiratory syndrome ("SARS"), Middle East respiratory syndrome ("MERS") and COVID-19. SARS-CoV-2 is the novel coronavirus first identified in humans in 2019 and is the cause of COVID-19. The risk of mortality increases with age and the risk of severe disease and mortality increases for persons with certain pre-existing diseases or comorbid conditions (e.g. cardiovascular disease, diabetes, chronic lung disease, obesity). Since late 2021, infections have been dominated by subvariants of the Omicron strain which continue to displace previous circulating strains by evading immunity and spreading more efficiently resulting in an increased risk of breakthrough infection among the vaccinated. As the world pivots from the kinds of responses needed during the pandemic, vulnerable populations need a vaccine strategy to provide protective durable immunity against current and emerging variants of SARS-CoV-2 to reduce the infection and disease burden for both the public and the health care systems globally. We therefore believe that SARS-CoV-2 represents a potential market opportunity for our exosome-based vaccine program.

Our Pipeline – Key Programs

CAP-1002: Duchenne Muscular Dystrophy Program: CAP-1002 is designed to slow disease progression in DMD through the immunomodulatory, anti-inflammatory, and anti-fibrotic actions of CDCs, with the goal of improving skeletal and cardiac muscle function in patients with DMD.

Phase 3 (HOPE-3) Clinical Trial: HOPE-3 is a Phase 3, multi-center, randomized, double-blind, placebo-controlled clinical trial comprised of two cohorts evaluating the safety and efficacy of CAP-1002 in participants with DMD and impaired skeletal muscle function who are on a stable regimen of systemic glucocorticoids. Non-ambulatory and ambulatory boys who meet eligibility criteria are randomly assigned to receive either CAP-1002 or placebo every 3 months for a total of 4 doses during the first 12-months of the study. Approximately 102 eligible study subjects will participate in this dual-cohort study. Enrollment has been completed for Cohort A where 61 subjects were randomized to either CAP-1002 or placebo in a 1:1 ratio and is intended to support a Biologics License Application ("BLA") submission. In December 2023, we announced a positive outcome of the interim futility analysis for Cohort A of HOPE-3, which was reviewed by the Data Safety Monitoring Board ("DSMB"). This resulted in a favorable recommendation to continue the HOPE-3 trial as planned. At this time, we expect to have topline data available from Cohort A in the fourth quarter of 2024. Cohort A uses product manufactured at our Los Angeles facility.

Performance of the Upper Limb (PUL entry items) [(1)]
(CAP-1002 current DMD target population)



(1) Image from HOPE-2 *Lancet* Publication (March 2022)

Enrollment is underway for Cohort B, which is designed to enroll approximately 44 participants randomized to either CAP-1002 or placebo in a 1:1 ratio. A primary efficacy and safety analysis will be performed for each individual cohort at month 12, following 4 administrations of CAP-1002 or placebo. We plan to complete enrollment for Cohort B in the second quarter of 2024. Cohort B uses product manufactured at our San Diego facility.

The primary outcome measure of the HOPE-3 study will be the Performance of the Upper Limb ("PUL") v2.0, a validated tool specifically designed for assessing high (shoulder), mid (elbow) and distal (wrist and hand) functions, with a conceptual framework reflecting weakness progression in upper limb function. HOPE-3 will also measure various secondary endpoints including cardiac function assessments.

Under our RMAT designation, in the third quarter of 2023, we met with the FDA in a Type-B meeting where we discussed our manufacturing plans in anticipation of potentially submitting a BLA application. In this meeting, we affirmed alignment with respect to our Phase 3, HOPE-3 program. Additionally, we discussed our plans with respect to commercial manufacturing activities, including our potency assay and other product release criteria to support commercialization. We plan to meet with FDA in the first quarter of 2024 to continue discussing our pathway to BLA. In the upcoming Type-B meeting, we intend to discuss our further CMC plans for commercial launch, if approved, with the aim of expediting our BLA submission pathway. Our ultimate goal is to file a BLA allowing for the use of CAP-1002 commercial product manufactured at our San Diego facility.

Phase 2 HOPE-2 Clinical Trial: HOPE-2 was a randomized, double-blind, placebo-controlled clinical trial conducted at multiple sites in the United States and was completed in 2021. The clinical trial was designed to evaluate the safety and efficacy of repeated, intravenous doses of CAP-1002, in boys and young men with evidence of skeletal muscle impairment regardless of ambulatory status. Approximately 90% of the patients in the study were non-ambulant and all patients were on a stable regimen of steroids. Demographic and baseline characteristics were similar between the two treatment groups. The final one-year results from HOPE-2 were published in *The Lancet* in March 2022, showing that the trial met its primary efficacy endpoint of the mid-level dimension of the PUL v1.2 ($p=0.01$) and additional positive endpoints of full PUL v2.0 ($p=0.04$). Although the PUL v1.2 for the mid-level was the primary endpoint established for the trial, we also conducted an analysis using the PUL v2.0 as the FDA suggested the use of the updated PUL v2.0 as the primary efficacy endpoint in support of a BLA. Left ventricular ejection fraction (LVEF), a global measure of cardiac pump function, decreased in the placebo group over time, but improved in the CAP-1002 group, showing a 107% slowing of the progression of cardiac disease ($p=0.002$). Additionally, the data suggested global improvements in cardiac function as measured by indexed volumes (LVESV, LVEDV). These are surrogate measures of cardiac function and are considered significant in relevance to long-term outcomes. Furthermore, the data showed a reduction in the biomarker CK-MB, an enzyme that is only released when there is cardiac muscle cell damage. In normal human subjects, there is typically no CK-MB measurable in the blood. It is well accepted that continuous muscle cell damage in DMD leads to pathologically high enzyme levels associated with cardiac muscle cell loss. To our knowledge, this is the first clinical study in DMD that correlates cardiac functional stabilization with a reduction of a biomarker of cell damage. With the exception of steroids, preservation of function in DMD is uncommon. The results of the placebo patients were consistent with natural history, but in the treated group, most patients were stable or improved on these endpoints throughout the one-year treatment period. CAP-1002 was generally safe and well tolerated throughout the study. With the exception of hypersensitivity

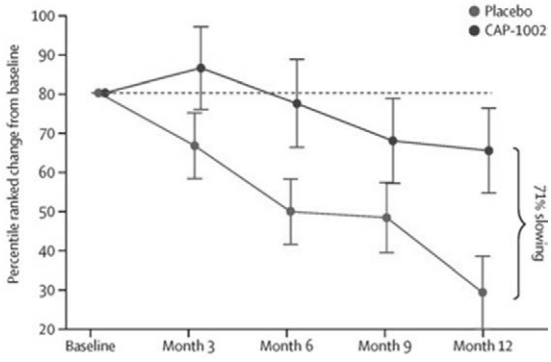
reactions early in the clinical trial, which were mitigated with a common pre-medication regimen, there were no serious safety signals identified by the HOPE-2 DSMB.

HOPE-2 Study Results - 12-Month Efficacy Data

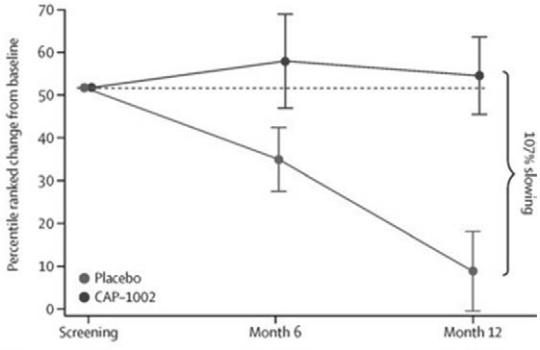
12-Month Difference in Change from Baseline†		
	Δ, CAP-1002 vs. Placebo (n=8, n=12)	**p-value**
Skeletal-Muscle (Upper Limb Function)		
Mid-level PUL (v1.2)*	2.6	0.01
Shoulder + Mid + Distal PUL (v1.2)	3.2	0.02
Shoulder + Mid + Distal PUL (v2.0)	1.8	0.04
Cardiac Function		
LV Ejection Fraction %*	4.0	0.002
LV End-Diastolic Volume, Indexed mL/m^2	-12.4‡	0.03
LV End-Systolic Volume, Indexed mL/m^2	-4.2‡	0.01
Creatine Kinase-MB (% of total CK)	-2.2‡	0.02

ITT (intent to treat) population shown
†Non-parametric mixed model repeated measures analysis with percentile ranked baseline, treatment, visit, visit-by-treatment interaction, PUL entry-item score at stratification, and site as model effects. Percentile ranked change from baseline converted back to original scale
‡Negative value favors CAP-1002
*Graphed figures below

PUL v1.2 mid-level dimension [(1)]



Left ventricular ejection fraction % (LVEF) [(1)]



(1) Images from HOPE-2 *Lancet* Publication (March 2022)

Phase 2 HOPE-2-Open Label Extension ("OLE") Clinical Trial: We are currently conducting an OLE clinical trial available to all patients who participated in the HOPE-2 study which includes those patients who received placebo.

12 patients elected to continue treatment. We announced positive one-year and two-year results from this ongoing OLE study. Data from the study suggests disease modification with statistically significant differences in the PUL v2.0 scale in the CAP-1002 original treatment group when compared to the original placebo group from HOPE-2. The HOPE-2-OLE study previously met its primary endpoint at the one-year timepoint on the PUL v2.0 scale (p=0.02). At the two-year timepoint, data showed statistically significant differences in the PUL v2.0 in the OLE treatment group when compared to the original rate of decline of the placebo group from HOPE-2 after one-year (p=0.021). LVEF was measured using cardiac magnetic resonance imaging (cMRI) and six of nine patients showed improvements in heart function with CAP-1002 treatment compared to their final assessment at the end of the HOPE-2 study. CAP-1002 treatment during the OLE portion of the study continues to yield a consistent safety profile and has been well-tolerated throughout the study. At this time, we expect to have three-year data available from this OLE study in the second quarter of 2024.

Phase 1/2 HOPE-Duchenne Clinical Trial: HOPE-Duchenne was a randomized, controlled, multi-center Phase 1/2 clinical trial which was designed to evaluate the safety and exploratory efficacy of CAP-1002 in patients with cardiomyopathy associated with DMD. Twenty-five patients were randomized in a 1:1 ratio to receive either CAP-1002 on top of usual care or usual care only. In patients receiving CAP-1002, 25 million cells were infused into each of their three main coronary arteries for a total dose of 75 million cells. It was a one-time treatment, and the last patient was infused in September 2016. Patients were observed over the course of 12 months. Efficacy was evaluated according to several exploratory outcome measures. This study was funded in part through a grant award from the CIRM. In 2019, this study was published in Neurology, the medical journal of the American Academy of Neurology. As shoulder function had already been lost in most of the HOPE-Duchenne participants, investigators used the combined mid-distal PUL subscales to assess changes in skeletal muscle function and found significant improvement in those treated with CAP-1002 in a defined post-hoc analysis. Among the lower-functioning patients, defined as patients with a baseline mid-distal PUL score < 55 out of 58, investigators reported sustained or improved motor function at 12 months in 8 of 9 (89%) patients treated with CAP-1002 as compared to none (0%) of the usual care participants (p=0.007). Additionally, we reported improvements in systolic thickening of the left ventricular wall as well as reduction in scarring of the heart muscle among those treated with CAP-1002 relative to the control group. CAP-1002 was generally safe and well-tolerated in the HOPE-Duchenne trial. There was no significant difference in the incidences of treatment-emergent adverse events in either group. There were no early study discontinuations due to adverse events.

CAP-1002 - Investigator Sponsored Clinical Trials: Capricor provided CAP-1002 for investigational purposes in two clinical trials sponsored by CSMC. These cells were developed as part of the Company's past research and development efforts. The first trial is known as "Regression of Fibrosis and Reversal of Diastolic Dysfunction in HFpEF Patients Treated with Allogeneic CDCs (the "REGRESS trial"). Dr. Eduardo Marbán is the named principal investigator under the study. The second trial is known as "Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells (the "ALPHA trial"). Enrollment of the REGRESS and ALPHA trials have been completed. In December 2023, the results from the ALPHA study were published in the peer-reviewed journal, *eBioMedicine*, a *Lancet* journal. The Phase 1 results were shown to be safe, with no short-term clinical safety adverse events related to the investigational product, which was the primary outcome measure of the study. Although this study was only designed to assess the safety of the CAP-1002 infusions, investigators observed encouraging changes that might indicate the 16 patients who received CAP-1002 infusions had improved cardiopulmonary health.

Exosome Platform: Our exosome platform program consists of engineered exosomes and exosomes derived from CDCs (CAP-2003), both of which are in preclinical development.

Exosome Platform: Engineered Exosome-Based Vaccines: The StealthX™ vaccine is a proprietary vaccine developed internally by Capricor utilizing exosomes that were engineered to express either spike or nucleocapsid proteins on the surface. Preclinical results from murine and rabbit models published in the peer-reviewed journal, *Microbiology Spectrum*, showed the StealthX™ vaccine, resulted in robust antibody production, potent neutralizing antibodies, a strong T-cell response and a favorable safety profile. These effects were obtained with administration of only nanogram amounts of protein and without adjuvant or synthetic lipid nanoparticles. Exosomes offer a new antigen delivery system that could potentially be utilized to rapidly generate multivalent protein-based vaccines. Recently, we were selected to be part of Project NextGen, an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines providing broader and more durable protection for COVID-19. As part of Project NextGen, the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, will conduct a Phase 1 clinical study with our StealthX™ vaccine, subject to regulatory approval. At this time, we have submitted an Investigational New Drug Application ("IND") to the FDA for our StealthX™ vaccine, which is currently under review and we anticipate that if the IND is approved, that NIAID plans to initiate this trial in late 2024. NIAID's Division of

Microbiology and Infectious Diseases (DMID) would oversee the study. If NIAID finds that our StealthX™ vaccine meets its criteria for safety and efficacy, they may consider our program for a funded Phase 2.

Exosome Platform: Engineered Exosome-Based Therapeutics: We are focused on developing a precision-engineered exosome platform technology that has the potential to deliver defined sets of effector molecules that exert their effects through defined mechanisms of action. At this time, we are exploring the use of our proprietary StealthX™ exosome platform for a broad range of therapeutic applications including targeted RNA, protein and small molecule therapeutics to treat or prevent a variety of diseases.

Exosome Platform: CDC-Derived Exosomes (CAP-2003): CAP-2003 is the name of our exosomes product candidate which are derived from CDCs. We have promising preclinical data in several indications from studies done utilizing CAP-2003 in our labs as well as in collaboration with other academic institutions. In 2020, we filed an IND with the FDA to investigate the use of CAP-2003 in patients with DMD. The FDA has requested more information related to manufacturing for this product candidate and we are evaluating the next steps for this program as we continue to further develop our exosome platform.

These programs represent our core technology and products.

The following table summarizes our active product development programs:

Product Candidate	Indication	Development Stage	Distributor/Partner/Collaborator
CAP-1002 (allogeneic CDCs)	Duchenne muscular dystrophy*	Phase 3 (HOPE-3) Cohort A: enrollment complete Cohort B: enrolling Phase 2 (HOPE-2) completed**	Nippon Shinyaku Co., Ltd. (U.S. and Japan rights)
Exosome protein-based vaccine (multivalent design)	SARS-CoV-2	IND submitted	Collaboration with National Institute of Allergy and Infectious Diseases
Engineered Exosomes (RNA, protein and small molecule delivery)	Evaluating	Preclinical	
CAP-2003 (CDC-exosomes)	Duchenne muscular dystrophy	IND submitted	

* The FDA has granted orphan drug, Regenerative Medicine Advanced Therapy, and Rare Pediatric Disease designations to CAP-1002 for the treatment of DMD.
**We are currently conducting an OLE study of the HOPE-2 trial.

Manufacturing, Supply and Distribution

We have developed proprietary Chemistry, Manufacturing and Controls ("CMC") and manufacturing capabilities that allow manufacturing and testing of our product candidates to support both clinical development as well as potential commercialization. Manufacturing is subject to extensive regulations that impose procedural and documentation requirements. These regulations govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance. We continue to enhance, refine and optimize our manufacturing processes. We currently maintain two manufacturing facilities for the production of CAP-1002. In 2022, we completed construction of our San Diego Research and Development Facility (GMP pilot manufacturing facility) as we prepare for potential commercial launch, subject to FDA approval. This facility was designed to be compliant with U.S. and European Medicines Agency ("EMA") standards. This facility is currently producing CAP-1002 product for clinical use in Cohort B of our HOPE-3 trial and supporting our OLE trials. We are preparing for a potential commercial launch, subject to FDA approval, from the San Diego facility. It is to be determined whether the FDA will ultimately approve commercial manufacturing at this facility. Our second manufacturing facility is located within our laboratory, research and manufacturing facilities at CSMC in Los Angeles pursuant to a Facilities Lease. In that portion of the leased premises where we manufacture CAP-1002 and may manufacture our exosome products for potential clinical use, we believe that we follow, current good manufacturing practices to the extent that they are applicable to the stage of our clinical programs although our facility at CSMC is not current Good Manufacturing Practices ("cGMP") qualified for commercial at this time. Capricor manufactured CAP-1002

in this facility for our current and previous studies including Cohort A of the HOPE-3 trial. Our Facilities Lease at CSMC has an expiration date of July 31, 2026.

In the third quarter of 2023, we met with the FDA, where we affirmed alignment with respect to our Phase 3, HOPE-3 program where the FDA agreed to allow us to submit a BLA supported by results using product manufactured at our Los Angeles manufacturing site. At this time, we are planning on utilizing such data for the submission of a BLA, but it is to be determined whether the FDA will ultimately approve commercial manufacturing at this facility. The sale of commercial product produced in our Los Angeles facility may require the consent of CSMC.

We are required to obtain and maintain certain other licenses in connection with our manufacturing facilities and activities. At this time, we have a Drug Manufacturing License issued from the State of California for both our San Diego and CSMC facilities. We are currently applying for a Tissue Bank License from the State of California for both of our facilities.

Additionally, in February 2024, we entered into a License and Services Agreement with Azzur Cleanrooms-on-Demand – San Diego, LLC (the "Azzur License Agreement") pursuant to which we have been granted an exclusive license to use certain space and the non-exclusive right to use certain equipment and property for our early phase clinical and/or pre-clinical manufacturing purposes. We are planning to use this facility to manufacture our exosome-based vaccine for potential clinical use to support our collaboration with NIAID.

Manufacturing Process for CAP-1002

The manufacturing process for CAP-1002 begins with material from an entire heart from a donor that was collected from an organ procurement organization ("OPO"). This tissue is then taken to the lab where the cells are isolated, expanded, and processed through a series of proprietary unit operations. After expanding, processing, release testing and quality review, the CAP-1002 product becomes available for administration to patients participating in clinical trials. CAP-1002 is cryo-preserved, enabling us to produce large lots that can be frozen and then administered to patients as needed.

Manufacturing Process for Engineered-Exosome Technologies

We have also made significant progress planning the next steps for the manufacturing process for our exosome product candidates. We believe these developments will enable us to scale up our manufacturing capabilities and allow us to manufacture enough material for early-stage clinical development, subject to FDA approval. We have explored the use of various cell sources to generate our exosomes for preclinical and potential clinical use.

Manufacturing Process for CDC-Exosomes (CAP-2003)

The process for manufacturing CAP-2003 starts with the proprietary process of creating a cell bank from donor heart tissue through the expansion of CDCs. Afterwards, exosomes are isolated from the expanded CDCs. After these exosomes are prepared, formulated, filled, tested, and validated, the exosomes product may become available for clinical investigation, subject to regulatory approval.

Material Agreements, License Agreements & Collaborations

To accelerate the advancement of our technologies, we have entered into, and intend to seek other opportunities to form collaborations with a diverse group of strategic partners. We have forged productive collaborations with pharmaceutical and biotechnology companies, government agencies, academic laboratories, and research institutes with diverse area expertise and resources in as effort to advance our programs.

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: United States)

On January 24, 2022, Capricor entered into a Commercialization and Distribution Agreement (the "U.S. Distribution Agreement") with Nippon Shinyaku, a Japanese corporation. Under the terms of the U.S. Distribution Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in the United States of CAP-1002 for the treatment of DMD.

Under the terms of the U.S. Distribution Agreement, Capricor will be responsible for the conduct of the HOPE-3 trial as well as the manufacturing of CAP-1002. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in the United States. Pursuant to the U.S Distribution Agreement, Capricor received an upfront payment of $30.0 million in the first quarter of 2022. The first milestone payment of $10.0 million was paid upon completion of the interim futility analysis of the HOPE-3 trial whereby the outcome was determined to be not futile. Additionally, there are potential milestones totaling up to $90.0 million leading up to and including the BLA approval. Further, there are various potential sales-based milestones, if commercialized, tied to the achievement of certain sales thresholds for annual net sales of CAP-1002 of up to $605.0 million. Further, pursuant to the U.S. Distribution Agreement, Capricor has the obligation to sell commercial product to Nippon Shinyaku, subject to regulatory approval, and Capricor will have the right to receive a meaningful mid-range double-digit share of product revenue.

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: Japan)

On February 10, 2023, Capricor entered into a Commercialization and Distribution Agreement (the "Japan Distribution Agreement") with Nippon Shinyaku. Under the terms of the Japan Distribution Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in Japan of CAP-1002 for the treatment of DMD.

Under the terms of the Japan Distribution Agreement, Capricor received an upfront payment of $12.0 million in the first quarter of 2023 and in addition, Capricor may potentially receive additional development and sales-based milestone payments of up to approximately $89.0 million, subject to foreign currency exchange rates, and a meaningful double-digit share of product revenue. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in Japan. Capricor will be responsible for the conduct of clinical development in Japan, as may be required, as well as the manufacturing of CAP-1002. Subject to regulatory approval, Capricor will sell commercial product to Nippon Shinyaku in Japan. In addition, Capricor or its designee will hold the Marketing Authorization in Japan if the product is approved in that territory.

Collaboration Agreement with NIH

In 2023, we were notified by the NIH that we had been selected to be part of Project NextGen, an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines providing broader and more durable protection for COVID-19. As part of Project NextGen, the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, will conduct a Phase 1 clinical study with our StealthX™ vaccine, subject to regulatory approval. NIAID's Division of Microbiology and Infectious Diseases (DMID) will oversee the study. Under the terms of the collaboration, Capricor will be responsible for supplying investigational product for the trial.

Cooperative Research and Development Agreement with the U.S. Army Institute of Surgical Research

In 2018, we entered into a Cooperative Research and Development Agreement with the USAISR, pursuant to which we agreed to cooperate in research and development on the evaluation of our CAP-2003 for the treatment of trauma related injuries and conditions. In 2021, in collaboration with the USAISR, we published a manuscript demonstrating CAP-2003 as a potential antishock therapeutic, if delivered early.

Intellectual Property Rights for Capricor's Technology - CAP-1002 and Exosomes

Capricor has entered into exclusive license agreements for intellectual property rights related to certain cardiac-derived cells with Università Degli Studi Di Roma La Sapienza (the "University of Rome"), JHU and CSMC. Capricor has also entered into an exclusive license agreement for intellectual property rights related to exosomes with CSMC and JHU. In addition, Capricor has filed patent applications related to the technology developed by its own scientists.

University of Rome License Agreement

Capricor and the University of Rome entered into a License Agreement, dated June 21, 2006 (the "Rome License Agreement"), which provides for the grant of an exclusive, world-wide, royalty-bearing license by the University of Rome to Capricor (with the right to sublicense) to develop and commercialize licensed products under the licensed patent rights in all fields.

Pursuant to the Rome License Agreement, Capricor paid the University of Rome a license issue fee, is currently paying minimum annual royalties in the amount of 20,000 Euros per year, and is obligated to pay a lower-end of a mid-range double-digit percentage on all royalties received as a result of sublicenses granted, which are net of any royalties paid to third parties under a license agreement from such third-party to Capricor. The minimum annual royalties are creditable against future royalty payments.

The Rome License Agreement will, unless extended or sooner terminated, remain in effect until the later of the last claim of any patent or until any patent application comprising licensed patent rights has expired or been abandoned. Under the terms of the Rome License Agreement, either party may terminate the agreement should the other party become insolvent or file a petition in bankruptcy. Either party may terminate the agreement upon the other party's material breach, provided that the breaching party will have up to 90 days to cure its material breach. Capricor may also terminate for any reason upon 90 days' written notice to the University of Rome.

The Johns Hopkins University License Agreements

License Agreement for CDCs

Capricor and JHU entered into an Exclusive License Agreement, effective June 22, 2006 (the "JHU License Agreement"), which provides for the grant of an exclusive, world-wide, royalty-bearing license by JHU to Capricor (with the right to sublicense) to develop and commercialize licensed products and licensed services under the licensed patent rights in all fields and a nonexclusive right to the know-how. Various amendments were entered into to revise certain provisions of the JHU License Agreement. Under the JHU License Agreement, Capricor is required to exercise commercially reasonable and diligent efforts to develop and commercialize licensed products covered by the licenses from JHU.

Pursuant to the JHU License Agreement, JHU was paid an initial license fee and, thereafter, Capricor is required to pay minimum annual royalties on the anniversary dates of the JHU License Agreement. The minimum annual royalties are creditable against a low single-digit running royalty on net sales of products and net service revenues, which Capricor is also required to pay under the JHU License Agreement, which running royalty may be subject to further reduction in the event that Capricor is required to pay royalties on any patent rights to third parties in order to make or sell a licensed product. In addition, Capricor is required to pay a low double-digit percentage of the consideration received by it from sublicenses granted and is required to pay JHU certain defined development milestone payments upon the successful completion of certain phases of its clinical studies and upon receiving approval from the FDA. The maximum aggregate amount of milestone payments payable under the JHU License Agreement, as amended, is $1,850,000. In March 2022, Capricor paid the $250,000 development milestone related to the Phase 2 study pursuant to the terms of the JHU License Agreement. The next milestone is triggered upon successful completion of a full Phase 3 study for which a payment of $500,000 will be due.

The JHU License Agreement will, unless sooner terminated, continue in effect in each applicable country until the date of expiration of the last to expire patent within the patent rights, or, if no patents are issued, then for twenty years from the effective date. Under the terms of the JHU License Agreement, either party may terminate the agreement should the other party become insolvent or file a petition in bankruptcy or fail to cure a material breach within 30 days after notice. In addition, Capricor may terminate for any reason upon 60 days' written notice.

License Agreement for Exosome-based Vaccines and Therapeutics

Capricor and JHU entered into an Exclusive License Agreement (the "JHU Exosome License Agreement"), effective April 28, 2021 for its co-owned interest in certain intellectual property rights related to exosome-mRNA vaccines and therapeutics. The JHU Exosome License Agreement provided for the grant of an exclusive, worldwide, royalty-bearing license of JHU's co-owned rights by JHU to Capricor, with the right to sublicense, in order to conduct research using the patent rights and know-how and to develop and commercialize products in the field using the patent rights and know-how. The JHU Exosome License Agreement was terminated by Capricor on December 15, 2023.

Cedars-Sinai Medical Center License Agreements

License Agreement for CDCs

On January 4, 2010, Capricor entered into an Exclusive License Agreement with CSMC (the "Original CSMC License Agreement"), for certain intellectual property related to its CDC technology. In 2013, the Original CSMC License Agreement was amended twice resulting in, among other things, a reduction in the percentage of sublicense fees which would have been payable to CSMC. Effective December 30, 2013, Capricor entered into an Amended and Restated Exclusive License Agreement with CSMC (the "Amended CSMC License Agreement"), which amended, restated, and superseded the Original CSMC License Agreement, pursuant to which, among other things, certain definitions were added or amended, the timing of certain obligations was revised and other obligations of the parties were clarified.

The Amended CSMC License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by CSMC to Capricor (with the right to sublicense) to conduct research using the patent rights and know-how and develop and commercialize products in the field using the patent rights and know-how. In addition, Capricor has the exclusive right to negotiate for an exclusive license to any future rights arising from related work conducted by or under the direction of Dr. Eduardo Marbán on behalf of CSMC. In the event the parties fail to agree upon the terms of an exclusive license for any future rights, Capricor will have a non-exclusive license to such future rights, subject to royalty obligations.

Pursuant to the Original CSMC License Agreement, CSMC was paid a license fee and Capricor was obligated to reimburse CSMC for certain fees and costs incurred in connection with the prosecution of certain patent rights. Additionally, Capricor is required to meet certain spending and development milestones.

Pursuant to the Amended CSMC License Agreement, Capricor remains obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a low double-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third-party for patent rights in connection with the royalty-bearing product.

The Amended CSMC License Agreement will, unless sooner terminated, continue in effect on a country by country basis until the last to expire of the patents covering the patent rights or future patent rights. Under the terms of the Amended CSMC License Agreement, unless waived by CSMC, the agreement shall automatically terminate: (i) if Capricor ceases, dissolves or winds up its business operations; (ii) in the event of the insolvency or bankruptcy of Capricor or if Capricor makes an assignment for the benefit of its creditors; (iii) if performance by either party jeopardizes the licensure, accreditation or tax exempt status of CSMC or the agreement is deemed illegal by a governmental body; (iv) within 30 days for non-payment of royalties; (v) after 90 days' notice from CSMC if Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights; (vi) if a material breach has not been cured within 90 days; or (vii) if Capricor challenges any of the CSMC patent rights. If Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights, and fails to cure that breach after 90 days' notice from CSMC, instead of terminating the license, CSMC has the option to convert any exclusive license to Capricor to a non-exclusive or co-exclusive license. Capricor may terminate the agreement if CSMC fails to cure any material breach within 90 days after notice.

Capricor and CSMC have entered into several amendments to the Amended CSMC License Agreement, pursuant to which the parties agreed to add and delete certain patent applications from the list of scheduled patents and extend the timing of certain development milestones, among other things. Capricor reimbursed CSMC for certain attorneys' fees and filing fees incurred in connection with the additional patent applications.

We recently received a letter from CSMC alleging that pursuant to the Amended CSMC License Agreement between CSMC and Capricor, Capricor has certain overdue payment obligations to CSMC arising out of a milestone payment received by Capricor pursuant to the U.S. Distribution Agreement entered into between Capricor and Nippon Shinyaku. The notice letter requests that Capricor cure the alleged breaches of the Amended CSMC License Agreement, and reserves CMSC's purported right to terminate the Amended CSMC License Agreement if such alleged breaches are not cured. We dispute the allegations in the letter from CSMC and intend to vigorously defend our position and pursue all available remedies, but there is no guarantee that any disputes that we have with CSMC will be resolved or if resolved, will not result in our incurring certain payment and other obligations.

License Agreement for Exosomes

On May 5, 2014, Capricor entered into an Exclusive License Agreement with CSMC (the "Exosomes License Agreement"), for certain intellectual property rights related to CDC-derived exosomes technology. The Exosomes License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by CSMC to Capricor (with the right to sublicense) in order to conduct research using the patent rights and know-how and to develop and commercialize products in the field using the patent rights and know-how. In addition, Capricor has the exclusive right to negotiate for an exclusive license to any future rights arising from related work conducted by or under the direction of Dr. Eduardo Marbán on behalf of CSMC. In the event the parties fail to agree upon the terms of an exclusive license, Capricor shall have a non-exclusive license to such future rights, subject to royalty obligations.

Pursuant to the Exosomes License Agreement, CSMC was paid a license fee and Capricor reimbursed CSMC for certain fees and costs incurred in connection with the preparation and prosecution of certain patent applications. Additionally, Capricor is required to meet certain non-monetary development milestones and is obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a single-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third-party for patent rights in connection with the royalty bearing product.

The Exosomes License Agreement will, unless sooner terminated, continue in effect on a country by country basis until the last to expire of the patents covering the patent rights or future patent rights. Under the terms of the Exosomes License Agreement, unless waived by CSMC, the agreement shall automatically terminate: (i) if Capricor ceases, dissolves or winds up its business operations; (ii) in the event of the insolvency or bankruptcy of Capricor or if Capricor makes an assignment for the benefit of its creditors; (iii) if performance by either party jeopardizes the licensure, accreditation or tax exempt status of CSMC or the agreement is deemed illegal by a governmental body; (iv) within 30 days for non-payment of royalties; (v) after 90 days if Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights; (vi) if a material breach has not been cured within 90 days; or (vii) if Capricor challenges any of the CSMC patent rights. If Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights and fails to cure that breach after 90 days' notice from CSMC, instead of terminating the license, CSMC has the option to convert any exclusive license to Capricor to a non-exclusive or co-exclusive license. Capricor may terminate the agreement if CSMC fails to cure any material breach within 90 days after notice.

Capricor and CSMC have entered into several amendments to the Exosomes License Agreement. Collectively, these amendments added additional patent applications and patent families to the Exosomes License Agreement, added certain defined product development milestone payments, modified certain milestone deadlines, added certain performance milestones with respect to product candidates covered by certain future patent rights in order to maintain an exclusive license to those future patent rights, and converted certain exclusive rights to co-exclusive rights. These amendments also obligated Capricor to reimburse CSMC for certain attorneys' fees and filing fees in connection with the additional patent applications and patent families.

Cell Line License Agreement with Life Technologies

On March 7, 2022, Capricor entered into a non-exclusive cell line license agreement with Life Technologies Corporation, a subsidiary of Thermo Fisher Scientific, Inc., for the supply of certain cells which we will use in connection with the development of our exosomes platform. An initial license fee payment was made in 2022 and additional milestone fees may become due based on the progress of our development program.

Patents and Proprietary Rights

Our goal is to obtain, maintain and enforce patent rights for our products, formulations, manufacturing processes, methods of use and other proprietary technologies, preserve our trade secrets, and operate without knowingly infringing on the valid and enforceable proprietary rights of other parties, both in the United States and abroad. Our policy is to actively seek to obtain, where appropriate, the broadest and focused intellectual property protection possible for our current product candidates and any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States and abroad. Even patent protection, however, may not always afford us with complete protection against competitors who seek to circumvent our patents. If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish. To this end, we require all of our employees, consultants, advisors and

other contractors to enter into confidentiality agreements that prohibit the disclosure and use of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions relevant to our technologies and important to our business.

The development of complex biotechnology products such as ours typically includes the early discovery of a technology platform – often in an academic institution – followed by increasingly focused development around a product opportunity, including identification and definition of a specific product candidate and development of manufacturing processes, formulations, patient selection and treatment regimes, and delivery and dosage regimens. As a result, biotechnology products are often protected by several families of patent filings that are made at different times in the development cycle and cover different aspects of the product. Earlier filed broad patent applications directed to the discovery of the platform technology thus usually expire ahead of patents covering later developments such as manufacturing processes, specific formulations, additional indications and dosing regimens. Patent expirations on products may therefore span several years and vary from country to country based on the scope of available coverage. Our patents, or patent applications, if issued and upon payment of patent maintenance fees, would expire as early as 2024 and as late as 2044 or beyond depending on any patent term adjustment or patent term extension. There are also limited opportunities to obtain extensions of patent terms in certain countries. The earlier expiring patents are generally directed to precursor cell populations or early non-DMD indications and administration methods. We have patents directed to CAP-1002 for the treatment of DMD that expire in 2038 unless otherwise extended under Hatch-Waxman. We continue to file patents on processes, indications, dosage forms and formulations directed to extend the patent portfolio related to CAP-1002 and our exosome technologies as our technology progresses.

Our product candidates and our technologies are primarily protected by composition of matter and process (methods of use and methods of making) patents and patent applications as well as trade secrets. As of the date of this filing, we have 46 granted patents and 15 pending patent applications covering processes and compositions of matter related to our CDC (CAP-1002) technology and 37 granted patents and 43 pending patent applications covering processes and compositions of matter related to our exosome technology.

Regulatory Designations

Regulatory Designations for CAP-1002 for the treatment of DMD

In 2015, the FDA granted orphan drug designation to CAP-1002 for the treatment of DMD. Orphan drug designation is granted by the FDA's Office of Orphan Drug Products to drugs intended to treat a rare disease or condition affecting fewer than 200,000 people in the United States or a disease or condition that affects more than 200,000 people in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. This designation confers special incentives to the drug developer, including tax credits on the clinical development costs and prescription drug user fee waivers and may allow for a seven-year period of market exclusivity in the United States upon FDA approval.

In 2017, the FDA granted Rare Pediatric Disease Designation to CAP-1002 for the treatment of DMD. The FDA defines a "rare pediatric disease" as a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and that affects fewer than 200,000 individuals in the United States, or a disease or condition that affects more than 200,000 people in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, upon the approval of a qualifying New Drug Application ("NDA") or BLA for the treatment of a rare pediatric disease, the sponsor of such application would be eligible for a Rare Pediatric Disease Priority Review Voucher that can be used to obtain priority review for a subsequent NDA or BLA. The Priority Review Voucher may be sold or transferred an unlimited number of times. If Capricor were to receive market approval for CAP-1002 by the FDA, Capricor would be eligible to receive a Priority Review Voucher based on its designation as a rare pediatric disease.

In 2018, we were granted the Regenerative Medicine Advanced Therapy ("RMAT") designation for CAP-1002 for the treatment of DMD. The FDA grants the RMAT designation to regenerative medicine therapies intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and for which preliminary clinical evidence indicates a potential to address unmet medical needs for that condition. The RMAT designation makes therapies eligible

for the same actions to expedite the development and review of a marketing application that are available to drugs that receive fast track or breakthrough therapy designation – including increased meeting opportunities, early interactions to discuss any potential surrogate or intermediate endpoints and the potential to support accelerated approval. CAP-1002 is one of the few therapies currently in development to help late-stage patients with DMD. To receive the RMAT designation, we submitted data from the HOPE-Duchenne Trial.

Trademarks

Our trademarks are generally filed to protect our corporate brand, our products and our platform technologies. We typically file trademark applications and pursue their registration in the U.S., Europe and other markets in which we anticipate using such trademarks. We are the owner of several common law, and federal trademark registrations or applications in the U.S. including, but not limited to, Capricor®, Capricor Therapeutics, STEALTHX™ and the Capricor logo. Trademark protection varies in accordance with local law, and continues in some countries as long as the trademark is used and in other countries as long as the trademark is registered. Trademark registrations generally are for fixed but renewable terms.

Research and Development

Capricor's research and development program has been advanced in part through federal and state grants and loan awards totaling approximately $28.0 million to date. Our ongoing research and development activities primarily concern CDCs and exosomes and are focused on the characterization of their composition and actions, the evaluation of their therapeutic potential in selected disease settings, the development of next generation product candidates, and the identification of new technologies and indications.

Competition

We are engaged in fields that are characterized by extensive worldwide research and competition by pharmaceutical companies, medical device companies, specialized biotechnology companies, hospitals, physicians, academic institutions, government agencies and research organizations both in the United States and abroad. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations that compete with us in developing various approaches to the treatment of DMD, which includes competitors both in the United States and internationally. With CAP-1002, we expect to face competition from existing products and products in development. In addition, at this time, there are four FDA conditionally approved exon skipping drugs: EXONDYS 51 (eteplirsen), AMONDYS 45 (casimersen) and VYONDYS 53 (golodirsen), which are phosphorodiamidate Morpholino oligomers (PMOs) approved for the treatment of DMD patients amenable to Exon 51, Exon 45 and Exon 53 skipping, respectively, and are marketed by Sarepta Therapeutics, Inc., and VILTEPSO (vitolarsen), a PMO approved for the treatment of DMD patients amenable to Exon 53 skipping, which is marketed by Nippon Shinyaku (U.S. subsidiary: NS Pharma, Inc.). In June 2023, the FDA approved Sarepta's BLA application seeking accelerated approval of Elevidys (delandistrogene moxeparvovec), its microdystrophin gene therapy, for the treatment of ambulant individuals with Duchenne. There are multiple other companies focused on developing genetic based therapies that target dystrophin mechanisms and non-dystrophin mechanisms for the treatment of DMD. Additionally, competition is particularly intense for products involving the treatment or prevention of diseases associated with COVID-19. The pharmaceutical industry is highly competitive, with a number of established, large pharmaceutical companies, as well as many smaller companies being involved. Many of the organizations competing with us have substantially greater financial resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals, and greater manufacturing and marketing capabilities than we do. We expect any future products and product candidates we develop to compete on the basis of, among other things, product efficacy and safety, time to market, price, extent of adverse side effects, and convenience of treatment procedures. The biotechnology and pharmaceutical industries are subject to rapid and significant technological change. The drugs that we are attempting to develop will have to compete with existing and future therapies. Our future success will depend in part on our ability to maintain a competitive position with respect to evolving cell therapy and exosome technologies. There can be no assurance that existing or future therapies developed by others will not render our potential products obsolete or noncompetitive. In addition, companies pursuing

different but related fields represent substantial competition. These organizations also compete with us to attract patients for clinical trials, qualified personnel and parties for acquisitions, joint ventures, or other collaborations.

Government Regulation

The research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, serialization and tracking, promotion, advertising, distribution and marketing, post-approval monitoring and reporting, and export and import, among other things, of our product candidates are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), and its implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as the FDA's refusal to approve a pending NDA or a pending BLA, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution. We would also be facing additional regulations and requirements from regulatory authorities in other countries outside the U.S. if we seek approval of our product candidates for sale or distribution within such countries.

FDA Approval Process for Drugs and Biologics

Pharmaceutical products, including biological products such as ours, may not be commercially marketed without prior approval from the FDA and comparable regulatory agencies in other countries. In the United States, the process for receiving such approval is long, expensive and risky, and includes the following steps:

- preclinical laboratory tests, animal studies, and formulation studies;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an IRB at each clinical site before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication;
- submission to the FDA of an NDA, for a drug, or BLA, for a biological product;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP;
- a potential FDA audit of the pre-clinical and clinical trial sites that generated the data in support of the NDA or BLA;
- the ability to obtain clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all;
- FDA review and approval of the NDA or BLA prior to any commercial marketing or sale of the drug in the United States; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy ("REMS"), and the potential requirement to conduct post-approval studies.

Sponsors submit NDAs in order to obtain marketing approval for drugs. Sponsors submit BLAs in order to obtain marketing approval for biologics, which include, among other product classes, vaccines.

Regulation by U.S. and foreign governmental authorities is a significant factor affecting our ability to commercialize any of our products, as well as the timing of such commercialization and our ongoing research and development activities. The commercialization of drug products requires regulatory approval by governmental agencies prior to commercialization. Various laws and regulations govern or influence the research and development, non-clinical and clinical testing, manufacturing, processing, packaging, validation, safety, labeling, storage, record keeping, registration, listing, distribution, advertising, sale, marketing and post-marketing commitments of our products. The lengthy process of seeking these approvals, and compliance with applicable laws and regulations, require expending substantial resources.

The results of preclinical testing, which include laboratory evaluation of product chemistry, formulation, toxicity and carcinogenicity animal studies to assess the potential safety and efficacy of the product and its formulations, details

concerning the drug manufacturing process and its controls, and a proposed clinical trial protocol and other information must be submitted to the FDA as part of an IND that must be reviewed and become effective before clinical testing can begin. The study protocol and informed consent information for patients in clinical trials must also be submitted to an independent Institutional Review Board ("IRB") for approval covering each institution at which the clinical trial will be conducted. Once a sponsor submits an IND, the sponsor must wait 30 calendar days before initiating any clinical trials. If the FDA has comments or questions within this 30-day period, the issue(s) must be resolved to the satisfaction of the FDA before a clinical trial can begin. In addition, the FDA or IRB may impose a clinical hold on ongoing clinical trials if, among other things, it believes that a clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable and significant risk to clinical trial patients. If the FDA imposes a clinical hold, clinical trials can only proceed under terms authorized by the FDA. If applicable, our preclinical and clinical studies must conform to the FDA's Good Laboratory Practice ("GLP"), and Good Clinical Practice ("GCP") requirements, respectively, which are designed to ensure the quality and integrity of submitted data and protect the rights and well-being of study patients. Information for certain clinical trials also must be publicly disclosed within certain time limits on the clinical trial registry and results databank maintained by the NIH.

Typically, clinical testing involves a three-phase process; however, the phases may overlap or be combined:

- Phase 1 clinical trials typically are conducted in a small number of volunteers or patients to assess the early tolerability and safety profile, the pattern of drug absorption, distribution and metabolism, the mechanism of action in humans, and may include studies where investigational drugs are used as research to explore biological phenomena or disease processes;
- Phase 2 clinical trials typically are conducted in a limited patient population with a specific disease in order to assess appropriate dosages and dose regimens, expand evidence of the safety profile and evaluate preliminary efficacy; and
- Phase 3 clinical trials typically are larger scale, multicenter, well-controlled trials conducted on patients with a specific disease to generate enough data to statistically evaluate the efficacy and safety of the product, to establish the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

A therapeutic product candidate being studied in clinical trials may be made available for treatment of individual patients, intermediate-size patient populations, or for widespread treatment use under an expanded access protocol, under certain circumstances. Pursuant to the 21st Century Cures Act (the "Cures Act"), which was signed into law in December 2016, the manufacturer of one or more investigational products for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational product.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA authorization under an FDA expanded access program; however, manufacturers are not obligated to provide investigational new drug products under the current federal right to try law.

The results of the preclinical and clinical testing, chemistry, manufacturing and control information, proposed labeling and other information are then submitted to the FDA in the form of either an NDA or BLA for review and potential approval to begin commercial sales. Within 60 days following submission of the application, the FDA reviews an application submission to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any application that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the application must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the application. In responding to an NDA or BLA, the FDA may grant marketing approval, or issue a Complete Response Letter ("CRL"). A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of an NDA or BLA and may require substantial additional testing or information. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter, which authorizes commercial marketing of the product with specific prescribing information for specific indications, and sometimes with specified post-marketing commitments and/or distribution and use restrictions imposed

under a Risk Evaluation and Mitigation Strategy program. Any approval required from the FDA might not be obtained on a timely basis, if at all.

Disclosure of Clinical Trial Information

Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to therapeutic candidates intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the U.S. or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a therapeutic candidate for this type of disease or condition will be recovered from sales in the U.S. for that therapeutic candidate. Orphan drug designation must be requested before submitting a marketing application for the therapeutic candidate for that particular disease or condition. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. Among the other benefits of orphan drug designation are tax credits for certain research and an exemption from the NDA or BLA application fee. The FDA may revoke orphan drug designation, and if it does, it will publicize that the drug is no longer designated as an orphan drug.

If a therapeutic candidate with orphan drug designation subsequently receives the first FDA approval for such drug for the disease for which it has such designation, the therapeutic candidate is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same therapeutic candidate for the same indication, for seven years, unless the sponsor of the subsequent application demonstrates clinical superiority, in the form of a greater efficacy, greater safety, or a major contribution to patient care. Orphan drug exclusivity, however, could also block the approval of one of our therapeutic candidates for seven years if a competitor obtains orphan drug designation and FDA approval of the same therapeutic candidate for the same condition or disease as our orphan-designated drug. For macromolecules, FDA considers a drug to be the same drug as an orphan-designated macromolecule if it contains the same principal molecular structural features, but not necessarily all of the same structural features.

In addition, as the FDA has interpreted the Orphan Drug Act, even if a previously approved same drug does not have unexpired orphan exclusivity, a demonstration of clinical superiority is required for a subsequent marketing application for the same orphan-designated drug for the same disease or condition to be awarded a 7-year period of orphan exclusivity upon marketing approval. In recent years, there have been multiple legal challenges to this FDA interpretation, and in August 2017, Congress amended the orphan drug provisions of the FDCA through enactment of the FDA Reauthorization Act of 2017 to codify FDA's longstanding interpretation. Section 527 of the FDCA now expressly provides that if a sponsor of an orphan-designated drug that is otherwise the same as an already approved drug for the same rare disease or condition is seeking orphan exclusivity, FDA shall require such sponsor to demonstrate that such drug is clinically superior to any already approved or licensed drug that is the same drug in order to obtain orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast Track product at any time during the clinical development of the product. Unique to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the

complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees. Upon submission of the first section of the application FDA may revoke the Fast Track designation if it believes that the designation is no longer supported by data emerging in the clinical trial process.

Products may also be eligible for other types of FDA programs intended to expedite development and review, such as Breakthrough Therapy designation, priority review and accelerated approval. Under the Breakthrough Therapy program, products intended to treat a serious or life-threatening disease or condition may be eligible for the benefits of the Fast Track program when preliminary clinical evidence demonstrates that such product may have substantial improvement on one or more clinically significant endpoints over existing therapies. Additionally, FDA will seek to ensure the sponsor of a breakthrough therapy product receives timely advice and interactive communications to help the sponsor design and conduct a development program as efficiently as possible.

A product is eligible for priority review if it is intended to treat a serious condition and, if approved, it would provide a significant improvement in safety or effectiveness. FDA intends to take action on a priority review marketing application within 6 months of filing, compared to 10 months of filing for regular review submissions.

Additionally, a product may be eligible for accelerated approval if it is intended to treat a serious or life-threatening disease or condition and would provide meaningful therapeutic benefit over existing treatments. Eligible products may receive accelerated approval on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality and is reasonably likely to predict an effect on irreversible morbidity, mortality, or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval diligently perform adequate and well-controlled post-marketing clinical studies demonstrating clinical benefit. In addition, the FDA requires as a condition for accelerated approval the submission of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, Breakthrough Therapy designation, priority review and accelerated approval do not change the standards for full approval but may expedite the development or approval process.

Regenerative Medicine Advanced Therapies (RMAT) Designation

The FDA has established a RMAT designation as part of its implementation of the Cures Act. The RMAT designation program is intended to fulfill the Cures Act requirement that the FDA facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as an RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

Rare Pediatric Disease Priority Review Voucher

The FDA generally defines a “rare pediatric disease” as a serious or life-threatening disease that affects fewer than 200,000 individuals in the U.S. primarily under the age of 18 years old. Under the FDA's Rare Pediatric Disease Priority Review Voucher (PRV) program, upon the approval of an application for a product for the treatment of a rare pediatric disease, the sponsor of such application is eligible for a Rare Pediatric Disease Priority Review Voucher. Currently, the Priority Review Voucher can be used to obtain priority review for any subsequent application and may be sold or transferred an unlimited number of times. Congress has only authorized the rare pediatric disease priority review voucher program until September 30, 2024. However, if a drug candidate receives Rare Pediatric Disease designation before September 30, 2024, it is eligible to receive a voucher if it is approved before September 30, 2026.

Post-Approval Requirements

FDA Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

Oftentimes, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval requirements are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA or BLA are required to report certain adverse reactions to the FDA, comply with certain requirements concerning advertising and promotional labeling for their products, and continue to have quality control and manufacturing procedures conform to cGMP after approval. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Among the conditions for an NDA or BLA approval is the requirement that the manufacturing operations conform on an ongoing basis with cGMP. In complying with cGMP, we must expend time, money and effort in the areas of training, production and quality control within our own organization and at our contract manufacturing facilities. A successful inspection of the manufacturing facility by the FDA is usually a prerequisite for final approval of a pharmaceutical product. Following approval of the NDA or BLA, we and our manufacturers will remain subject to periodic inspections by the FDA to assess compliance with cGMP requirements and the conditions of approval. We will also face similar inspections coordinated by foreign regulatory authorities if we are selling or manufacturing in foreign countries. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under an REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, including total or partial suspension of production, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

In addition, the distribution of prescription drug products is subject to the Prescription Drug Marketing Act (the "PDMA") which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription drug product samples and impose requirements to ensure accountability in distribution.

Pricing, Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any of our products, if and when approved. Sales of pharmaceutical products depend, in part, on the availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs, such as Medicare, Medicaid, TRICARE, and the Veterans Administration, as well as commercial insurance, and managed healthcare organizations. Prices at which we or our customers seek reimbursement for our therapeutic product candidates may be subject to challenge, reduction, or denial by payors. Third-party payors may limit coverage to specific products on an approved list or formulary, which might not include all of the FDA-approved products for a particular indication. Also, third-party payors may refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or another alternative is available. Third-party payors are increasingly challenging the prices charged for medical products and services.

The process for determining whether a payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. A payor's decision to provide coverage for a product does not imply reimbursement will be available at a rate that covers our costs, including research, development, manufacture, and sales and distribution costs. Additionally, in the United States there is no uniform policy among payors for determining coverage or reimbursement. Many third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will likely be a time-consuming process. If coverage and adequate reimbursement are not available, or are available only at limited levels, successful commercialization of, and obtaining a satisfactory financial return on, any product we develop may not be possible.

Third-party payors are increasingly challenging the prices and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payors may not consider our product candidates to be medically necessary or cost-effective compared to other available therapies, or payor negotiations may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products once approved as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis. Decreases in third-party reimbursement for our products once approved or a decision by a third-party payor to not cover our products could reduce or eliminate utilization of our products and have an adverse effect on our sales, results of operations, and financial condition.

Additionally, efforts to contain healthcare costs (including drug prices) have become a priority of federal and state governments. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution by generic products. There has also been heightened governmental scrutiny recently over the manner in which drug 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. Several federal healthcare reform efforts have been adopted in recent years which aim to restrict drug product pricing and limit reimbursement. For further details, See Part I, Item 1- Healthcare Reform. We anticipate additional state and federal healthcare reform measures will be adopted in the future. These may include price controls and cost-containment measures, or more restrictive policies in jurisdictions with existing controls and measures, any of which could limit the amounts that federal and state governments will pay for healthcare products

and services, and potentially could reduce demand for our products once approved, create additional pricing pressures, or ultimately limit our net revenue and results.

In addition, in some non-U.S. jurisdictions, the proposed pricing for a product candidate must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, product candidates launched in the EU do not follow price structures of the U.S. and generally tend to have price structures that are significantly lower.

In Japan, almost all medical-use drugs that have been approved (i.e., whose efficacy and safety have been confirmed) under the Pharmaceuticals and Medical Devices Act may be covered by the National Health Insurance ("NHI"). In order to be covered by the NHI, a drug must be listed on the NHI drug price standard within 60 or 90 days after approval for marketing. After the NHI drug price is listed, the NHI price, which is the official price of drugs, will be reviewed and updated on a regular basis. In principle, NHI price revisions are conducted once every two years in conjunction with the April revision of medical fees. When NHI drug prices are revised, most drugs will be priced lower than before the revision. The reason for this is that between pharmaceutical wholesalers and medical institutions and pharmacies, drugs are sold at prices lower than the NHI price, and the basic principle of NHI price revision is to reduce the NHI price in line with the prevailing market price. Accordingly, the NHI drug price revisions every two years may lead to the cut of the drug price in Japan.

Other Healthcare Fraud and Abuse Laws

Although we currently do not have any products on the market and do not make patient referrals or bill Medicare, Medicaid, or other government or commercial third-party payors, our activities, including current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers, may be subject to additional healthcare laws, regulations and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting, and physician sunshine laws. Some of our pre-commercial activities also may be subject to some of these laws.

The U.S. federal Anti-Kickback Statute prohibits, among other things, any person or entity, including a prescription drug manufacturer or a party acting on its behalf, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service that may be reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers, purchasers, and formulary managers, among others, on the other, including, for example, arrangements relating to consulting/speaking arrangements, discount and rebate offers, grants, charitable contributions, and patient support offerings. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common business activities from prosecution under the Anti-Kickback Statute. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated. Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Affordable Care Act" or the "ACA"), to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. A violation of the federal Anti-Kickback Statue includes per violation civil monetary penalties and significant criminal fines under the statute, additional civil penalties and treble damages under the False Claims Act, as discussed in more detail below, possible imprisonment, and mandatory exclusion from participation in the federal healthcare programs, meaning that federal healthcare programs would no longer reimburse (directly or indirectly) for products or services furnished by the excluded entity or individuals.

The U.S. federal civil False Claims Act, prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed. Persons and entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, certain of our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information, and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. Penalties for federal civil False Claims Act violations may include up to three times the actual damages sustained by the government, plus mandatory civil penalties of between $13,946 and $27,894 per false claim or statement for penalties assessed after January 15, 2024 with respect to violations occurring after November 2, 2015. Other penalties include the potential for exclusion from participation in federal healthcare programs. Additionally, although the federal False Claims Act is a civil statute, False Claims Act violations may also implicate various federal criminal statutes.

There is also the U.S. federal criminal False Claims Act, which is similar to the federal civil False Claims Act and imposes criminal liability on those that make or present a false, fictitious or fraudulent claim to the federal government. The Federal Criminal Statute on False Statements Relating to Health Care Matters makes it a crime to knowingly and willfully falsify, conceal, or cover up a material fact, make any materially false, fictitious, or fraudulent statements or representations, or make or use any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items, or services.

The U.S. Federal Civil Monetary Penalties Law (the "CMPL") authorizes the imposition of substantial monetary penalties against an entity, such as a pharmaceutical manufacturer, that engaged in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the ACA amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors, or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. Regulatory guidance and obligations continue to evolve. For example, on December 10, 2020, the Office for Civil Rights ("OCR") issued a proposed rule aimed at reducing regulatory burdens that may exist in discouraging coordination of care, among other changes. Finally, pursuant to legislation passed in 2021, OCR recently issued guidance on recognized security practices for covered entities and business associates. OCR indicated that recognized security practices will not be an aggravating factor in OCR investigations, but that implementation of recognized security practices strengthen an organization's cybersecurity and regulatory posture, as well as possibly lessening enforcement penalties in a potential regulatory enforcement. As HIPAA and HITECH requirements evolve, we may be required to update our compliance strategies or modify our business processes to comply.

The Federal Trade Commission ("FTC") and many state attorneys general are interpreting existing federal and state consumer protection laws to impose evolving standards for the collection, use, dissemination and security of health-related and other personal information. Privacy laws require us to publish statements that describe how we handle personal information and choices individuals may have about the way we handle their personal information. Violating individuals' privacy rights, publishing false or misleading information about security practices, or failing to take appropriate steps to keep individuals' personal information secure may constitute unfair or deceptive acts or practices in violation of Section 5 of the FTC Act. Additionally, the FTC recently published an advance notice of proposed rule making on "commercial surveillance" and data security, and is seeking comment on whether it should implement new trade regulation rules or other regulatory alternatives concerning the ways in which companies (1) collect, aggregate, protect, use, analyze, and retain consumer data, as well as (2) transfer, share, sell, or otherwise monetize that data in ways that are unfair or deceptive. Federal regulators, state attorneys general and plaintiffs' attorneys have been and will likely continue to be active in this space, and if we do not comply with existing or new laws and regulations related to patient health information, we could be subject to criminal or civil sanctions.

In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts. For instance, the California Consumer Privacy Act ("CCPA") became effective on January 1, 2020, giving California residents expanded privacy rights, and requiring businesses to provide detailed information about their data practices. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Although there are limited exemptions for PHI and certain clinical trial data, the CCPA's implementation standards and enforcement practices may increase our compliance costs and legal risks. Additionally, the California Privacy Rights Act ("CPRA") was passed in November 2020 and amended the CCPA beginning in 2023. The CPRA imposes additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Similar laws have been adopted in other states or proposed in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging. Additional compliance investment and potential business process changes may be required to respond to this rapidly changing privacy law landscape. If we fail to comply with existing or new privacy laws and regulations, we could face legal liability from regulatory actions or litigation, as well as reputational damage.

Additionally, the U.S. federal Physician Payments Sunshine Act (the "Sunshine Act"), created under the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to Centers for Medicare and Medicaid Services ("CMS") information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists, and licensed chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists, certified nurse-midwives and U.S. teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 (adjusted annually for inflation) per year and up to an aggregate of $1,000,000 (adjusted annually for inflation) per year for "knowing failures." Covered manufacturers are required to submit reports on aggregate payment data to the Secretary of the U.S. Department of Health and Human Services on an annual basis.

Many states have similar statutes or regulations to the above federal laws that may be broader in scope and may apply regardless of payor. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, drug pricing or marketing expenditures. These laws may differ from each other in significant ways and may not have the same effect, further complicating compliance efforts. Additionally, to the extent that we have business operations in foreign countries or sell any of our products in foreign countries and jurisdictions, including Japan or the European Union, we may be subject to additional regulations.

Although we do not currently have any products on the market, once our product candidates or clinical trials are covered by federal health care programs, we will be subject to additional healthcare statutory and regulatory requirements

and enforcement by the federal and state governments of the jurisdictions in which we conduct our business. Because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we intend to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we will or may become subject. Although the development and implementation of compliance programs can mitigate the risk of violating these laws, and the subsequent investigation, prosecution, and penalties assessed for violations of these laws, the risks cannot be entirely eliminated.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject, without limitation, to significant civil, criminal and administrative penalties, damages, fines, individual imprisonment, disgorgement, exclusion from participation in federal and state healthcare programs, reputational harm, diminished profits and future earnings, additional oversight and reporting obligations pursuant to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with applicable laws and regulations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Additionally, we expect our products, if and when approved, may be eligible for coverage under Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain pharmaceutical products, that are medically necessary to treat a beneficiary's health condition. In addition, our products may be covered and reimbursed under other government programs, such as Medicaid and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to statutorily defined covered entities that participate in the program. As part of the requirements to participate in certain government programs, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average manufacturer price ("AMP") and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely.

Healthcare Reform

In the United States and foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to healthcare systems that could affect our future results of operations.

In the United States, the pharmaceutical industry has been a particular focus of healthcare reform efforts and has been significantly affected by major legislative and regulatory initiatives, including the ACA, which has had, and is expected to continue to have, a significant impact on the healthcare industry. This law was designed to expand access to health insurance coverage for uninsured and underinsured individuals while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the ACA contains provisions that may potentially affect the profitability of our products, including, for example, subjecting biologics potential competition by lower-cost biosimilars, increased rebates for products sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain products under Medicare Part D, expansion of entities eligible for discounts under the Public Health Service's pharmaceutical pricing program, and a significant annual fee on companies that manufacture or import certain branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare providers and entities.

Additionally, there have been executive, judicial, and legislative challenges to certain aspects of the ACA. For example, while Congress has not passed legislation to comprehensively repeal the ACA, the Tax Cuts and Jobs Act included a provision that, effective January 1, 2019, changed to $0 the tax-based shared responsibility payment imposed by ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." Additionally, in March 2021, Congress enacted the American Rescue Plan Act of 2021, which included among its provisions a temporary increase in premium tax credit assistance for individuals eligible to receive qualified health plan premium subsidies for 2021 and 2022 and temporarily removed the 400% federal poverty level limit that otherwise applies for purposes of eligibility to receive premium such tax credits. The Inflation Reduction Act of 2022 ("IRA") extended this increased tax credit assistance and removal of the 400% federal poverty limit through 2025. Moreover, on June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden had issued an executive order that instructed certain governmental agencies to review and

reconsider their existing policies and rules that limit access to healthcare, including among others, policies that create barriers to obtaining access to health insurance coverage through the ACA marketplaces.

We cannot predict what effect the healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal, amend or replace the ACA would have on our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 included reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislation, will stay in effect into through the first six months of the fiscal year 2032 sequestration order (with the exception of a temporary suspension due to the COVID-19 pandemic from May 1, 2020 through March 31, 2022 and a subsequent reduction to 1% from April 1, 2022 until June 30, 2022). Additionally, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In the future, there may be additional challenges and/or amendments to the ACA. It remains to be seen precisely what any new legislation will provide, when or if it will be enacted, and what impact it may have on the availability and cost of healthcare items and services, including drug products.

In addition, in recent years the pricing and costs of prescription pharmaceuticals has been the subject of considerable discussion in the United States. A number of federal reports and inquiries have focused on these issues, and various legislative and regulatory provisions have been proposed and enacted at the federal and state level that seek to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the out-of-pocket cost of prescription drugs, and reform government program reimbursement methodologies for drugs. Additionally, on December 21, 2020, Congress passed a $900 billion U.S. coronavirus relief and government appropriations legislation, the Consolidated Appropriations Act of 2021, which contains several important new drug price reporting and transparency measures that could result in additional transparency with respect to manufacturers' prescription drug prices. Among other things, the Act includes provisions requiring Medicare Part D prescription drug plan (the "PDP") sponsors and Medicare Advantage organizations ("MAOs") to implement tools to display Medicare Part D prescription drug benefit information in real time and provisions requiring group and health insurance issuers offering health insurance coverage to report information on certain pharmacy benefit and drug costs to the Secretaries of HHS, Labor, and the Treasury.

Further, the Biden Administration and Congress have each indicated that it will continue to pursue new legislative and administrative measures to control drug costs. For example, the American Rescue Plan Act of 2021 included among its provisions a sunset of the ACA's cap on pharmaceutical manufacturers' rebate liability under the Medicaid Drug Rebate Program. Under the ACA, manufacturers' rebate liability was capped at 100% of the average manufacturer price for a covered outpatient drug. However, effective January 1, 2024, manufacturers' Medicaid Drug Rebate Program rebate liability is no longer be capped, potentially resulting in a manufacturer paying more in Medicaid Drug Rebate Program rebates than it receives on the sale of certain covered outpatient drugs. Further, in August 2022, President Biden signed into law IRA, which implements substantial changes to the Medicare program, including drug pricing reforms and the creation of new Medicare inflation rebates. Namely, the IRA imposes inflation rebates on drug manufacturers for products reimbursed under Medicare Parts B and D if the prices of those products increase faster than inflation; implements changes to the Medicare Part D benefit that, beginning in 2025, will cap beneficiary annual out-of-pocket spending at $2,000, while imposing new discount obligations for pharmaceutical manufacturers; and, beginning in 2026, establishes a "maximum fair price" for a fixed number of high expenditure pharmaceutical and biological products covered under Medicare Parts B and D following a price negotiation process with the CMS. Since its enactment, CMS has taken steps to implement various drug pricing provisions of the IRA. This includes, without limitation, issuing guidance on June 30, 2023 detailing the requirements and parameters of the first round of price negotiations, to take place during 2023 and 2024, for products subject to the "maximum fair price" provision that would become effective in 2026; on August 29, 2023, releasing the initial list of 10 drugs subject to price negotiations; and on December 14, 2023 releasing a list of 48 Medicare Part B products that had adjusted coinsurance rates based on the inflationary rebate provisions of the IRA for the time period of January 1, 2024 to March 31, 2024. Several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the Department of Health and Human Services, the Secretary of the Department of Health and Human Services, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA's drug price negotiation provisions. We cannot predict whether the IRA, or any of its component parts, will be overturned, repealed, replaced, or amended nor can we predict the likelihood, nature, or extent of other health reform initiatives that may arise from future legislation, administrative, or other action. However, we expect these initiatives to increase pressure on drug pricing.

Furthermore, the Biden administration continues to direct the Department of Health and Human Services to consider new healthcare payment and delivery models that would lower drug costs and promote access to innovative therapies for beneficiaries enrolled in the Medicare and Medicaid programs. For example, on October 14, 2022 President Biden issued an Executive Order on Lowering Prescription Drug Costs for Americans, which instructed the Secretary of the Department of Health and Human Services to consider whether to select for testing by the CMS Innovation Center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs. On February 14, 2023, the Department of Health and Human Services issued a report in response to the October 14, 2022 Executive Order, which, among other things, selects three potential drug affordability and accessibility models to be tested by the CMS Innovation Center. Specifically, the report addresses: (1) a model that would allow Part D Sponsors to establish a "high-value drug list" setting the maximum co-payment amount for certain common generic drugs at $2; (2) a Medicaid-focused model that would establish a partnership between CMS, manufacturers, and state Medicaid agencies that would result in multi-state outcomes-based agreements for certain cell and gene therapy drugs; and (3) a model that would adjust Medicare Part B payment amounts for Accelerated Approval Program drugs to advance the developments of novel treatments. We cannot predict how, or to what extent, the Biden administration's drug pricing policies will affect our products. We cannot predict what other healthcare reforms will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation. Accordingly, we face uncertainties that might result from additional reforms.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control biopharmaceutical and biologic 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. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any product that is ultimately approved, if approved. In addition, several recently passed state laws require disclosures related to state agencies and/or commercial purchasers with respect to certain price increases that exceed a certain level as identified in the relevant statutes. Another emerging trend at the state level is the establishment of prescription drug affordability boards, some of which will prospectively permit certain states to establish upper payment limits for drugs that the state has determined to be "high-cost." Some of these laws and regulations contain ambiguous requirements that government officials have not yet clarified. Given the lack of clarity in the laws and their implementation, our future reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations will be changed or what the effect of such changes, if any, may be.

Corporate Information

Our corporate and research headquarters are located at 10865 Road to the Cure, Suite 150, San Diego, California 92121. Our telephone number is (858) 727-1755 and our internet address is *www.capricor.com*. The information on, or accessible through, our website is not incorporated into this Annual Report on Form 10-K or any other filings we make with the U.S. Securities and Exchange Commission (the "SEC"). We have included our website address in this Annual Report on Form 10-K solely as an inactive textual reference.

Employees

As of December 31, 2023, we had 102 employees, of whom 101 are full-time employees with 34 holding advanced degrees. None of our employees are covered by a collective bargaining agreement. We believe that our relations with our employees are satisfactory. We have also retained several consultants to perform various operational and administrative functions. Certain officers of Capricor are also serving as officers of the Company.

ITEM 1A. RISK FACTORS

Investment in our common stock involves significant risk. You should carefully consider the information described in the following risk factors, together with the other information appearing elsewhere in this Annual Report on Form 10-K, before making an investment decision regarding our common stock. If any of the events or circumstances described in these risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or a part of your investment in our common stock. Moreover, the risks described below are not the only ones that we face.

Summary Risk Factors

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, clinical and commercialization activities, the manufacturing of our product candidates, intellectual property, third-party relationships, competition factors, product and environmental liability, and common stock. These risks are discussed more fully below and include, but are not limited to, risks related to:

Risks Related to Our Business

- substantial additional funding is needed to complete the development of our product candidates;
- the Company has incurred significant losses and may never be profitable;
- the occurrence of security breaches, improper access to or disclosure of our data or user data, and other cyber incidents or undesirable cyber activity related to our, or our third-party vendor's systems and data; and
- we may not have adequate personnel and may not be able to attract or retain personnel needed to develop our products.

Risks Related to Clinical and Commercialization Activities

- our success depends upon the viability of our product candidates, all of which require regulatory approval to commercialize and we cannot be certain any of them will receive regulatory approval to be commercialized;
- delays in commencement, enrollment, and completion of clinical testing could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates;
- our exosome technologies are unproven in their ability to achieve sufficient biological activity or scale in development to date;
- product candidates can fail to meet their efficacy endpoints at any time during the clinical development process, which would likely make them ineligible for becoming commercial products;
- we may not be able to use our facilities to manufacture CAP-1002 product for commercial purposes;
- we may be required to obtain consent from CSMC in order to sell commercial product from our Los Angeles facility;
- we may not be able to satisfy clinical and/or regulatory requirements necessary for the approval of our product in the U.S. or Japan;
- we may not be able to reach the milestones set forth in our distribution agreements therefore preventing us from receiving the financial benefits of those agreements; and
- our partners may not perform as expected and therefore deny us the financial benefits of those agreements.

Risks Related to the Manufacturing of our Product Candidates

- the manufacturing of our product candidates is heavily reliant on supply chain requirements including the availability of donor hearts and other raw materials that are critical for the manufacturing of our product candidates;
- we may need to rely upon third-party manufacturers for the expansion of our manufacturing capabilities for later-stage clinical trials and for ultimate commercialization;
- we may not have adequate manufacturing facilities required for any scale-up of manufacturing which may be required in the future;
- we may not be able to replicate our manufacturing processes;
- we may not be able to comply with cGMP regulations;

- we may not be able to identify or retain necessary manufacturing personnel;
- the FDA may not accept the viability or comparability of our manufacturing processes; and
- the FDA may not approve our manufacturing facilities for the manufacture of commercial products.

Risks Related to Our Intellectual Property

- we may not be able to obtain, maintain, protect, and enforce our intellectual property rights;
- we may face potential challenges to the validity, enforceability, or scope of our intellectual property;
- we may experience claims from third parties that we are infringing their patents or other intellectual property rights; and
- we may not be able to satisfy our obligations under our licensing agreements.

Risks Related to Our Relationships with Third Parties

- we depend on our relationships with our licensors, collaborators, and other third parties and there is no guarantee that such relationships will continue; and
- we will depend on the ability of Nippon Shinyaku to perform according to the terms of the U.S. Distribution and Japan Distribution Agreements and all applicable laws, and to successfully commercialize our lead product CAP-1002 in DMD.

Risks Related to Competitive Factors

- our products will likely face intense competition; and
- any of our product candidates for which we receive regulatory approval may not achieve broad market acceptance, which could limit the revenue that we will generate from their sales, if any.

Risks Related to Product and Environmental Liability

- our products may expose us to potential product liability.

Risks Related to Our Common Stock

- we expect that our stock price will continue to fluctuate significantly; and
- we have never paid dividends and we do not anticipate paying dividends in the future.

Risks Related to Our Business

We need substantial additional funding before we can complete the development of our product candidates. If we are unable to obtain such additional capital, we will be forced to delay, reduce or eliminate our product development and clinical programs and may not have the capital required to otherwise operate our business.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials and establishing manufacturing capabilities, is expensive. As of December 31, 2023, we had cash, cash equivalents, and marketable securities totaling approximately $39.5 million. Additionally, we received a milestone payment of $10.0 million in the first quarter of 2024 under the terms of our U.S. Distribution Agreement with Nippon Shinyaku and we may potentially receive other additional development and sales-based milestones. We have not generated any revenues from the commercial sale of products. We will not be able to generate any product revenues until, and only if, we receive approval to sell our drug candidates from the FDA or other regulatory authorities.

From inception, we have financed our operations through private and public sales of our equity securities, government grants and payments from distribution agreements and collaboration partners. As we have not generated any revenue from the commercial sale of our products to date, and we do not expect to generate revenue for several years, if ever, we will need to raise substantial additional capital in order to fund our general corporate activities and to fund our research and development, including our long-term plans for clinical trials and new product development.

We may seek to raise additional funds through various potential sources, such as equity and debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations or, if such funds are available to us, that such additional financing will be sufficient to meet our needs. Moreover, to the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates, or grant licenses on terms that may not be favorable to us.

If we are unable to raise sufficient funds to support our current and planned operations, we may elect to discontinue certain of our ongoing activities or programs. The inability to raise additional funds could also prevent us from taking advantage of opportunities to pursue promising new or existing programs in the future.

Our forecasts regarding our beliefs in the sufficiency of our financial resources to support our current and planned operations are forward-looking statements and involve significant risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, cost and results of our research and development activities, especially our CAP-1002 and exosomes programs;
- the next steps in the development of our DMD program, which includes our HOPE-3 clinical trial for our CAP-1002 product candidate for DMD;
- the availability of funding from government programs including the NIH, DoD, and CIRM, if applicable;
- the costs of developing adequate manufacturing processes and facilities;
- the costs associated with and timing of regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs and risks involved in conducting clinical trials and manufacturing operations in the U.S. and internationally;
- the effect of competing technological and market developments;
- the terms and timing of any collaboration, licensing or other arrangements that we may establish;
- our ability to manufacture commercial-scale GMP CAP-1002 product at our San Diego manufacturing facility;
- the cost and timing of technology transfer for, and completion of, clinical and commercial-scale outsourced manufacturing activities; and
- the costs of establishing sales, marketing and distribution capabilities, as applicable, for any product candidates for which we may receive regulatory approval.

If our business plans are not successful, we may not be able to continue operations as a going concern and our stockholders may lose their entire investment in us.

Our audited financial statements include a statement that there is substantial doubt about our ability to continue as a going concern. We have historically incurred substantial losses to fund our business operations including our research and development activities and more recently manufacturing scale-up activities. We will, in all likelihood, sustain operating expenses without corresponding revenues for the foreseeable future. This may result in our incurring net operating losses that will increase continuously until we are able to obtain regulatory approval for, and commercialize, our product candidates, the occurrence of which cannot be assured. While we have historically been able to adjust the timing associated with our R&D efforts, as well as reducing headcount and implementing certain budget restrictions, to alleviate

uncertainties surrounding our ability to continue as a going concern, if ultimately we cannot continue as a going concern, our stockholders may lose their entire investment in us.

We have a history of net losses, and we expect losses to continue for the foreseeable future. In addition, a number of factors may cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We have a history of net losses, expect to continue to incur substantial net losses for the foreseeable future, and may never achieve or maintain profitability. Our operations to date have been primarily limited to organizing and staffing our company, developing our technology, and undertaking preclinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approval for any of our product candidates. Specifically, our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors:

- our need for substantial additional capital to fund our trials and development programs;
- delays in the commencement, enrollment, and timing of clinical testing;
- the viability of CAP-1002 as a potential product candidate and its development through all stages of clinical development;
- the viability of our exosome technologies as potential product candidates and the advancement of our exosome technologies through all stages of its preclinical and clinical development;
- any delays in regulatory review and approval of our product candidates in clinical development;
- our ability to receive regulatory approval or commercialize our product candidates, within and outside the United States;
- potential side effects of our current or future products and product candidates that could delay or prevent commercialization or cause an approved treatment to be taken off the market;
- market acceptance of our product candidates;
- our ability to establish an effective sales and marketing infrastructure once our products are commercialized, as necessary or to establish partnerships with other companies who have greater sales and marketing capabilities;
- the ability of our distribution partner, Nippon Shinyaku, to successfully market and sell our CAP-1002 product if and to the extent it is approved;
- our ability to establish or maintain collaborations, licensing or other arrangements, including strategic partnerships for CAP-1002 outside of DMD and our exosomes technologies;
- our ability and third parties' abilities to obtain and protect intellectual property rights;
- competition from existing products or new products that may emerge;
- guidelines and recommendations of therapies published by various organizations;
- the ability of patients to obtain coverage of, or sufficient reimbursement for, our product candidates;
- our ability to maintain adequate insurance policies;
- our ability to successfully manufacture our product candidates in sufficient quantities and on a timely basis to meet clinical trial and potential commercial demand;
- our dependency on third parties to formulate and manufacture our product candidates, as necessary;
- our ability to maintain and staff our current manufacturing facilities;
- our ability to build or secure new manufacturing facilities, if necessary, and achieve and maintain cGMP and obtain required certifications as required;
- costs related to and outcomes of potential intellectual property litigation;
- compliance with obligations under intellectual property licenses with third parties;
- our ability to implement additional internal systems and infrastructure;
- our ability to adequately support future growth;
- if our products are approved for commercial sale, the ability to secure adequate reimbursement levels for our products;
- our ability to attract and retain key personnel to manage our business effectively; and
- the ability of members of our senior management to manage our business and operations.

The Company's technology is not yet proven and each of our product candidates is still in clinical or preclinical development.

The Company's product candidates, CAP-1002 and our exosome technologies, are in development and each requires further and, in some cases, extensive clinical testing before it may be approved by the FDA, or another regulatory authority in a jurisdiction outside the United States, which could take several years to complete, if ever. The Company's failure to establish the efficacy of its technologies would have a material adverse effect on the Company. We cannot predict with any certainty the results of such clinical testing, including the results of our ongoing Phase 3 trial of our CAP-1002 product candidate for DMD. Additionally, we cannot predict with any certainty if, or when, we might commence any additional clinical trials of our product candidates, whether we will be able to secure additional strategic partners, or whether our current trials will yield sufficient data to permit us to proceed with additional clinical development and ultimately submit an application for regulatory approval of our product candidates in the United States or abroad, or whether such applications will be accepted by the appropriate regulatory agencies. We are also unable to predict whether our preclinical studies of our exosomes products will result in a viable clinical development program.

Our business depends entirely on the successful development and commercialization of our product candidates. We currently have no products approved for sale and generate no revenues from sales of any products, and we may never be able to develop a marketable product.

Our product candidates will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote our product candidates before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of our product candidates will depend on several factors, including the following:

- successful and timely completion of our clinical trials;
- initiation and successful patient enrollment and completion of additional clinical trials on a timely basis;
- the impact of COVID-19 or some other infectious disease outbreak on our operations, ability to conduct clinical trials and on the ability of our regulators to review and approve or authorize our products;
- our ability to demonstrate our products' safety, tolerability and efficacy to the FDA or any comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing approval for our products;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- avoiding and successfully defending against any claims that we have infringed, misappropriated or otherwise violated any intellectual property of any third-party;
- the performance of our current and future distributors or collaborators, if any;
- the extent of, and our ability to timely complete, any required post-marketing approval commitments imposed by FDA or other applicable regulatory authorities;
- successfully developing a companion diagnostic test on a timely and cost effective basis, if required;
- establishment of supply arrangements with third-parties for raw materials and product supplies and potential manufacturers who are able to manufacture clinical trial and commercial quantities of drug substance and drug products;
- our ability to develop, validate and maintain a commercially viable manufacturing process that is compliant with cGMP at a scale sufficient to meet anticipated demand;
- establishment of arrangements with potential manufacturers who are able to develop, validate and maintain a commercially viable manufacturing process that is compliant with cGMP at a scale sufficient to meet anticipated demand and over time enable us to reduce our cost of manufacturing, if necessary;
- establishment of scaled production arrangements with third-party manufacturers to obtain finished products that are compliant with cGMP and appropriately packaged for sale;
- successful launch of commercial sales following marketing approval;
- a continued acceptable safety profile following marketing approval;
- commercial acceptance by patients, the medical community and third-party payors;

- the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- our ability to compete with other therapies; and
- our ability to conduct post-marketing surveillance and comply with requirements of FDA and other comparable regulatory authorities after product approval.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of our products. If we are not successful in marketing or commercializing our products, or are significantly delayed in doing so, our business will be materially harmed.

Business disruptions such as natural disasters, widespread infectious diseases, or pandemics or geopolitical conflicts could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our corporate headquarters and our manufacturing and research facilities are located in San Diego and in the greater Los Angeles, California area, a region known for seismic activity, as well as being susceptible to drought and fires. A significant natural disaster, such as an earthquake, flood or fire, occurring at our headquarters or manufacturing facilities, or at the facilities of any third-party manufacturer or vendor, could have a material adverse effect on our business, financial condition and results of operations. In addition, outbreaks of viruses, infectious diseases or pandemics (including, for example, the outbreak of the novel coronavirus (COVID-19), terrorist acts or acts of war targeted at the United States, and specifically in the California region, or geopolitical conflicts, such as the Russia-Ukraine conflict and the conflicts in the Middle East, could cause damage or disruption to us, our employees, facilities, contractors and collaborators, which could have a material adverse effect on our business, financial condition and results of operations.

A breakdown, corruption or breach of our information technology systems or computer systems, or those used or hosted by our CROs, contractors, consultants or third-party vendors could subject us to liability or interrupt the operation of our business.

We are increasingly dependent upon information technology systems, computer systems and data, as well as the information technology systems, computer systems and data of our current and future clinical research organizations ("CROs"), contractors, consultants and third-party vendors, especially if we expand our clinical trials and therefore our databases of patient information.

Our information technology systems, computer systems and data (and those of our current and future CROs, contractors, consultants and third-party vendors) are potentially vulnerable to breakdown, corruption, deliberate attacks, malicious intrusion or software, as well as unintentional cybersecurity incidents, such as system misconfigurations, misuses or human error. Likewise, data privacy or security breaches by individuals authorized to access our information technology systems or others may pose a risk that sensitive data, including intellectual property, trade secrets or personal information belonging to us, our patients, customers or other business partners, may be exposed to unauthorized persons or to the public.

We utilize and rely on services of third parties in connection with our clinical trials, which services involve the collection, use, storage and analysis of personal health information. While we receive assurances from these third parties that their systems and services are compliant with HIPAA and other applicable privacy and cybersecurity laws, there can be no assurance that such third parties will comply with applicable laws or regulations. Non-compliance by such third parties or weaknesses in their cybersecurity programs may result in liability for us which would have a material adverse effect on our business, financial condition and results of operations.

Despite the implementation of security measures, our information technology systems and computer systems, and those of our current and future CROs, contractors, consultants and other third parties are potentially vulnerable to breakdown, corruption, disruption or cybersecurity incidents. Cyber-attacks are increasing in their frequency, sophistication and intensity and are becoming increasingly difficult to detect. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of

clinical trial data from completed or future 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 confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be significantly delayed.

We continue to build and improve our information systems and infrastructure and believe we have taken appropriate security measures to minimize these risks to our data, information technology systems and computer systems, and we intend to defend against and respond to data security incidents. There can be no assurance that our efforts will prevent breakdowns or breaches in our systems, or adequately contain and mitigate risks from a data security incident, which could result in a material disruption of our development programs and business operations, and our business, financial condition, results of operations and prospects could be adversely impacted.

If we achieve our near-term product development milestones, we may not be able to manage any subsequent growth.

Should we achieve our near-term product development milestones, of which no assurance can be given, our long-term viability will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources, especially if we expand our business and operations internationally. To manage this growth, we may need to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

Risks Related to Clinical and Commercialization Activities

Our success depends upon the viability of our product candidates and we cannot be certain any of them will receive regulatory approval to be commercialized.

We will need FDA approval to market and sell any of our product candidates in the United States and approvals from FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any of our product candidates, we must submit to the FDA an NDA or BLA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal testing, which are referred to as preclinical studies, as well as human testing, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity, and novelty of the product candidate, and requires substantial resources for research, development, testing and manufacturing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA and other foreign regulatory agencies have substantial discretion in the approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation, administrative action or changes in FDA policy that occur prior to or during our regulatory review.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs or BLAs, as applicable. We cannot be sure that we will ever obtain regulatory clearance for our product candidates. Failure to obtain FDA approval of any of our product candidates will reduce our number of potentially salable products, if any, and, therefore, corresponding product revenues, and will have a material and adverse impact on our business.

We have limited experience in conducting late-stage clinical trials, which are complex and subject to strict regulatory oversight.

We have limited late-stage clinical trial experience with respect to its product candidates. The clinical testing process is governed by stringent regulations and is highly complex, costly, time-consuming, and uncertain as to outcome, and pharmaceutical products and products used in the regeneration of tissue may invite particularly close scrutiny and requirements from the FDA and other regulatory bodies. Our failure or the failure of our collaborators to conduct clinical trials successfully or our failure to capitalize on the results of clinical trials for our product candidates would have a material adverse effect on the Company. If our clinical trials of our product candidates or future product candidates do not sufficiently enroll or produce results necessary to support regulatory approval in the United States or elsewhere, or if they show undesirable side effects, we will be unable to commercialize these product candidates.

To receive regulatory approval for the commercial sale of our product candidates, we must conduct adequate and well-controlled clinical trials to demonstrate efficacy and safety in humans. Clinical failure can occur at any stage of testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. In addition, the results of our clinical trials may show that our product candidates are ineffective or may cause undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in the denial of regulatory approval by the FDA and other regulatory authorities. Furthermore, negative, delayed or inconclusive results may result in:

- the withdrawal of clinical trial participants;
- the termination of clinical trial sites or entire trial programs;
- costly litigation arising out of the trials;
- substantial monetary awards to patients or other claimants;
- the requirement that additional trials be conducted;
- impairment of our business reputation;
- loss of revenues; and
- the inability to commercialize our product candidates.

As the results of earlier preclinical studies or clinical trials are not necessarily predictive of future results, any product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Even if our preclinical studies and clinical trials are completed as planned, we cannot be certain that their results will support the claims of our product candidates. Positive results in preclinical testing and early clinical trials do not ensure that results from later clinical trials will also be positive, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing.

Our clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay or cause us to refrain from the filing of our NDAs and/or BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials to date involve small patient populations. Because of the small sample size, the results of these clinical trials may not be indicative of future results.

Despite the results reported in earlier clinical trials for our product candidates, we do not know whether any Phase 2, Phase 3 or other clinical trial which we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates. A number of companies in the pharmaceutical industry, including those with greater resources and experience, have suffered significant setbacks in Phase 2 or Phase 3 clinical trials, even after seeing promising results in earlier clinical trials.

Our exosome technologies are based on a novel therapeutic approach which makes it difficult to predict the time and cost of development and the probability of subsequently obtaining regulatory approval, if at all.

Our exosome technologies involve a relatively new therapeutic approach which will face both clinical and regulatory challenges. To date, and to the best of our knowledge, no products based on exosomes have been approved in the United States for therapeutic use. It is therefore difficult to accurately predict the developmental challenges we may face for our exosome technologies as they proceed through preclinical studies and clinical trials. In addition, because we have only conducted preclinical studies with our exosome technologies, we have not yet been able to assess their safety in humans, and there may be short-term or long-term effects from treatment with our exosomes that we cannot predict at this time. Also, animal models for the indications we may explore may not exist or may be difficult to obtain for our preclinical studies. As a result of these factors, we are unable to predict the time and cost of development of our exosome technologies and we cannot predict whether the application of our exosome technologies, or any similar or competitive exosome technologies, will result in regulatory approval of any products. There can be no assurance that any development problems we experience in the future related to our exosomes or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also decide to discontinue exosome development programs if we believe that there is excessive competition in a disease target. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any product candidates we may develop on a timely or profitable basis, if at all.

The clinical trial requirements of the FDA, the EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity and intended use and market of the product candidate. As a result, the regulatory approval process for our exosomes is uncertain and may be more expensive and take longer than the approval process for other product candidates. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our exosomes in either the United States or the European Union or other regions of the world or how long it will take to commercialize our product candidates, if at all. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product candidate to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects may be adversely impacted.

Negative developments in the field of exosomes could damage public perception of any product candidates that we develop, which could adversely affect our ability to conduct our business or obtain regulatory approvals for such product candidates.

Exosome-based therapeutics and vaccines are novel and unproven therapies which may not gain the acceptance of the public, patients or the medical community. To date, efforts by others to leverage natural exosomes have generally demonstrated an inability to generate exosomes with predictable biologically active properties or to manufacture exosomes at suitable scale to treat more than a small number of patients. Our success will depend on our ability to demonstrate that our exosome technologies can overcome these challenges.

Additionally, our success will depend upon physicians who specialize in the treatment of diseases targeted by our exosomes prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Adverse events in clinical trials of our exosomes or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of exosome therapeutics, could result in a decrease in demand for any products that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of, or modification to, our clinical trials. Any future negative developments in the field of exosomes and their use as therapies could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our exosomes or other potential future product candidates. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for our exosomes or any other product candidates which we may develop in the future.

Advancing product candidates based on our exosome platform as novel products creates significant challenges for us, including:

- to our knowledge, obtaining marketing approval from the FDA or comparable foreign regulatory authorities has never been done before;
- educating medical personnel regarding the potential efficacy and safety benefits, as well as the challenges, of incorporating our product candidates, if approved, into treatment regimens; and
- establishing the sales and marketing capabilities to gain market acceptance, if approved.

We may not be able to file INDs to commence additional clinical trials on the timelines we expect, and even if we are able to do so, the FDA may not permit us to proceed.

We hope to file additional INDs over the next several years, including with respect to our exosome technologies in one or more indications. However, the timing of our filing of these INDs is primarily dependent on receiving further data from our preclinical studies, having sufficient processes in place in connection with the manufacturing of the exosomes and the availability of necessary funding for any potential clinical trial.

We cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that result in the suspension or termination of such clinical trials. Any IND we submit could be denied by the FDA or the FDA could place any future investigation of ours on clinical hold until we provide additional information, either before or after clinical trials are initiated. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trial set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future. The FDA may also impose clinical holds at any time before or during clinical trials due to unacceptable and significant risks to clinical trial subjects or non-compliance with FDA requirements. Unfavorable future trial results or other factors, such as insufficient capital to continue development of a product candidate or program, could also cause us to voluntarily withdraw an effective IND.

Delays in the commencement, enrollment, and completion of clinical testing could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates.

Delays in the commencement, enrollment or completion of clinical testing could significantly affect our product development costs. Additionally, a clinical trial may be suspended or terminated by the Company, the FDA, or other regulatory authorities due to a number of factors. The commencement and completion of clinical trials require us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for the same indication as our product candidates or may otherwise be resource constrained. We may be required to withdraw from a clinical trial as a result of changing standards of care, or we may become ineligible to participate in clinical studies. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement, enrollment and completion of clinical trials can be delayed for a number of reasons, including, but not limited to, delays related to:

- findings in preclinical studies;
- reaching agreements on acceptable terms with prospective CROs, vendors and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, vendors and trial sites;
- obtaining regulatory clearance to commence a clinical trial;
- complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial, or being required to conduct additional trials before moving on to the next phase of trials;
- obtaining IRB approval to conduct a clinical trial at numerous prospective sites;
- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including the size of the patient population, nature of trial protocol, meeting the enrollment criteria for our studies, screening failures, the inability of the sites to conduct trial procedures properly, the inability of the sites to devote their resources to the trial, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- the impact of COVID-19 on site personnel availability, patient screening and patient enrollment;
- competition from other companies operating in the same disease setting;
- developing and validating any companion diagnostic to be used in the trial, to the extent we are required to do so;
- patients failing to comply with the clinical trial protocol or dropping out of a trial;
- clinical trial sites failing to comply with the clinical trial protocol or dropping out of a trial;
- addressing any conflicts with new or existing laws or regulations;
- the need to add new clinical trial sites;
- retaining patients who have initiated their participation in a clinical trial but may withdraw due to the treatment protocol, lack of efficacy, personal issues, or side effects from the therapy, or who are lost to further follow-up;
- manufacturing sufficient quantities of a product candidate for use in clinical trials on a timely basis;
- obtaining advice from regulatory authorities regarding the statistical analysis plan to be used to evaluate the clinical trial data or other trial design issues;
- demonstrating the bioequivalence of products we manufacture to prior products manufactured by us;
- complying with design protocols of any applicable special protocol assessment we receive from the FDA;
- severe or unexpected drug-related side effects experienced by patients in a clinical trial;
- collecting, analyzing and reporting final data from the clinical trials;
- breaches in quality of manufacturing runs that compromise all or some of the doses made; positive results in FDA-required viral testing; karyotypic abnormalities in our cell product; or contamination in our manufacturing facilities, all of which events would necessitate disposal of all cells made from that source;
- availability of materials provided by third parties necessary to manufacture our product candidates;
- availability of adequate amounts of acceptable tissue for preparation of master cell banks for our products;
- requirements to conduct additional trials and studies, and increased expenses associated with the services of the Company's CROs and other third parties; and
- meeting logistical requirements for the delivery of investigational product.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, we or our development partners, if any, may be delayed in obtaining, or may not be able to obtain or maintain, clinical or marketing approval for these product candidates. We may not be able to obtain approval for

indications that are as broad as intended, or we may be able to obtain approval only for indications that are entirely different from those indications for which we sought approval.

Changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. In August 2023, the FDA published a guidance document, Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors, which supersedes past guidance and finalizes draft guidance on informed consent. The FDA's new guidance presents evolving requirements for informed consent which may affect recruitment and retention of patients in clinical trials. Further, in December 2023, the FDA published a final rule, Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations, which allows exceptions from informed consent requirements when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. Modifications to informed consent or other clinical trial requirements may affect enrollment or retention of patients, require modifications to trial documents and may cause delays to the trial.

Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination which may impact the costs, timing, or successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed or will not be realized. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same or similar indications may have been introduced to the market and already established a competitive advantage. Any delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; or
- diminish any competitive advantages that we may otherwise enjoy.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including our CROs, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we, our investigators, or any of the overseeing IRBs or ethics committees might decide to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- 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;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are insufficiently positive to support marketing approval, or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are narrower or more limited in scope than intended or desired;
- obtain marketing approval subject to significant use or distribution restrictions or with labeling that includes significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the drug removed from the market after obtaining marketing approval.

Our drug development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Furthermore, we rely on third-party CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring drugs to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, interim results of a clinical trial do not necessarily predict final results, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable drugs. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any future collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. We will be required to demonstrate with substantial evidence through adequate and well-controlled clinical trials that our product candidates are safe and effective for use in treating specific conditions in order to obtain marketing approvals for their commercial sale. Success in preclinical studies and early-stage clinical trials does not mean that future larger registration clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. Product candidates that have shown promising results in preclinical studies and early-stage clinical trials may still suffer significant setbacks in subsequent registration clinical trials. Additionally, the outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later-stage clinical trials.

From time to time, we may publish or report interim or preliminary data from our clinical trials, once initiated. Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available.

In addition, the design of a clinical trial can determine whether its results will support approval of a drug and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing late-stage clinical trials and may be unable to design and conduct a clinical trial to support marketing approval. Further, if our product candidates are found to be unsafe or lack efficacy, we will not be able to obtain marketing approval for them and our business would be harmed. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in preclinical studies and earlier clinical trials.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates.

In the event that an adverse safety issue, clinical hold or other adverse finding occurs in one or more of our clinical trials, once initiated, such event could adversely affect our other clinical trials using the same product candidate. Moreover, there is a relatively limited safety data set for product candidates using an exosome platform. An adverse safety issue or other adverse finding in a clinical trial conducted by a third-party with a product candidate similar to ours could adversely affect our clinical trials.

Further, our product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials or registration trials. The FDA or comparable foreign regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal clinical trial that has the potential to result in approval by the FDA or comparable foreign regulatory authorities. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. In addition, the FDA or other comparable foreign regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

Before obtaining marketing approval for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and adequate and well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA and elsewhere to the satisfaction of other comparable foreign regulatory authorities, that the product candidate is safe and effective for use for that target indication. There is no assurance that the FDA or other comparable foreign regulatory authorities will consider our future clinical trials to be sufficient to serve as the basis for approval of one of our product candidates for any indication. The FDA and other comparable foreign regulatory authorities retain broad discretion in evaluating the results of our clinical trials and in determining whether the results demonstrate that a product candidate is safe and effective. If we are required to conduct additional clinical trials of a product candidate than we expect prior to its approval, we will need substantial additional funds and there is no assurance that the results of any such additional clinical trials will be sufficient for approval in our target markets, including the United States and Japan.

The regulatory pathway for COVID-19 or other infectious disease vaccines is continually evolving and may result in unexpected or unforeseen challenges.

The speed at which select parties have acted to create and test many therapeutics and vaccines for COVID-19 or other infection diseases is atypical. Further, changing plans or priorities within the FDA or the regulatory authorities in other jurisdictions, including changes based on new knowledge of COVID-19 or other infectious diseases, and new variants of the virus, may significantly affect the regulatory timeline for further authorizations or approvals. We cannot anticipate or predict with certainty the timelines or regulatory processes that may be required for the development of our potential COVID-19 vaccine that may be developed to fight against variants of the SARS-CoV-2 virus. We may also decide to discontinue exosome development programs if we believe that there is excessive competition in a disease target.

We may not be successful in our efforts to identify or discover additional potential product candidates or additional indications for our existing product candidates.

Our research programs may initially show promise in identifying potential product candidates or potential additional indications for existing product candidates, yet fail to lead to successful clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential product candidates;
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval and/or achieve market acceptance; and
- potential product candidates may not be safe or effective in treating their targeted diseases.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable compounds for preclinical and clinical development, our business would be harmed.

If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability, or that of any future distributors or collaborators, to market the drug could be compromised.

Clinical trials of our product candidates must be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives marketing approval and we, or others, discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the drug or seize the drug;
- we, or any future collaborators, may be required to recall the drug, change the way the drug is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular drug;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- the drug may become less competitive in the marketplace; and
- our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price.

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate sufficient revenues from sales of drugs to cover our costs and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to alternative therapies;
- the prevalence and severity of any side effects;
- whether the product is designated under physician and other provider treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration for patients and healthcare practitioners compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions and safety information contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- the performance of third-party distributors, such as our exclusive distributor for our lead product candidate, CAP-1002;

- changes in the standard of care for the targeted indications for the product; and
- the availability of coverage by, and the amount of reimbursement from, government payors, managed care plans and other third-party payors.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The pharmaceutical and biotechnology industries are highly competitive and characterized by rapidly advancing technologies, evolving understanding of disease etiology and a strong emphasis on proprietary drugs. We face competition with respect to any product candidates that we may seek to discover and develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies. Potential competitors also include academic institutions and governmental agencies and public and private research institutions.

Many of the companies that we compete or may compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations that compete with us in developing various approaches to the treatment of DMD which includes competitors both in the United States and internationally. We have competitors both in the United States and internationally. With CAP-1002, we expect to face competition from existing products and products in development. In addition, at this time, there are four FDA conditionally approved exon skipping drugs: EXONDYS 51 (eteplirsen), AMONDYS 45 (casimersen) and VYONDYS 53 (golodirsen), which are PMOs approved for the treatment of DMD patients amenable to Exon 51, Exon 45 and Exon 53 skipping, respectively, and are marketed by Sarepta Therapeutics, Inc., and VILTEPSO (vitolarsen), a PMO approved for the treatment of DMD patients amenable to Exon 53 skipping, which is marketed by Nippon Shinyaku (U.S. subsidiary: NS Pharma, Inc.). In June 2023, the FDA approved Sarepta's BLA application seeking accelerated approval of Elevidys (delandistrogene moxeparvovec), its microdystrophin gene therapy, for the treatment of ambulant individuals with Duchenne. There are multiple other companies focused on developing genetic based therapies that target dystrophin mechanisms and non-dystrophin mechanisms for the treatment of DMD.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may develop. Our competitors also may obtain FDA or other comparable foreign regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

The FDA has granted orphan drug status and an RMAT designation to CAP-1002 for the treatment of DMD, but we may be unable to maintain or receive the benefits associated with orphan drug status, including market exclusivity, or an RMAT designation.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition or for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for a disease or condition will be recovered from sales in the United States for that drug or biologic. If a biological product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity.

We have received orphan drug status for CAP-1002 for the treatment of DMD. Even though we have received orphan drug designation (ODD) as described above, we may not be the first to obtain marketing approval for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. For any product candidate for which we have been or will be granted ODD in a particular indication, it is possible that another company also holding ODD for the same product candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires.

In addition, our exclusive marketing rights in the United States, if obtained, may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure the availability of sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Even though we have obtained orphan drug designation for CAP-1002 for a select indication, we may be unable to seek or obtain orphan drug designation for our future product candidates and we may not be the first to obtain marketing approval for any particular orphan indication.

In addition, Congress is considering updates to the orphan drug provisions of the FDCA in response to a recent 11th Circuit decision. Any changes to the orphan drug provisions could change our opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and would materially adversely affect our business, financial condition, results of operations, cash flows and prospects.

We have also obtained an RMAT designation for CAP-1002 for the treatment of DMD. The RMAT designation program is intended to fulfill the Cures Act requirement that the FDA facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or may be able to rely upon data obtained from a meaningful number of sites, including through expansion to additional sites. RMAT designation does not change the standards for product approval, and there is no assurance that such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

Even if we were to obtain approval for CAP-1002 for the treatment of DMD with the rare pediatric disease designation, the Rare Pediatric Disease Priority Review Voucher Program may no longer be in effect at the time of such approval.

CAP-1002 has received rare pediatric disease designation from the FDA for the treatment of DMD. The FDA generally define a "rare pediatric disease" as a serious or life-threatening disease that affects fewer than 200,000 individuals in the U.S. primarily under the age of 18 years old. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, upon the approval of a NDA or BLA for the treatment of a rare pediatric disease, the sponsor of such application would be eligible for a Rare Pediatric Disease Priority Review Voucher that can be used to obtain priority review for a subsequent NDA or BLA. The Priority Review Voucher may be sold or transferred an unlimited number of times, as long as the sponsor making the transfer has not yet submitted the application. Also, although Priority Review Vouchers may be sold or transferred to third parties, there is no guaranty that we will be able to realize any value if we were to sell a Priority Review Voucher. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval.

Congress has only authorized the rare pediatric disease priority review voucher program until September 30, 2024. However, if a drug candidate receives Rare Pediatric Disease designation before September 30, 2024, it is eligible to receive a voucher if it is approved before September 30, 2026. This program has been subject to criticism, including by the FDA, and it is possible that even if we obtain approval for CAP-1002 and qualify for such a Priority Review Voucher, the program may no longer be in effect at the time of approval.

Providing product for use in third-party trials or for compassionate use poses risks to our product candidates.

In addition to manufacturing CAP-1002 for its own clinical trials, Capricor provided CAP-1002 for investigational purposes in two clinical trials sponsored by CSMC. Additionally, we recently were selected to be part of Project NextGen, an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines for COVID-19. As part of Project NextGen, the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, will conduct a Phase 1 clinical study with our StealthX™ vaccine, subject to regulatory approval. NIAID's Division of Microbiology and Infectious Diseases (DMID) would oversee the study.

Providing product for clinical trials sponsored by third parties poses significant risks for the Company as we will not have control over the conduct of the trial even though we have used our commercially reasonable efforts to ensure that the investigative sites are contractually bound to follow the protocol and other procedures established by Capricor. Similarly, providing product for compassionate use can pose risks for the Company as its use will not be subject to the same protocol and procedures established in our clinical trials. Additionally, even though the investigative sites have experience in conducting clinical trials, any adverse event that may occur during the trial may have a negative impact on our efforts to obtain regulatory approval for our product. There are no assurances that the clinical trial sites will perform the studies in accordance with the protocol, the manuals provided by Capricor or the sponsor's instructions, or otherwise act in accordance with applicable law. There is no assurance that if research injuries are sustained, any insurance carrier will compensate Capricor for any liabilities or other losses sustained by Capricor arising out of these injuries. We have been informed by CSMC that both of the CAP-1002 (REGRESS and ALPHA) trials have ceased enrollment and that the trials have been concluded. Notwithstanding their cessation, there is a risk that injuries could result from the use of the product or other claims may arise.

Our products face a risk of failure due to adverse immunological reactions.

A potential risk of an allogeneic therapy such as that being tested by the Company with CAP-1002 is that patients might develop an immune response to the cells being infused. Such an immune response may induce adverse clinical effects which would impact the safety and efficacy of the Company's products and the success of our trials. Additionally, if research subjects have pre-existing antibodies or other immune sensitization to our cells, our cells and the therapy could potentially be rendered ineffective which could have a negative impact on the regulatory pathway for our product as well as the viability for other potential indications. After a patient in the HOPE-2 trial had a serious adverse event in the form of anaphylaxis, we put a voluntary hold on dosing in December 2018 to develop a plan to manage potential allergic reactions. The investigation suggests that the patient may have been allergic to something contained in the investigational product, including possibly an excipient, or inactive ingredient, in the formulation. To reduce the risk of future events, we initiated a pre-medication strategy commonly used by physicians to prevent and treat allergic reactions. We cannot provide any assurances that this will not happen again in our current trials or in any future studies. If these or other reactions continue to occur, it could have a material adverse impact on the effectiveness of the product, our ability to receive approval of our product candidates, and could result in substantial delays, increased costs and potentially termination of the trial.

Our business faces significant government regulation, and there is no guarantee that our product candidates will receive regulatory approval.

Our research and development activities, preclinical studies, clinical trials, and manufacturing and marketing of our potential products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, as well as by regulatory authorities in other countries. In the United States, our product candidates are subject to regulation as biological products or as combination biological products/medical devices under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act and other statutes, and as further provided in the Code of Federal Regulations. Different regulatory requirements may apply to our products depending on how they are categorized by the FDA under these laws. These regulations can be subject to substantial and significant interpretation, addition, amendment or revision by the FDA and by the legislative process. The FDA may determine that we will need to undertake clinical trials beyond those currently planned. Furthermore, the FDA may determine that results of clinical trials do not support approval for the product. Similar determinations may be encountered in foreign countries including determinations that our manufacturing processes being utilized in the United States are not compliant with the regulations adopted in those foreign countries. The FDA will continue to monitor products in the market after approval, if any, and may determine to withdraw its approval or otherwise seriously affect the marketing efforts for any such product. The same possibilities exist for trials to be conducted outside of the United States that are subject to regulations established by local authorities and local law. Any such determinations

would delay or deny the introduction of our product candidates to the market and have a material adverse effect on our business, financial condition, and results of operations.

Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, other federal agencies and corresponding state agencies to ensure strict compliance with good manufacturing practices, and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards, nor can we guarantee that we will maintain compliance with such regulations in regards to our own manufacturing processes. Other risks include:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication, or field alerts to physicians and pharmacies;
- regulatory authorities may withdraw their approval of the IND or the product or require us to take our approved products off the market;
- we may be required to change the way the product is manufactured or administered, and we may be required to conduct additional clinical trials or change the labeling of our products;
- we will be required to manufacture on our own behalf or retain the services of a commercial manufacturer to develop product suitable for commercial sale in compliance with cGMP requirements;
- we may have limitations on how we or our distributor promote our products;
- we may be subject to litigation or product liability claims; and
- the products we manufacture may experience failures in the manufacturing process.

There are additional risks involved in conducting clinical trials internationally.

If we decide to expand or conduct one or more of our clinical trials to investigative sites in Europe, Japan, or other countries outside of the United States, we will have additional regulatory requirements that we will have to meet in connection with our manufacturing, distribution, use of data and other matters. For example, if we decide to conduct our trials in Europe, we may have to move our manufacturing facility to a facility located in Europe, enter into an agreement with a European manufacturer to manufacture our product candidates for us, enter into an agreement with a domestic manufacturer who maintains an acceptable cGMP facility or ensure that our facility meets Japanese, European or other foreign specifications. Any of those options would involve a significant monetary investment, time delays, and increased risk and may impact the progress of our clinical trials and regulatory approvals.

Further, we have entered into the Japanese Distribution Agreement with Nippon Shinyaku for the distribution of CAP-1002 in Japan. In order for us to be able to sell CAP-1002 in Japan, we will be required to satisfy the requirements of and get approval from the PMDA. At this time, we are uncertain as to the type or types of trials that may be required, whether the PMDA in Japan will accept product manufactured at our facilities, if approved, the price at which our product may be sold and market acceptance.

To the extent we conduct business in the European Union ("EU"), or receive information about EU residents, we will also have to comply with the EU General Data Protection Regulation (the "GDPR"), which was officially adopted in April 2016 and went into effect in May 2018. The GDPR introduces new data protection requirements in the EU, as well as substantial fines for breaches of data protections rules. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements and onerous new obligations on services providers. Non-compliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of providing our products and services or even prevent us from offering certain services in jurisdictions in which we operate.

Additionally, the U.S. Foreign Corrupt Practices Act ("FCPA") prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations. As we expand our business outside of the United States, ensuring compliance with the FCPA and the laws of other countries will involve additional monetary and time commitments on behalf of the Company.

Even if our product candidates receive regulatory approval, we may still face future development and FDA regulatory difficulties.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies. If any of our products were granted accelerated approval, the FDA could require post-marketing confirmatory trials to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. FDA may withdraw approval of a drug or indication approved under the accelerated approval pathway if any of the following were to occur: a trial required to verify the predicted clinical benefit of the product fails to verify such benefit; other evidence demonstrates that the product is not shown to be safe or effective under the conditions of use; the applicant fails to conduct any required post-approval trial of the drug with due diligence; or the applicant disseminates false or misleading promotional materials relating to the product. In addition, the FDA currently requires as a condition for accelerated approval the pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Given the number of recent high-profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials, and restrictions on direct-to-consumer advertising. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA's drug approval process and the FDA's efforts to assure the safety of marketed drugs have resulted in the proposal of new legislation addressing drug safety issues. If enacted, any new legislation could result in delays or increased costs during the period of product development, clinical trials, and regulatory review and approval, as well as increased costs to assure compliance with any new post-approval regulatory requirements. Any of these restrictions or requirements could force us to conduct costly studies or increase the time for us to become profitable. For example, any labeling approved for any of our product candidates may include a restriction on the term of its use, or it may not include one or more of our intended indications.

Our product candidates will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping, and submission of safety and other post-market information on the drug. New issues may arise during a product lifecycle that did not exist, or were unknown, at the time of product approval, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured. Since approved products, manufacturers, and manufacturers' facilities are subject to continuous review and periodic inspections, these new issues post-approval may result in voluntary actions by Capricor or may result in a regulatory agency imposing restrictions on that product or us, including requiring withdrawal of the product from the market or for use in a clinical trial. If our product candidates fail to comply with applicable regulatory requirements, such as good manufacturing practices, a regulatory agency may:

- issue warning or untitled letters;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions, and penalties for noncompliance;
- impose other civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

In order to market and commercialize any product candidate outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding manufacturing, safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Failure to obtain regulatory approval in other countries, or any delay or setback in obtaining such approval, could have the same adverse effects detailed above regarding FDA approval in the United States. Such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on product sales and potential royalties,

and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

If we or current or future collaborators, manufacturers, or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions and substantial penalties, which could affect our ability to develop, market and sell our products and may harm our reputation.

Although we do not currently have any products on the market, if our therapeutic candidates or clinical trials become covered by federal health care programs, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal, state and foreign governments of the jurisdictions in which we conduct our business. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any therapeutic candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse, transparency, and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our therapeutic candidates for which we obtain marketing approval. Some of our pre-commercial activities also may be subject to some of these laws. For more information on potentially applicable healthcare laws and regulations, See Part I, Item 1 – Other Healthcare Fraud and Abuse Laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. If our operations are found to be in violation of any of these or any other healthcare regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or similar programs in other countries or jurisdictions, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement and curtailment or restructuring of our operations, any of which could adversely impact our ability to operate our business and our results of operations.

Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation, even the mere issuance of a subpoena or the fact of an investigation alone, regardless of the merit, could result in negative publicity, a drop in our share price, or other harm to our business, financial condition and results of operations. Defending against any such actions could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

Any drugs we develop may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices or healthcare reform initiatives, thereby harming our future business prospects.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenues we are able to generate from the sale of the product in that country.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. However, there may be significant delays in obtaining coverage

for newly-approved drugs. Moreover, eligibility for coverage does not necessarily signify that a drug will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution costs. Also, interim payments for new drugs, if applicable, may be insufficient to cover our costs and may not be made permanent. Thus, even if we succeed in bringing one or more products to the market, these products may not be considered medically necessary or cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of reimbursement. In addition, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we develop.

Increasingly, the third-party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are seeking greater upfront discounts, additional rebates and other concessions to reduce the prices for pharmaceutical products. If the price we are able to charge for any products we develop, or the reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be adversely affected.

We currently expect that certain drugs we develop may need to be administered under the supervision of a physician on an outpatient basis. Under currently applicable U.S. law, certain drugs that are not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Specifically, Medicare Part B coverage may be available for eligible beneficiaries when the following, among other requirements have been satisfied:

- the product is reasonable and necessary for the diagnosis or treatment of the illness or injury for which the product is administered according to accepted standards of medical practice;
- the product is typically furnished incident to a physician's services;
- the indication for which the product will be used is included or approved for inclusion in certain Medicare-designated pharmaceutical compendia (when used for an off-label use); and
- the product has been approved by the FDA.

Average prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Reimbursement rates under Medicare Part B would depend in part on whether the newly approved product would be eligible for a unique billing code. Self-administered, outpatient drugs are typically reimbursed under Medicare Part D, and drugs that are administered in an inpatient hospital setting are typically reimbursed under Medicare Part A under a bundled payment. It is difficult for us to predict how Medicare coverage and reimbursement policies will be applied to our products in the future and coverage and reimbursement under different federal healthcare programs are not always consistent. Medicare reimbursement rates may also reflect budgetary constraints placed on the Medicare program.

Third-party payors often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement rates. These coverage policies and limitations may rely, in part, on compendia listings for approved therapeutics. Our inability to promptly obtain relevant compendia listings, coverage, and adequate reimbursement from both government-funded and private payors for new drugs that we develop and for which we obtain regulatory approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our financial condition.

There have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality of care and/or expanding access to care

and the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs, once marketing approval is obtained. See Part I, Item 1 – Healthcare Reform for additional detail on recent legislative and regulatory changes that could affect our operations.

Our risk mitigation measures cannot guarantee that we effectively manage all operational risks and that we are in compliance with all potentially applicable U.S. federal and state regulations and all potentially applicable foreign regulations and other requirements.

The development, manufacturing, distribution, pricing, sale, marketing and reimbursement of our product candidates, together with our general operations, are subject to extensive federal and state regulation in the United States and may be subject to extensive regulation in foreign countries. In addition, our business is complex, involves significant operational risks and includes the use of third parties to conduct business. While we intend to implement numerous risk mitigation measures to comply with such regulations in this complex operating environment, we cannot guarantee that we will be able to effectively mitigate all operational risks. We cannot guarantee that we, our employees, our consultants, our contractors or other third parties are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws, and all potentially applicable foreign regulations and/or laws. If we fail to adequately mitigate our operational risks or if we or our agents fail to comply with any of those regulations or laws, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Any of these occurrences could have a material and adverse effect on our business and results of operations.

Our employees and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee or consultant fraud or other misconduct. Misconduct by our employees or consultants could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. Employee and consultant misconduct could involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter such 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. 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 material adverse effect on our business, financial condition and results of operations, and result in the imposition of significant fines or other sanctions against us.

Our ability to obtain reimbursement or funding for our programs from the federal government may be impacted by possible reductions in federal spending.

U.S. federal government agencies currently face potentially significant spending reductions. For example, as a result of the Budge Control Act of 2011, the Bipartisan Budget Act ("BBA"), and the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), an annual 2% reduction to Medicare payments took effect on April 1, 2013, and has been extended into through the first six months of the fiscal year 2032 sequestration order (with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 and a subsequent reduction to 1% from April 1, 2022 until June 30, 2022). The U.S. federal budget remains in flux, which could, among other things, result in additional cuts to Medicare payments to providers and otherwise affect federal spending on clinical and preclinical research and development. The Medicare program is frequently mentioned as a target for spending cuts. The full impact on our business of any future cuts in Medicare or other programs is uncertain. In addition, we cannot predict any impact which the actions of President Biden's administration and the U.S. Congress may have on the federal budget. If federal spending is reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health, to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or

eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve drug research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Vaccines carry unique risks and uncertainties, which could have a negative impact on future results of operations.

We are planning to potentially develop vaccine candidates using our exosome technologies. The successful development, testing, manufacturing and commercialization of vaccines is a long, complex, expensive and uncertain process. There are unique risks and uncertainties associated with vaccines, including:

- There may be limited access to, and supply of, normal and diseased tissue samples, cell lines, media pathogens, bacteria, viral strains, synthesized nucleic acids, including mRNA and other biological materials. In addition, government regulations in multiple jurisdictions, such as the United States, Japan and the EU, could result in restricted access to, or the transport or use of, such materials. If the Company in unable to access sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, the Company may not be able to conduct research or product development activities as planned and may incur additional costs.
- The development, manufacturing and marketing of vaccines are subject to regulation by the FDA, the EMA, PMDA and other regulatory bodies that are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the United States, a BLA, including both preclinical and clinical trial data and extensive data regarding the manufacturing procedures, is required for human vaccine candidates, and FDA approval is generally required for the release of each manufactured commercial lot.
- Vaccines are frequently costly to manufacture because production ingredients are inactive biological materials derived from virus, animals, or plants and most biologics and vaccines cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines.

Risks Related to the Manufacturing of our Product Candidates

We have limited manufacturing capability and may not be able to maintain our manufacturing licenses.

In 2022, we completed construction of our new primary manufacturing facility located within our Research and Development Facility in San Diego, California as we prepare for potential commercial launch. This facility is designed to produce commercial-scale GMP CAP-1002 product for clinical and potential commercial use, subject to FDA approval.

Additionally, we also maintain a portion of our laboratories, research and manufacturing facilities in leased premises at CSMC in Los Angeles, California. Currently, in the area of our leased premises at CSMC where we manufacture CAP-1002 and may potentially manufacture our exosome technologies, we believe that we follow good manufacturing practices sufficient for an investigational stage product. Capricor has been manufacturing CAP-1002 in this facility for our current and previous studies including Cohort A of the HOPE-3 trial. We are using product manufactured from our San Diego facility to support Cohort B of the ongoing HOPE-3 trial and supporting our OLE trials. Furthermore, it is to be determined whether the FDA will ultimately approve commercial manufacturing at this facility. Our plans to use the CSMC facility for future trials could change if we fail to meet the specifications necessary to produce our product in a qualified manner. Currently, our CSMC Facilities Lease is scheduled to expire on July 31, 2026. There can be no assurance that the Facilities Lease for the manufacturing space will be continued beyond July 31, 2026 or whether the facility will be approved by the FDA for commercial manufacturing following approval of the BLA.

In the third quarter of 2023, we met with the FDA, where we affirmed alignment with respect to our Phase 3, HOPE-3 program where the FDA agreed to allow us to submit a BLA supported by results using product manufactured at our Los Angeles manufacturing site. At this time, we can provide no assurance that the FDA will ultimately approve this facility for commercial use, or that CMSC will allow us to market commercial product from this facility. Should this facility ultimately not be approved to manufacture commercial product, this may result in delays and significant expenses which would materially impact our business and product development.

In addition, FDA may consider the data we provide are insufficient to prove that the drug used in Cohort B of our HOPE-3 study is comparable to the drug produced in our Los Angeles facility and used in our prior clinical studies. This could result in us being required to conduct further comparability testing and may result in us being required to conduct

additional clinical and/or nonclinical studies before we are able to submit a BLA for approval. Additional testing or clinical trial requirements could lead us not to pursue an application for approval. Conducting a clinical trial may prove too difficult or too expensive, and the process of designing a clinical trial, enrolling enough patients, and completing treatment and data collection under the protocol could take a significant amount of time, effort, and resources. Even if we do complete the clinical trial, the study may not meet its prespecified endpoints, and even if it does, the FDA may still disagree with our determination that the trial is sufficient to support the submission and approval of a BLA application.

We obtain the donor hearts from which our CDCs are manufactured from organ procurement organizations ("OPOs"). There is no guarantee that the OPOs which currently provide donor hearts to us will be able to continue to supply us with donor hearts in the future or, in that case, that an alternative OPO will be available to us. If those OPOs or an alternative OPO is not able or willing to supply us with donor hearts, we would be unable to produce our CDCs or CDC-exosomes and the development of our lead product candidate would be significantly impaired and possibly terminated. Additionally, OPOs are subject to regulations of various government agencies. There is no guarantee that laws and regulations pursuant to which our OPOs provide donor hearts will not change, making it more difficult or even impossible for the OPOs to continue to supply us with the hearts we need to produce our product candidates.

We are required to obtain and maintain certain licenses in connection with our manufacturing facilities and activities. For example, we have recently entered into Azzur License Agreement with Azzur Cleanrooms-on-Demand – San Diego, LLC pursuant to which we have been granted an exclusive license to use certain space and the non-exclusive right to use certain equipment and property for our early phase clinical and/or pre-clinical manufacturing purposes. We are planning to use this facility to manufacture our exosome-based vaccine for potential clinical use. There is no guarantee that any licenses issued to us will not expire, be revoked, forfeited by operation of law or otherwise. If we were denied any required license or if any of our licenses were to be revoked or forfeited, we would suffer significant harm. Additionally, if a serious adverse event in any of our clinical trials were to occur during the period in which any required license was not in place, we could be exposed to additional liability if it were determined that the event was due to our fault and we had not secured the required license. Other states may impose additional licensing requirements upon us which, until obtained, would limit our ability to conduct our trials in such states.

The process of manufacturing our products is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-up of our manufacturing capabilities.

We are currently producing doses of CAP-1002 in order to conduct our ongoing clinical trials at both of our facilities. The process of manufacturing our products is complex, highly regulated and subject to multiple risks. The complex processes associated with the manufacture of our product candidates expose us to various manufacturing challenges and risks, which may include delays in manufacturing adequate supply of our product candidates, limits on our ability to increase manufacturing capacity, and the potential for product failure and product variation that may interfere with preclinical and clinical trials, along with additional costs. We also may make changes to our manufacturing process at various points during development, and even after commercialization, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of current or future clinical trials, or the performance of the product, once commercialized. In some circumstances, changes in the manufacturing process may require us to perform ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical trials or at earlier portions of a trial to the product used in later clinical trials or later portions of the trial. We may also make further changes to our manufacturing process before or after commercialization, and such changes may require us to show the comparability of the resulting product to the product used in the clinical trials using earlier processes. We may be required to collect additional clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If clinical data are not ultimately comparable to that seen in the earlier trials in terms of safety or efficacy, we may be required to make further changes to our process and/or undertake additional clinical and/or nonclinical testing, which could significantly delay the clinical development or commercialization of the associated product candidate.

Although we continue to build on our experience in manufacturing our product candidates, we have no experience, as a company, manufacturing product candidates for commercial supply. We may never be successful in manufacturing product candidates in sufficient quantities or with sufficient quality for commercial use. Our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, operator error,

natural disasters, unavailability of qualified personnel, difficulties with logistics and shipping, problems regarding yields or stability of product, contamination or other quality control issues, power failures, and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

Furthermore, compliance with cGMP requirements and other quality issues may arise during our internal efforts to scale-up manufacturing, and with our current suppliers, or any future CMOs. If contaminants are discovered in our supply of our product candidates or in our manufacturing facilities or those of our CMOs, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, we may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If we were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

We are subject to a number of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.

The process of manufacturing our product candidates is complex, highly regulated, and subject to several risks. For example, the process of manufacturing our product candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes for any of our product candidates could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. In addition, the manufacturing facilities in which our product candidates are made could be adversely affected by supply chain issues, equipment failures, labor shortages, natural disasters, power failures and numerous other factors.

We may need to rely exclusively on third parties to formulate and manufacture our product candidates and provide us with the devices and other products necessary to administer such a product.

Our resources and expertise to formulate or manufacture our product candidates on a large or commercial scale basis are still very limited. If we need to secure an additional manufacturer of our product candidates, demand for third-party manufacturing or testing facilities may grow at a faster rate than their existing capacity, which could disrupt our ability to find and retain third-party manufacturers capable of producing sufficient quantities of such raw materials, components, parts, and consumables required to manufacture our products. If CAP-1002 or any of our exosome technologies receives FDA approval, we may need to ultimately rely on one or more third-party contractors to manufacture supplies of these products which may cause delays in our ability to sell commercially. Our current and anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers needed to manufacture our product candidates on acceptable terms or at all because the number of potential manufacturers is limited, and subsequent to approval of an NDA or BLA, the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer may have to be educated in, or develop substantially equivalent processes for, production of our products or the devices after receipt of FDA approval, if any.
- Our third-party manufacturers may not be able to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any.
- Our third-party manufacturers may not be able to manufacture or supply us with sufficient quantities of acceptable materials necessary for the development or use of our product candidates.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products or the materials needed to manufacture or utilize our product candidates.
- Our contract manufacturers may elect to terminate our agreements with them.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, and corresponding state agencies to ensure strict compliance with good manufacturing practices and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA, or the commercialization of our product candidates, or result in higher costs or deprive us of potential product revenues.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Our product candidates, if approved, will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, such as cGMPs, a regulatory agency may:

- issue warning letters or untitled letters;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for non-compliance;
- impose other civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

The third parties we use in the manufacturing process for our product candidates may fail to comply with cGMP regulations.

If we decide to transfer the manufacturing of our product candidates for future clinical trials or for commercial supply, our contract manufacturers will be required to produce our products in compliance with cGMP. These contract manufacturers are subject to periodic unannounced inspections by the FDA and corresponding state and foreign authorities to ensure strict compliance with cGMP and other applicable government regulations and corresponding foreign requirements. We do not have control over a third-party manufacturer's compliance with these regulations and requirements. In addition, changes in cGMP could negatively impact the ability of our contract manufacturers to complete the manufacturing process of our product candidates in a compliant manner on the schedule we require for clinical trials or for potential commercial use. The failure to achieve and maintain high quality compliance, including failure to detect or control anticipated or unanticipated manufacturing errors, could result in patient injury or death or product recalls. Any difficulties or delays in our contractors' manufacturing and supply of product candidates, or any failure of our contractors to maintain compliance with the applicable regulations and requirements could increase our costs, make us postpone or cancel clinical trials, prevent or delay regulatory approvals by the FDA and corresponding state and foreign authorities, prevent the import and/or export of our products, cause us to lose revenue, result in the termination of the development of a product candidate, or have our product candidates recalled or withdrawn from use.

Risks Related to Our Intellectual Property

We may face uncertainty and difficulty in obtaining and enforcing our patents and other proprietary rights.

Our success will depend in large part on our ability to obtain, maintain, and defend patents on our product candidates, obtain licenses to use third-party technologies, protect our trade secrets and operate without infringing the valid and enforceable proprietary rights of others. Legal standards regarding the scope of claims and validity of biotechnology patents are uncertain and evolving. There can be no assurance that our pending, in-licensed or Company-owned patent applications will be approved, or that challenges will not be instituted against the validity or enforceability of any patent licensed-in or owned by us. Additionally, we have entered into various confidentiality agreements with employees and third parties. There is no assurance that such agreements will be honored by such parties or enforced in whole or part by the courts. The cost of litigation to uphold the validity and enforce against infringement of a patent is substantial. Furthermore, there can be no assurance that others will not independently develop substantially equivalent technologies not covered by patents to which we have rights or obtain access to our know-how. In addition, the laws of

certain countries may not adequately protect our intellectual property. Our competitors may possess or obtain patents on products or processes that are necessary or useful to the development, use, or manufacture of our product candidates.

There can also be no assurance that our proposed technology will not infringe upon valid and enforceable patents or proprietary rights owned by others, with the result that others may bring infringement claims against us and require us to license such proprietary rights, which may not be available on commercially reasonable terms, if at all. Any such litigation, if instituted, could have a material adverse effect, potentially including monetary penalties, diversion of management resources, and injunction against continued manufacture, use, or sale of certain products or processes.

Some of our technology has resulted and/or will result from research funded by agencies of the U.S. government and the State of California. As a result of such funding, the U.S. government and the State of California have certain rights in the technology developed with the funding. These rights may include a non-exclusive, non-transferable, irrevocable, paid-up, worldwide license to practice or have practiced for or on behalf of the government(s) such inventions. In addition, the government(s) has the right to "march in" and require us to grant third parties licenses to such technology, in certain circumstances, such as if we fail to take effective steps to achieve practical application of such inventions.

The licenses by which we have obtained some of our intellectual property are subject to the rights of the funding agencies. We also rely upon non-patented proprietary know-how and trade secrets. There can be no assurance that we can adequately protect our rights in such non-patented proprietary know-how and trade secrets, or that others will not independently develop substantially equivalent proprietary information or techniques or gain access to our proprietary know-how and trade secrets. Any of the foregoing events could have a material adverse effect on us. In addition, if any of our trade secrets, know-how or other proprietary information were to be disclosed, or misappropriated, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

In September 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the U.S. Patent and Trademark Office ("USPTO"), and may become involved in derivation, post-grant review, or *inter partes* review, proceedings challenging our patent rights or the patent rights of our licensors. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our or our licensors' patent rights, which could adversely affect our competitive position.

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If we fail to protect or enforce our intellectual property rights adequately or secure rights to patents of others, the value of our intellectual property rights and product candidates would diminish.

Our commercial viability will depend, in part, on obtaining and maintaining patent protection and trade secret protection of our product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell, or importing our products is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

We have licensed certain patent and other intellectual property rights that cover cardiospheres (CSps), and cardiosphere-derived cells (CDCs), (including our CAP-1002 product candidate) from the University of Rome, JHU, and CSMC. We have also licensed certain patent and other intellectual property rights from CSMC that cover extracellular vesicles, such as exosomes and microvesicles. Under the license agreements with the University of Rome and JHU, those institutions prosecute and maintain their patents and patent applications in collaboration with us. We rely on these institutions to file, prosecute, and maintain patent applications, and otherwise protect the intellectual property to which we have a license, and we have not had and do not have primary control over these activities for certain of these patents or patent applications and other intellectual property rights. We cannot be certain that such activities by these institutions have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Under our Amended and Restated Exclusive License Agreement with CSMC and our Exclusive License Agreement with CSMC, as the same have been amended, we have assumed, in coordination with CSMC, financial responsibility for the prosecution and maintenance of certain patents and patent applications

thereunder. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity and/or unenforceability of these patents would also be subject to the cooperation of the University of Rome, JHU, and/or CSMC.

The patent positions of pharmaceutical and biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent laws regarding the breadth of claims allowed in biopharmaceutical patents has emerged to date in the United States. The biopharmaceutical patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or that are in-licensed. Further, if any of our owned or in-licensed patents are determined by legal authority to be invalid or unenforceable, it could impact our ability to commercialize or license our technology.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of any of our patents;
- we might not have been the first to make the inventions covered by any issued patents or patent applications we may have (or third parties from whom we license intellectual property may have);
- we might not have been the first to file patent applications for these inventions;
- it is possible that any pending patent applications we may have will not result in issued patents;
- any issued patents may not provide us with any competitive advantage, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary technologies that are patentable or protectable under trade secrets law; and
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators, and other advisors may unintentionally or willfully disclose our information to competitors. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how.

If any of our trade secrets, know-how or other proprietary information is improperly disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

Our viability also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors, as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, we require all of our employees, consultants, advisors and contractors to enter into agreements which prohibit unauthorized disclosure and use of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements are often limited in duration and may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. In addition, enforcing a claim that a third-party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. If any of our trade secrets, know-how or other proprietary information is improperly disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

We may incur substantial costs as a result of litigation or other adversarial proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

If we choose to go to court to stop a third-party from using the inventions covered by our patents, that individual or company has the right to ask the court to rule that such patents are invalid and/or should not be enforced against that third-party. These lawsuits are expensive and would consume time and other resources, even if we were successful in

discontinuing the infringement of our patents. In addition, there is a risk that the court will determine that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to these patents. In addition, the U.S. Supreme Court has modified certain legal tests so as to make it harder to obtain patents from the USPTO, and to defend issued patents against invalidity challenges. As a consequence, issued patents may be found to contain invalid claims according to the revised legal standards. Some of our own or in-licensed patents may be subject to challenge and subsequent invalidation in a variety of post-grant proceedings, before the Patent Trial and Appeal Board (the PTAB) of the USPTO or in litigation under the revised legal standards, which make it more difficult to defend the validity of claims in already issued patents.

Furthermore, a third-party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third-party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect the results of our operations and divert the attention of managerial and technical personnel. There is a risk that a court could determine that we or our commercialization partners are infringing the third-party's patents and order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court could order us or our partners to pay the other party damages for having violated the other party's patents. We have agreed to indemnify certain of our commercial partners against certain patent infringement claims brought by third parties. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products, manufacturing processes or methods of use. The coverage of patents is subject to claim construction by the courts, which is not always predictable or reasonable. If we are sued for patent infringement, we would need to demonstrate that our products, manufacturing processes or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a proof by clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

As some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent applications may have priority over our patent applications or patents, which could further require us to obtain licenses to these issued patents covering such technologies. For patent applications filed before the Leahy-Smith Act, if another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation or *inter partes* review proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Some jurisdictions in which we operate have enacted legislation which allows members of the public to access information under statutes similar to the U.S. Freedom of Information Act. Even though we believe our information would be excluded from the scope of such statutes, there are no assurances that we can protect our confidential information from being disclosed under the provisions of such laws. If any confidential or proprietary information is released to the public, such disclosures may negatively impact our ability to protect our intellectual property rights.

We may be subject to claims that we or our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used, misappropriated or disclosed confidential information of these third parties or our employees' former employers. Litigation

may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, trade secrets, know-how and proprietary technology, both our own and that licensed from others. We have several license agreements, including with the University of Rome, JHU and CSMC. These licenses may be terminated upon certain conditions, including in some cases, if we fail to meet certain minimum funding or spending requirements, fail to take certain developmental actions, fail to pay certain minimum royalties, or fail to maintain the licensed intellectual property. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including: the scope of rights granted under the license agreement and other contract interpretation-related issues; whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; our right to sublicense patent and other rights to third parties under collaborative development relationships; our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

Risks Related to Our Relationships with Third Parties

We will depend on our exclusive distributor, Nippon Shinyaku, for the commercial sale of our lead product CAP-1002 in DMD in the United States and Japan, if we receive regulatory approval in those territories.

We believe that a substantial portion of our revenue for the foreseeable future will depend on milestones and other payments received from our distributor, Nippon Shinyaku. Nippon Shinyaku has exclusive distribution rights for CAP-1002 in the United States and Japan for a significant period of time, with only limited rights of either party to terminate these agreements.

We are dependent on our relationships with our licensors and collaborators and there is no guarantee that such relationships will be maintained or continued.

We have entered into certain license agreements for certain intellectual property rights which are essential to enable us to develop and commercialize our products. Agreements have been entered into with the University of Rome, JHU and CSMC. Each of those agreements provides for an exclusive license to certain patents and other intellectual property and requires the payment of fees, milestone payments and/or royalties to the institutions that will reduce our net revenues, if and to the extent that we have future revenues. Each of those agreements also contains additional obligations that we are required to satisfy. There is no guarantee that we will be able to satisfy all of our obligations under our license agreements to each of the institutions and that such license agreements will not be terminated. By way of example, we recently received a letter from CSMC alleging that pursuant to the Amended CSMC License Agreement between CSMC and Capricor, Capricor has certain overdue payment obligations to CSMC arising out of a milestone payment received by Capricor pursuant to the U.S. Distribution Agreement entered into between Capricor and Nippon Shinyaku. The notice letter requests that Capricor cure the alleged breaches of the Amended CSMC License Agreement, and reserves CMSC's purported right to terminate the Amended CSMC License Agreement if such alleged breaches are not cured. We dispute the allegations in the letter from CSMC and intend to vigorously defend our position and pursue all available remedies, but there is no guarantee that any disputes that we have with CSMC will be resolved or if resolved, will not result in our incurring certain payment and other obligations.

Each of the institutions receives funding from independent sources such as the NIH and other private or not-for-profit sources and are investigating scientific and clinical questions of interest to their own principal investigators as well as the scientific and clinical communities at large. These investigators (including Capricor, Inc.'s founder, Dr. Eduardo

Marbán, who is the Director of the Smidt Heart Institute at CSMC) are under no obligation to conduct, continue, or conclude either current or future studies utilizing our cell therapy or exosomes technology, and they are not compelled to license any further technologies or intellectual property rights to us except as may be stated in the applicable licensing agreements or research agreements between those institutions and us. Further, the failure of any third-party licensor to comply with its licensing obligations under its respective agreement with us would have a material adverse effect on us. We are substantially dependent on our relationships with these institutions from which we license the rights to our technologies and know-how. If requirements under our license agreements are not met, including meeting defined milestones, we could suffer significant harm, including losing rights to our product candidates.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to the proprietary technology.

Finally, we may be required to obtain licenses to patents or other proprietary rights of third parties (including and other than the University of Rome, JHU and CSMC) in connection with the development and use of our product candidates and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

We have received government grants and a loan award which impose certain conditions on our operations.

Commencing in 2009, we received several grants from the NIH and DoD to fund various projects. Some of these awards remain subject to annual and quarterly reporting requirements and require us to allocate expenses to the applicable project.

On June 16, 2016, Capricor entered into the CIRM Award with CIRM in the amount of approximately $3.4 million to fund, in part, the HOPE-Duchenne trial. Pursuant to terms of the CIRM Award, disbursements were tied to the achievement of specified operational milestones. The CIRM Award is further subject to the conditions and requirements set forth in the CIRM Grants Administration Policy for Clinical Stage Projects. Such requirements include, without limitation, the filing of quarterly and annual reports with CIRM, the sharing of intellectual property pursuant to Title 17, California Code of Regulations (CCR) Sections 100600-100612, and the sharing with the State of California of a fraction of licensing revenue received from a CIRM funded research project and net commercial revenue from a commercialized product which resulted from the CIRM funded research as set forth in Title 17, CCR Section 100608. The maximum royalty on net commercial revenue that Capricor may be required to pay to CIRM is equal to nine times the total amount awarded and paid to Capricor.

If we enter into strategic partnerships, we may be required to relinquish important rights to and control over the development of our product candidates or otherwise be subject to terms unfavorable to us.

We are actively looking into potential additional strategic partnerships for our product candidates, particularly for CAP-1002 in additional territories outside the United States and Japan and our exosomes product candidates. If we do not establish strategic partnerships, we potentially will have to undertake development and commercialization efforts with respect to our product candidates on our own, which would be costly and adversely impact our ability to commercialize any future products or product candidates. If we enter into any strategic partnerships with pharmaceutical, biotechnology or other life science companies, we will be subject to a number of risks, including:

- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of product candidates;
- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic partners may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- strategic partners may not commit adequate resources to the marketing and distribution of any future products, limiting our potential revenues from these products;
- disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;

- strategic partners may experience financial difficulties;
- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic partner's business strategy may also adversely affect a strategic partner's willingness or ability to complete its obligations under any arrangement; and
- strategic partners could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

We rely and will rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We depend and will depend upon independent investigators and collaborators, such as universities, medical institutions, CROs, vendors and strategic partners to conduct our preclinical and clinical trials under agreements with us. We negotiate budgets and contracts with CROs, vendors and trial sites which may result in delays to our development timelines and increased costs. We rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices ("cGCPs"), which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. Further, GCP requirements may evolve. In June 2023, the FDA published a draft guidance, E6(R3) Good Clinical Practice (GCP), which seeks to unify standards for clinical trial data for ICH member countries and regions. Changes to data requirements may cause the FDA or comparable foreign regulatory authorities to disagree with data from preclinical studies or clinical trials, and may require further studies.

Biologic products for commercial purposes must also be produced under cGMP. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws and regulations.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, which in some instances may be limited, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third-party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

Risks Related to Competitive Factors

Our products will likely face intense competition.

The Company is engaged in fields that are characterized by extensive worldwide research and competition by pharmaceutical companies, medical device companies, specialized biotechnology companies, hospitals, physicians and academic institutions, both in the United States and abroad. We will experience intense competition with respect to our existing and future product candidates. The pharmaceutical industry is highly competitive, with a number of established, large pharmaceutical companies, as well as many smaller companies. Many of these organizations competing with us have substantially greater financial resources, larger research and development staffs and facilities, greater clinical trial experience, longer drug development history in obtaining regulatory approvals, and greater manufacturing, distribution, sales and marketing capabilities than we do. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies, and research organizations actively engaged in research and development of products which may target the same indications as our product candidates. We expect any future products and product candidates that we develop to compete on the basis of, among other things, product efficacy and safety, time to market, price, extent of adverse side effects, and convenience of treatment procedures. One or more of our competitors may develop products based upon the principles underlying our proprietary technologies earlier than we do, obtain approvals for such products from the FDA more rapidly than we do, or develop alternative products or therapies that are safer, more effective and/or more cost effective than any product developed by us. Our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, useful, and less costly than ours, and may also be more successful than us in manufacturing and marketing their products.

Our future success will depend in part on our ability to maintain a competitive position with respect to evolving therapies as well as other novel technologies. Existing or future therapies developed by others may render our potential products obsolete or noncompetitive. The drugs that we are attempting to develop will have to compete with existing therapies. In addition, companies pursuing different but related fields represent substantial competition. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures, or other collaborations.

If we are unable to retain and recruit qualified scientists and advisors, or if any of our key executives, key employees or key consultants discontinues his or her employment or consulting relationship with us, it may delay our development efforts or otherwise harm our business. In addition, several of our consultants render services on a part-time basis to other entities which may result in the creation of intellectual property rights in favor of those entities.

Because of the specialized nature of our technology, we are dependent upon existing key personnel and on our ability to attract and retain qualified executive officers and scientific personnel for research, clinical studies, and development activities conducted or sponsored by us. There is intense competition for qualified personnel in our fields of research and development, and there can be no assurance that we will be able to continue to attract additional qualified personnel necessary for the development and commercialization of our product candidates or retain our current personnel.

We have experienced employee turnover from time to time, including involving some of our key employees. The loss of any of our current key employees or key consultants could impede the achievement of our research and development objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future is critical to the Company's success, both to enable the Company to grow, and to allow the Company to replace any employees or consultants whose relationships with the Company have been terminated. The market for employees with experience in the cell therapy and exosome industries is especially competitive, and we may not be able to recruit employees needed to develop and manufacture our products or be able to retain the employees whom we do recruit.

There has been a close working relationship between the academic lab at CSMC and our research and development team where employees and consultants of both entities from time to time have contributed time and services to the research being performed by the other. As a result, it can sometimes be unclear whether intellectual property developed out of these services for CSMC would be owned by CSMC or by the Company, although if owned by CSMC, the Company may have rights to that intellectual property under the terms of its license agreements with CSMC.

The Company may be unable to attract and retain personnel on acceptable terms given the competition among biotechnology, biopharmaceutical, and health care companies, universities, and non-profit research institutions for experienced scientists. Certain of the Company's officers, directors, scientific advisors, and/or consultants or certain of the officers, directors, scientific advisors, and/or consultants hereafter appointed may from time to time serve as officers, directors, scientific advisors, and/or consultants of other biopharmaceutical or biotechnology companies. The Company currently does not maintain "key man" insurance policies on any of its officers or employees. All of the Company's employees will be employed "at will" and, therefore, each employee may leave the employment of the Company at any time. If we are unable to retain our existing employees, including qualified scientific and manufacturing personnel, and attract additional qualified candidates, the Company's business and results of operations could be adversely affected.

If we do not establish strategic partnerships, we will have to undertake development and commercialization efforts on our own, which would be costly and delay our ability to commercialize any future products or product candidates.

An element of our business strategy includes potentially partnering with pharmaceutical, biotechnology and other companies to obtain assistance for the development and potential commercialization of our product candidates, including having access to the cash and other resources we need for such development and potential commercialization. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. If we are unable to negotiate strategic partnerships for our product candidates, we may be forced to curtail the development of a particular candidate, reduce, delay, or terminate its development program, delay its potential commercialization, reduce the scope of our sales or marketing activities or undertake development or commercialization activities at our own expense. In addition, we will bear all risk related to the development of that product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to obtain substantial additional capital, which may not be available to us on acceptable terms, or at all. If we do not secure sufficient funds, we will not be able to complete our trials or bring our product candidates to market and generate product revenue. We have entered into the U.S. Distribution Agreement and the Japan Distribution Agreement with Nippon Shinyaku for the exclusive commercialization and distribution rights in the United States and Japan of CAP-1002 for DMD. We continue to evaluate additional potential partners for this program in other territories outside of these territories, subject to any rights of Nippon Shinyaku.

We have no experience selling, marketing, or distributing products and no current internal capability to do so.

The Company currently has no sales, marketing, or distribution capabilities. We do not anticipate having resources in the foreseeable future to allocate to the sales and marketing of our proposed products. Our future success depends, in part, on our ability to enter into and maintain sales and marketing collaborative relationships, or on our ability to build sales and marketing capabilities internally. As we entered into the U.S. Distribution Agreement and the Japan Distribution Agreement with Nippon Shinyaku, we will depend upon Nippon Shinyaku's strategic interest in our CAP-1002 product candidate and Nippon Shinyaku's ability to successfully market and sell any such products, if and when approved. If any of our other product candidates are cleared for commercialization, we intend to pursue collaborative arrangements regarding the sales and marketing of such products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that such collaborators will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources, and time will be required to establish and develop an in-house marketing and sales force with sufficient technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, such as our partnership with Nippon Shinyaku, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If any of our product candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenues that we generate from their sales, if any, will be limited.

The commercial viability of our product candidates for which we may obtain marketing approval from the FDA or other regulatory authorities will depend upon their acceptance among physicians, the medical community, patients, and coverage and reimbursement of them by third-party payors, including government payors. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

- limitations or warnings contained in a product's FDA-approved labeling;

- changes in the standard of care for the targeted indications for any of our product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval;
- limitations inherent in the approved indication for any of our product candidates compared to more commonly understood or addressed conditions;
- lower demonstrated clinical safety and efficacy compared to other products;
- prevalence and severity of adverse effects;
- ineffective marketing and distribution efforts;
- lack of availability of reimbursement from managed care plans and other third-party payors;
- lack of cost-effectiveness;
- timing of market introduction and perceived effectiveness of competitive products;
- availability of alternative therapies at similar costs; and
- potential product liability claims.

Our ability to effectively promote and sell our product candidates in the marketplace will also depend on pricing, including our ability to manufacture a product at a competitive price. We will also need to demonstrate acceptable evidence of safety and efficacy and may need to demonstrate relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. If our approved drugs fail to achieve market acceptance, we will not be able to generate significant revenue, if any.

Our development of a potential vaccine for COVID-19 or other indications is at an early stage and is subject to significant risks.

Our development of a vaccine is in early stages and we may be unable to produce a vaccine that successfully treats a particular virus in a timely manner, if at all. Even if we were able to successfully develop and obtain regulatory approval for a vaccine, if the outbreak is effectively contained or the risk of coronavirus infection is diminished or eliminated before we can successfully develop and manufacture our vaccine, we may not be able to generate product revenues from the vaccine. Additionally, a number of pharmaceutical companies have already obtained regulatory approval for COVID-19 vaccines, and other companies with significantly more resources and visibility than us are developing COVID-19 vaccines. Even if we were able to successfully develop and obtain regulatory approval for a COVID-19 vaccine, vaccines produced by these other companies may be superior to our vaccine. Even if a vaccine that we develop is not inferior to other available vaccines, it could be difficult to obtain market acceptance. We are committing financial resources and personnel to the development of a COVID-19 vaccine which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties surrounding the longevity and extent of coronavirus as a global health concern. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our vaccine, if developed, may not be partially or fully effective, or for which better vaccine options may be available.

Even if our product candidates are approved, our ability to generate product revenues will be diminished if our products sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our or our collaborators' ability to generate significant sales of our products, if approved, depends on the availability of adequate coverage and reimbursement from third-party payors. Healthcare providers that purchase medicine or medical products for treatment of their patients generally rely on third-party payors to reimburse all or part of the costs and fees associated with the products. Adequate coverage and reimbursement from governmental payors, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of our products. Orphan drugs in particular have received negative publicity for the perceived high prices charged for them by their manufacturers, and as a result, other orphan drug developers such as us may be negatively impacted by such publicity and any U.S. or other government regulatory response.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Many third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes to decide which drugs they

will pay for and establish reimbursement levels. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If any of our product candidates fail to demonstrate attractive efficacy profiles, they may not qualify for coverage and reimbursement. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop through approval will be made on a plan-by-plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and adequate reimbursement for the product. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will likely be a time-consuming process. Each plan determines whether or not it will provide coverage for a drug, what amount it will pay for the drug, the applicable formulary tier, and whether to require step therapy or other utilization management controls. Such decisions can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and treating healthcare providers generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients may be unlikely to use and prescribers unlikely to prescribe our products unless adequate coverage is provided and reimbursement is available.

Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors, such as government or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, drug products. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We may also be required to conduct expensive pharmacoeconomic studies to justify the coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage or reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any product candidates that we develop.

Further, there have been a number of legislative and regulatory proposals to change the healthcare system that could affect our ability to sell any future drugs profitably. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution by generic products. We anticipate additional state and federal healthcare reform measures will be adopted in the future. These may include price controls and cost-containment measures, or more restrictive policies in jurisdictions with existing controls and measures, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and potentially could reduce demand for our products once approved, create additional pricing pressures, or ultimately limit our net revenue and results. There can be no assurance that any of our product candidates, if approved, will be considered medically reasonable and necessary, that they will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available, or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not harm our ability to sell our product candidates profitably, if they are approved for sale.

Risks Related to Product and Environmental Liability

Our products may expose us to potential product liability, and there is no guarantee that we will be able to obtain and maintain adequate insurance to cover these liabilities.

The testing, marketing, and sale of human cell therapeutics, pharmaceuticals, biologics, and services entail an inherent risk of adverse effects or medical complications to patients and, as a result, product liability claims may be asserted against us. A future product liability claim or product recall could have a material adverse effect on the Company. There can be no assurance that product liability insurance will be available to us in the future on acceptable terms, if at all, or that coverage will be adequate to protect us against product liability claims. In the event of a successful claim against the Company, insufficient or lack of insurance or indemnification rights could result in liability to us, which could have a material adverse effect on the Company and its future viability. The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval, if at all, expose the Company to the risk of product liability claims. Product liability claims might be brought against the Company by consumers, health care providers or others using,

administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- decreased demand for our product candidates;
- impairment of our business reputation;
- loss of revenues; and
- the inability to commercialize our product candidates.

The Company has obtained clinical trial insurance coverage for its clinical trials. However, such insurance coverage may not reimburse the Company or the levels of coverage may not be sufficient to reimburse it for expenses or losses it may suffer or for its indemnification obligations. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect the Company against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against the Company could have a material adverse effect on us and, if judgments exceed our insurance coverage, could significantly decrease our cash position and adversely affect our business.

In addition, our clinical trial agreements and most agreements with third-party vendors contain provisions requiring us to maintain certain levels of insurance extending for multiple years beyond the termination or expiration of the agreement as well as indemnification obligations requiring us to indemnify them from any losses and claims that may be brought in connection with their provision of services, testing, manufacture or other activities in connection with the use of our products.

Our business involves risk associated with handling hazardous and other dangerous materials.

Our research and development activities involve the controlled use of hazardous materials, chemicals, human blood and tissue, animal blood and blood products, animal tissue, biological waste, and various radioactive compounds. The risk of accidental contamination or injury from these materials cannot be completely eliminated. The failure to comply with current or future regulations could result in the imposition of substantial fines against the Company, suspension of production, alteration of our manufacturing processes, or cessation of operations.

Our business depends on compliance with ever-changing environmental and human health and safety laws.

We cannot accurately predict the outcome or timing of future expenditures that may be required to comply with comprehensive federal, state and local environmental laws and regulations, as well as laws and regulations designed to protect employees and others who handle hazardous materials. We must comply with environmental laws that govern, among other things, all emissions, waste water discharge and solid and hazardous waste disposal, and the remediation of contamination associated with generation, handling and disposal activities. To date, the Company has not incurred significant costs and is not aware of any significant liabilities associated with its compliance with federal, state and local environmental laws and regulations. However, both federal and state environmental laws have changed in recent years and the Company may become subject to stricter environmental standards in the future and may face large capital expenditures to comply with environmental laws. We have limited capital and we are uncertain whether we will be able to pay for significantly large capital expenditures that may be required to comply with new laws. Also, future developments, administrative actions or liabilities relating to environmental matters may have a material adverse effect on our financial condition or results of operations.

Risks Related to Our Common Stock

We expect that our stock price will continue to fluctuate significantly.

The stock market, particularly in recent years, has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. Our operating results may fluctuate from period to period for a number of reasons, and as a result our stock price may be subject to significant fluctuations. Factors that could cause volatility in the market price of our common stock include, but are not limited to:

- our financial condition, including our need for additional capital, as well as the impact of any terms imposed on our business and operations by the providers of additional capital;
- results from, delays in, or discontinuation of, any of the clinical trials for our drug candidates, including delays resulting from slower than expected or suspended patient enrollment or discontinuations resulting from a failure to meet pre-defined clinical endpoints;
- announcements concerning clinical trials and regulatory developments;
- failure or delays in entering drug candidates into clinical trials;
- failure or discontinuation of any of our research or development programs;
- developments in establishing and maintaining new strategic alliances or with existing alliances or collaborators;
- failure to meet milestone requirements under distribution agreements, including the U.S. Distribution Agreement and Japan Distribution Agreement with Nippon Shinyaku;
- failure to satisfy licensing obligations, including our ability to meet milestone requirements under our license agreements;
- market conditions in the pharmaceutical, biotechnology and other healthcare related sectors;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- issues in manufacturing our drug candidates or drugs;
- issues with the supply or manufacturing of any devices or materials needed to manufacture or utilize our drug candidates;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- the risks and costs of increased operations, including clinical and manufacturing operations, on an international basis;
- market acceptance of our drugs when they enter the market;
- third-party healthcare coverage and reimbursement policies;
- litigation or public concern about the safety of our drug candidates or drugs or the operations of the Company;
- issuance of new or revised securities analysts' reports or recommendations;
- additions or departures of key personnel;
- potential delisting of our stock from the Nasdaq Stock Market; or
- volatility in the stock prices of other companies in our industry.

We have never paid dividends and we do not anticipate paying dividends in the future.

We have never paid dividends on our capital stock and do not anticipate paying any dividends for the foreseeable future. We anticipate that the Company will retain its earnings, if any, for future growth. Investors seeking cash dividends should not invest in the Company's common stock for that purpose.

We may issue shares of blank check preferred stock without stockholder approval in the future.

Our certificate of incorporation authorizes the issuance of up to 5,000,000 shares of preferred stock, none of which are currently issued or currently outstanding. If issued, our Board of Directors will have the authority to fix and determine the relative rights and preferences of preferred shares, as well as the authority to issue such shares, without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that is senior to our common stock that would grant to holders preferred rights to our assets upon liquidation, the right to receive dividends, additional registration rights, anti-dilution protection, and the right to the redemption of such shares, together with other rights, none of which will be afforded holders of our common stock.

Market and economic conditions may adversely affect our industry, business and ability to obtain financing.

Recent global market and economic conditions have been unpredictable and challenging. These conditions and any adverse impact on the financial markets may adversely affect our liquidity and financial condition, including our ability to access the capital markets to meet our liquidity needs.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. If no or few analysts maintain coverage of us, the trading price of our stock could decrease. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could also decline. If one or more of these analysts cease to cover our stock altogether, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

The operational and other projections and forecasts that we may make from time to time are subject to inherent risks, many of which are beyond our control.

The projections and forecasts that our management may provide from time to time (including, but not limited to, those relating to timing, progress and anticipated results of clinical development, regulatory processes, clinical trial timelines and any anticipated benefits of our product candidates) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections in (or incorporated by reference in) this prospectus should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such. Additionally, final data may differ significantly from preliminary reported data.

Our certificate of incorporation and by-laws contain provisions that may discourage, delay or prevent a change in our management team that stockholders may consider favorable.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that may have the effect of preserving our current management, such as:

- authorizing the issuance of "blank check" preferred stock without any need for action by stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

These provisions could make it more difficult for our stockholders to affect our corporate policies or make changes in our Board of Directors and for a third-party to acquire us, even if doing so would benefit our stockholders.

A significant number of shares of our common stock are issuable pursuant to outstanding stock awards and warrants, and we expect to issue additional stock awards and shares of common stock in the future. Exercise of these awards and warrants, and sales of shares will dilute the interests of existing security holders and may depress the price of our common stock.

As of December 31, 2023, there were approximately 31.1 million shares of common stock outstanding and approximately 5.0 million common warrants outstanding, as well as outstanding awards to purchase approximately 8.2 million shares of common stock under various incentive stock plans of the Company. Additionally, as of December 31, 2023, there were approximately 1.2 million shares of common stock available for future issuance under our incentive plans. This number of shares available for future issuance under those plans was subsequently increased by 1,557,416 shares in accordance with the terms of our 2021 equity incentive plan which include an automatic increase previously approved by our Board and stockholders. We may issue additional common stock, warrants and other convertible securities from time to time to finance our operations. We may also issue additional shares to fund potential acquisitions or in connection with additional stock options or other equity awards granted to our employees, officers, directors and consultants under our various incentive plans. The issuance of additional shares of common stock, warrants or other convertible securities and the perception that such issuances may occur or exercise of outstanding warrants or options may have a dilutive impact on other stockholders and could have a material negative effect on the market price of our common stock.

The Company's ability to utilize Nile's net operating loss and tax credit carryforwards in the future is subject to substantial limitations and may further be limited as a result of the merger with Capricor.

Federal and state income tax laws impose restrictions on the utilization of net operating loss ("NOL"), and tax credit carryforwards in the event that an "ownership change" occurs for tax purposes, as defined by Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"). In general, an ownership change occurs when stockholders owning 5% or more of a "loss corporation" (a corporation entitled to use NOL or other loss carryforwards) have increased their aggregate ownership of stock in such corporation by more than 50 percentage points during any three-year period. If an "ownership change" occurs, Section 382 of the Code imposes an annual limitation on the amount of post-ownership change taxable income that may be offset with pre-ownership change NOLs of the loss corporation experiencing the ownership change. The annual limitation is calculated by multiplying the loss corporation's value immediately before the ownership change by the greater of the long-term tax-exempt rate determined by the U.S. Internal Revenue Service ("IRS") in the month of the ownership change or the two preceding months. This annual limitation may be adjusted to reflect any unused annual limitation for prior years and certain recognized built-in gains and losses for the year. Section 383 of the Code also imposes a limitation on the amount of tax liability in any post-ownership change year that can be reduced by the loss corporation's pre-ownership change tax credit carryforwards.

The merger between Nile and Capricor resulted in an "ownership change" of Nile. In addition, previous or current changes in the Company's stock ownership may have triggered or, in the future, may trigger an "ownership change," some of which may be outside of our control. Accordingly, the Company's ability to utilize Nile's NOL and tax credit carryforwards may be substantially limited. These limitations could, in turn, result in increased future tax payments for the Company, which could have a material adverse effect on the business, financial condition, or results of operations of the Company.

The requirements of being a public company may strain our resources and divert management's attention.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and other applicable securities rules and regulations, and are subject to the listing requirements of The Nasdaq Stock Market LLC ("Nasdaq"). Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results and maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight is required. In addition, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results. Although we have hired employees in order to comply with these requirements, we may need to hire more employees in the future, which will increase our costs and expenses.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our business and stock price.

The Sarbanes-Oxley Act of 2002, as amended ("Sarbanes-Oxley"), as well as rules implemented by the SEC, Nasdaq and any market on which the Company's shares may be listed in the future, impose various requirements on public companies, including those related to corporate governance practices. The Company's management and other personnel will need to devote a substantial amount of time to these requirements. Moreover, these rules and regulations will increase the Company's legal and financial compliance costs and will make some activities more time consuming and costly.

Section 404 of Sarbanes-Oxley ("Section 404") requires that we establish and maintain an adequate internal control structure and procedures for financial reporting. Our annual reports on Form 10-K must contain an assessment by management of the effectiveness of our internal control over financial reporting and must include disclosure of any material weaknesses in internal control over financial reporting that we have identified. The requirements of Section 404 are ongoing and also apply to future years. We expect that our internal control over financial reporting will continue to evolve as our business develops. Although we are committed to continue to improve our internal control processes and we will continue to diligently and vigorously review our internal control over financial reporting in order to ensure compliance with Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. Therefore, we cannot be certain that in the future material weaknesses or significant deficiencies will not exist or otherwise be discovered. If material weaknesses or other

significant deficiencies occur, these weaknesses or deficiencies could result in misstatements of our results of operations, restatements of our consolidated financial statements, a decline in our stock price, or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share paid by any investor. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by any investor, and investors purchasing shares or other securities in the future could have rights superior to you. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by any investor.

If our business plans are not successful, our stockholders may lose their entire investment in us.

We have historically incurred substantial losses to fund our business operations including our research and development activities. We will, in all likelihood, sustain operating expenses without corresponding revenues for the foreseeable future. This may result in our incurring net operating losses that will increase continuously until we are able to obtain regulatory approval for, and commercialize, our product candidates, the occurrence of which cannot be assured. If our business plans are not successful, our stockholders may lose their entire investment in us.

We may be at risk of securities class action litigation or litigation initiated by individual stockholders.

We may subject to securities class action litigation or litigation initiated by individual stockholders. This risk is especially relevant due to our dependence on positive clinical trial outcomes and regulatory approvals. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. Additionally, we may be subject to litigation and business challenges in the operation of our company due to actions instituted by activist stockholders. Perceived uncertainties as to our future direction as a result of stockholder activism may lead to the perception of a change in the direction of the business or other instability and may affect our relationships with vendors, distributors, collaborators, prospective and current employees and others. Responding to legal and/or business challenges related to securities class action litigation, or litigation initiated by individual stockholders, including activist stockholders, could be costly and time-consuming, may not align with our business strategies, and could divert management's attention and resources from the pursuit of our business strategies, any of which could harm our business and result in a decline in the market price of our common stock.

In the event we fail to satisfy any of the listing requirements of The Nasdaq Capital Market, our common stock may be delisted, which could affect our market price and liquidity.

Our common stock is listed on The Nasdaq Capital Market. For continued listing on The Nasdaq Capital Market, we will be required to comply with the continued listing requirements, including the minimum market capitalization standard, the minimum stockholders' equity requirement, the corporate governance requirements and the minimum closing bid price requirement, maintaining board diversity among other requirements. In the event that we fail to satisfy any of the listing requirements of The Nasdaq Capital Market, our common stock may be delisted. If our securities are delisted from trading on The Nasdaq Stock Market, however, and we are not able to list our securities on another exchange or to have them quoted on The Nasdaq Stock Market, our securities could be quoted on the OTC Markets or on the "pink sheets." As a result, we could face significant adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock," which would require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3) or obtain additional financing in the future.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

We operate in the biotechnology sector, which is subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations, including intellectual property theft; fraud; extortion; harm to employees; violation of privacy laws and other litigation and legal risk; and reputational risk. We have implemented a risk-based approach to identify and assess the cybersecurity threats that could affect our business and information systems. We use various tools and methodologies to manage cybersecurity risk that are tested on a regular cadence to the best of our ability. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans and penetration tests.

Our business depends on the availability, reliability, and security of our information systems, networks, data, and intellectual property. Any disruption, compromise, or breach of our systems or data due to a cybersecurity threat or incident could adversely affect our operations, research, product development, and competitive position. They may also result in a breach of our contractual obligations or legal duties to protect the privacy and confidentiality of our stakeholders. Such a breach could expose us to business interruption, future lost revenue, ransom payments, remediation costs, liabilities to affected parties, cybersecurity protection costs, lost assets, litigation, regulatory scrutiny and actions, reputational harm, and harm to our vendor relationships.

The company is currently in the process of implementing a more formalized cybersecurity program.

ITEM 2. PROPERTIES

We do not own any real property. Our primary operations are conducted at the leased facilities summarized in the below table. We believe our facilities are adequate and suitable for our current needs and that we will be able to obtain new or additional leased space in the future, if necessary.

Location of Property	Lease Expiration Date [1]	Purpose	Square Footage (approximate)
10865 Road to the Cure, Suite 150, San Diego, California	September 30, 2026	Corporate Headquarters: Laboratory, manufacturing and office space	12,161
10865 Road to the Cure, Room 7, San Diego, California	October 31, 2024	Laboratory space	234
8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California	Month-to-Month, terminable on 90-day notice	Office space	1,627
8700 Beverly Blvd., Davis Building, Los Angeles, California	July 31, 2026	Laboratory, manufacturing and office space	1,892

[1] Certain leases have specific options for potential renewal or extensions.

ITEM 3. LEGAL PROCEEDINGS

We are not involved in any material pending legal proceedings and are not aware of any material threatened legal proceedings against us by any governmental authority. We draw your attention to the disclosure in Item 1A. above under "Risk Factors -- Risks Related to Our Relationships with Third Parties -- We are dependent on our relationships with our licensors and collaborators and there is no guarantee that such relationships will be maintained or continued."

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market for Common Stock

Our common stock is traded on the Nasdaq Capital Market under the symbol "CAPR".

Holders

According to the records of our transfer agent, Equiniti Trust Company LLC, as of March 7, 2024, we had 126 holders of record of common stock, which does not include holders who held in "street name" or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

Dividends

We have never declared or paid a dividend on our common stock and do not anticipate paying any cash dividends in the foreseeable future. The ability of our Board of Directors to declare a dividend is subject to limits imposed by Delaware corporate law.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this item is set forth in the section entitled "Securities Authorized for Issuance Under Equity Compensation Plans" in our Definitive Proxy Statement for our 2024 Annual Meeting of Stockholders, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023, and is incorporated herein by reference.

Performance Graph

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide a performance graph.

Recent Sales of Unregistered Securities and Use of Proceeds

Not applicable.

Issuer Purchases of Equity Securities

None.

ITEM 6. RESERVED

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

The following discussion of our financial condition and results of operations should be read in conjunction with the audited consolidated financial statements and the related audited consolidated notes to those statements included elsewhere in this Annual Report on Form 10-K. This discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those set forth under Item 1A., "Risk Factors" or elsewhere in this annual report, our actual results may differ materially from those anticipated in these forward-looking statements.

Company Overview

Capricor Therapeutics, Inc. is a clinical-stage biotechnology company focused on the development of transformative cell and exosome-based therapeutics for treating Duchenne muscular dystrophy ("DMD"), a rare form of muscular dystrophy which results in muscle degeneration and premature death, and other diseases with high unmet medical needs.

Since our inception, we have devoted substantial resources to developing CAP-1002 and our other product candidates including our exosomes platform, developing our manufacturing processes, staffing our company and providing general and administrative support for these operations. We do not have any products approved for sale. Our ability to eventually generate any product revenue sufficient to achieve profitability will depend on the successful development, approval and eventual commercialization of CAP-1002 for the treatment of DMD and our other product candidates. If successfully developed and approved, we intend to commercialize CAP-1002 in the United States and Japan with our partner, Nippon Shinyaku Co., Ltd., a Japanese corporation ("Nippon Shinyaku"), and may enter into licensing agreements or strategic collaborations in other markets. If we generate product sales or enter into licensing agreements or strategic collaborations, or further distribution relationships, we expect that any revenue we generate will fluctuate from quarter-to-quarter and year-to-year as a result of the timing and amount of any product sales, license fees, milestone payments and other payments. If we fail to complete the development of our product candidates in a timely manner, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

A summary description of our key product candidates, is as follows:

- **CAP-1002 for the treatment of DMD (Phase 3):** Our core program is focused on the development and commercialization of a cell therapy technology (referred herein as CAP-1002) comprised of CDCs, which are a population of stromal cells isolated from donated cells of healthy human hearts, for the treatment of DMD. CAP-1002 is designed to slow disease progression in DMD through the immunomodulatory, anti-inflammatory, and anti-fibrotic actions of CDCs, which are mediated by secreted exosomes laden with bioactive cargo. Among the cargo elements known to be bioactive in CDC exosomes are microRNAs. Collectively, these non-coding RNA species alter gene expression in macrophages and other target cells, dialing down generalized inflammation and stimulating tissue regeneration in DMD (and in a variety of other inflammatory diseases). This mechanism of action, consistent with the changes observed in clinical studies to date in circulating inflammatory biomarkers, contrasts with that of exon-skipping oligonucleotides and gene therapy approaches, which aim to restore dystrophin expression. DMD is a rare form of muscular dystrophy which results in muscle degeneration and premature death. DMD pathophysiology is driven by the impaired production of functional dystrophin which normally functions as a structural protein in muscle. The reduction of functional dystrophin in muscle cells leads to significant cell damage and ultimately causes muscle cell death and fibrotic replacement. The annual cost of care for patients with DMD is very high and increases with disease progression. We therefore believe that DMD represents a significant market opportunity for our product candidate, CAP-1002. Our CAP-1002 cell therapy program for the treatment of DMD is currently in Phase 3 clinical development in the United States, for which we expect to have top-line data available in the fourth quarter of 2024.

  To date, we have completed two promising clinical trials investigating CAP-1002 for DMD. Data from the first trial, a Phase I/II trial named HOPE-Duchenne, suggested improvements in skeletal and cardiac endpoints. In HOPE-2, a Phase II clinical trial conducted in the United States, CAP-1002 was used to treat patients with late-stage DMD. In March 2022, we announced that the final one-year results from HOPE-2 were published in *The Lancet* showing that the trial met its primary efficacy endpoint of the mid-level dimension of the Performance of the Upper Limb ("PUL") v1.2 ($p=0.01$) and additional positive endpoints

of full PUL v2.0 (p=0.04) and a cardiac endpoint of left ventricular ejection fraction (p=0.002). CAP-1002 was generally safe and well-tolerated throughout the studies.

Additionally, we are currently conducting an open label extension ("OLE") study of the HOPE-2 trial in which 12 patients have elected to continue treatment of CAP-1002. We announced positive one-year and two-year results from this ongoing OLE study. The HOPE-2-OLE study previously met its primary endpoint at the one-year timepoint on the PUL v2.0 scale (p=0.02). At the two-year timepoint, data showed statistically significant differences in the PUL v2.0 in the OLE treatment group when compared to the original rate of decline of the placebo group from HOPE-2 after one-year (p=0.021). CAP-1002 treatment during the OLE portion of the study continues to yield a consistent safety profile and has been well-tolerated throughout the study. At this time, we expect to have three-year data available from this OLE study in the second quarter of 2024.

Phase 3 (HOPE-3) Clinical Trial: HOPE-3 is a Phase 3, multi-center, randomized, double-blind, placebo-controlled clinical trial comprised of two cohorts evaluating the safety and efficacy of CAP-1002 in participants with DMD and impaired skeletal muscle function who are on a stable regimen of systemic glucocorticoids. Non-ambulatory and ambulatory boys who meet eligibility criteria are randomly assigned to receive either CAP-1002 or placebo every 3 months for 4 doses during the first 12-months of the study. Approximately 102 eligible study subjects will participate in this dual-cohort study. Enrollment has been completed for Cohort A where 61 subjects were randomized to either CAP-1002 or placebo in a 1:1 ratio and is intended to support a Biologics License Application ("BLA") submission. In December 2023, we announced a positive outcome of the interim futility analysis for Cohort A of HOPE-3, which was reviewed by the Data Safety Monitoring Board ("DSMB"). This resulted in a favorable recommendation to continue the HOPE-3 trial as planned. At this time, we expect to have topline data available from Cohort A in the fourth quarter of 2024. Cohort A uses product manufactured at our Los Angeles facility.

Enrollment is underway for Cohort B which is designed to enroll approximately 44 participants randomized to either CAP-1002 or placebo in a 1:1 ratio. A primary efficacy and safety analysis will be performed for each individual cohort at month 12, following 4 administrations of CAP-1002 or placebo. We plan to complete enrollment for Cohort B in the second quarter of 2024. Cohort B uses product manufactured at our San Diego facility.

The primary outcome measure of the HOPE-3 study will be the Performance of the Upper Limb ("PUL") v2.0, a validated tool specifically designed for assessing high (shoulder), mid (elbow) and distal (wrist and hand) functions, with a conceptual framework reflecting weakness progression in upper limb function. HOPE-3 will also measure various secondary endpoints including cardiac function assessments.

Under our RMAT designation, in the third quarter of 2023, we met with the FDA in a Type-B meeting where we discussed our manufacturing plans in anticipation of potentially submitting a BLA application. In this meeting, we affirmed alignment with respect to our Phase 3, HOPE-3 program. Additionally, we discussed our plans with respect to commercial manufacturing activities, including our potency assay and other product release criteria to support commercialization. We plan to meet with FDA in the first quarter of 2024 to continue discussing our pathway to BLA. In the upcoming Type-B meeting, we intend to discuss our further CMC plans for commercial launch, if approved, with the aim of expediting our BLA submission pathway. Our ultimate goal is to file a BLA allowing for the use of CAP-1002 commercial product manufactured at our San Diego facility.

The regulatory pathway for CAP-1002 is supported by RMAT designation as well as orphan drug designation. In addition, if Capricor were to receive FDA marketing approval for CAP-1002 for the treatment of DMD, Capricor would be eligible to receive a Priority Review Voucher ("PRV") based on its previous receipt of a rare pediatric disease designation. Capricor retains full rights to the PRV, if received. Further, Capricor has entered into two Commercialization and Distribution Agreements with Nippon Shinyaku appointing Nippon Shinyaku as its exclusive distributor of CAP-1002 in the United States and Japan.

- **Exosome-Based Platform (Preclinical):** Extracellular vesicles, including exosomes and microvesicles, are nano-scale, membrane-enclosed vesicles which are secreted by most cells and contain characteristic lipids, proteins and nucleic acids such as mRNA and microRNAs. They can signal through the binding and activation of membrane receptors or the delivery of their cargo into the cytosol of target cells. Exosomes act

as messengers to regulate the functions of neighboring or distant cells and have been shown to regulate functions such as cell survival, proliferation, inflammation and tissue regeneration. Their size, low or null immunogenicity and ability to communicate in native cellular language potentially make them an exciting new class of therapeutic agents with the potential to expand our ability to address complex biological responses. Because exosomes are cell-free substances, they can be stored, handled, reconstituted and administered in similar fashion to common biopharmaceutical products such as antibodies.

We are focused on developing a precision-engineered exosome platform technology that has the ability to deliver defined sets of effector molecules that exert their effects through defined mechanisms of action. Aspects of our exosome pipeline have been supported through collaborations and alliances. Our collaborations and research around exosomes include the National Institutes of Health ("NIH"), the National Institute of Allergy and Infectious Diseases ("NIAID"), Johns Hopkins University ("JHU"), the Department of Defense ("DoD"), the U.S. Army Institute of Surgical Research ("USAISR"), and Cedars-Sinai Medical Center ("CSMC"). We have published preclinical data on our StealthX™ platform showing the rapid development of a recombinant protein-based vaccine for immunization and prevention against SARS-CoV-2, the virus causing COVID-19. Our platform builds on advances in fundamental RNA and protein science, targeting technology and manufacturing, providing us the opportunity to potentially build a broad pipeline of new therapeutic candidates. Recently, we were selected to be part of Project NextGen, an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines providing broader and more durable protection for COVID-19. As part of Project NextGen, the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, will conduct a Phase 1 clinical study with our StealthX™ vaccine, subject to regulatory approval. At this time, we have submitted an Investigational New Drug Application ("IND") to the FDA for our StealthX™ vaccine, which is currently under review and we anticipate that once the IND is approved, that NIAID plans to initiate this trial in late 2024. Furthermore, If NIAID finds that our StealthX™ vaccine meets its criteria for safety and efficacy, they may consider our program for a funded Phase 2. At this time, we are developing exosome-based vaccines and therapeutics for infectious diseases, monogenic diseases and other potential indications. Our current strategy is focused on securing partners who will provide capital and additional resources to enable us to bring this program into the clinic.

As of December 31, 2023, we had cash, cash equivalents, and marketable securities totaling approximately $39.5 million. In the fourth quarter of 2023, we announced a positive outcome of the interim futility analysis for HOPE-3, which was reviewed by the Data Safety Monitoring Board. This resulted in a favorable recommendation to continue the HOPE-3 trial as planned, and in accordance with our U.S. Distribution Agreement with Nippon Shinyaku, triggered a milestone payment of $10.0 million which was received in January 2024. We estimate this will fund our operating expenses and capital expenditure requirements into the first quarter of 2025. This expectation includes the $10.0 million milestone payment but excludes any additional potential milestone payments under our Commercialization and Distribution agreements with Nippon Shinyaku. We have not generated any revenues from the commercial sale of products. We will not be able to generate any product revenues until, and only if, we receive approval to sell our drug candidates from the FDA or other regulatory authorities.

Due to our significant research and development expenditures, and general administrative costs associated with our operations, we have generated substantial operating losses in each period since our inception. Our net losses were $22.3 million and $29.0 million, for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $159.4 million. We expect to incur significant expenses and operating losses for the foreseeable future.

During the year ended December 31, 2023, we sold 877,821 shares of common stock at an average price of approximately $4.78 per share pursuant to a sales agreement by and between us and H.C. Wainwright & Co. LLC ("Wainwright") under our at-the-market offering, resulting in net proceeds of $4.1 million. Additionally, in October 2023, we completed a registered direct offering for gross proceeds of approximately $23.0 million.

Recent Operational Developments

CAP-1002 DMD Program Updates

- Enrollment has been completed for Cohort A in our Phase 3 trial which enrolled 61 subjects randomized to either CAP-1002 or placebo in a 1:1 ratio.

- Reported a positive outcome from the interim futility analysis for Cohort A which triggered the first milestone payment of $10.0 million under our U.S. Commercialization Agreement with Nippon Shinyaku. There is an additional $90.0 million in potential milestone payments up to the time of approval which are triggered upon certain regulatory-based achievements. Following potential approval, there is an additional $605.0 million in potential milestones payments which may be payable to Capricor based on various sales-based targets being met.
- Next steps for Cohort A: plan to readout top-line data in the fourth quarter of 2024.
- Enrollment is underway for Cohort B designed to enroll approximately 44 subjects randomized to either CAP-1002 or placebo in a 1:1 ratio.
- Next steps for Cohort B: expect to complete enrollment in the second quarter of 2024.
- Announced the scale-up to expand the manufacturing capacity of CAP-1002 to our new San Diego facility, intended for commercial use, subject to regulatory approval. This facility was designed to be a versatile and cost-effective way to bring CAP-1002 to market efficiently and it is expected that our enhanced manufacturing capacity will increase our supply capabilities and improve our margins on ultimate product sales, if any. We are currently producing CAP-1002 doses at our San Diego facility for use in Cohort B.
- Announced a positive outcome from a Type-B meeting held with FDA in the third quarter of 2023. In the meeting, the FDA affirmed alignment on the current HOPE-3 clinical trial design comprised of two cohorts and our plan to submit a BLA supported by results from Cohort A which uses product manufactured from our Los Angeles manufacturing facility.
- We plan to meet with FDA in the first quarter of 2024 to continue discussing our pathway to BLA. In the upcoming Type-B meeting, we intend to discuss our further CMC plans for commercial launch, if approved, with an aim to expedite the approval pathway to our BLA filing. Our ultimate goal is to transition to our San Diego manufacturing facility for commercial manufacturing as quickly as possible.
- Hosted a webinar in conjunction with Parent Project Muscular Dystrophy (PPMD) where key updates on our DMD program were outlined.
- Presented a late-breaking poster at the 28th International Annual Congress of the World Muscle Society (WMS). Highlights from the poster included data from the HOPE-2 OLE trial measured by the Performance of the Upper Limb (PUL 2.0) showing a delta change=4.9 points, p=0.021 after 24-months of treatment, compared with the placebo patient group.

Exosome Program

- Announced that our proprietary StealthX™ exosome-based multivalent vaccine (StealthX™ vaccine) for the prevention of SARS-CoV-2 was selected to be part of Project NextGen, an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines providing broader and more durable protection for COVID-19. As part of Project NextGen, NIAID, part of the National Institutes of Health, will conduct and fund a Phase 1 clinical trial with our StealthX™ vaccine, subject to regulatory approval. Under the terms of the collaboration, Capricor will supply the investigational product and NIAID's Division of Microbiology and Infectious Diseases (DMID) will oversee the trial.
- Next steps for this project: NIAID plans to initiate the Phase 1 clinical trial in late 2024, subject to regulatory approval.
- Currently, in collaboration with an undisclosed pharmaceutical company, we are also investigating the therapeutic application of our StealthX™ exosome platform.
- Presented a late-breaking poster at the WMS on the application of our StealthX™ exosome platform for the delivery of antisense oligonucleotides (ASO). Highlights from the poster included data showing the presence of exosomes loaded with a labeled ASO in the lower limbs of mice 24 hours post-intravenous (IV) injection. Notably, the exosomes carrying the muscle-targeting moiety were not detected in any other tissues except for the expected clearance pathways (kidney and liver) with a single dose.

Corporate Updates

- Announced receipt of our first milestone payment of $10.0 million under our U.S. Exclusive Distribution and Commercialization Agreement with Nippon Shinyaku.
- Announced completion of a registered direct offering with participation from Nippon Shinyaku for gross proceeds of approximately $23.0 million.

As we seek to develop and commercialize CAP-1002 or any other product candidates including those related to our exosomes program, we anticipate that our expenses will increase significantly and that we will need substantial additional funding to support our continuing operations. Until such time when we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity financings, debt financings or other sources, which may include licensing agreements or strategic collaborations or other distribution agreements. We may be unable to raise additional funds or enter into such agreements or arrangements when needed on favorable terms, if at all. If we fail to raise capital or other potential funding or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development or commercialization of CAP-1002 or our other product candidates.

Financial Operations Overview

We have no commercial product sales to date and will not have the ability to generate any commercial product revenue until after we have received approval from the FDA or equivalent foreign regulatory bodies to begin selling our product candidates. Developing biological products is a lengthy and very expensive process. Even if we obtain the capital necessary to continue the development of our product candidates, whether through a strategic transaction or otherwise, we do not expect to complete the development of a product candidate for several years, if ever. To date, most of our development expenses have related to our product candidates, consisting of CAP-1002 and our exosome technologies. As we proceed with the clinical development of CAP-1002, and as we further develop our exosome technologies, our expenses will further increase. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance the development of our products and our clinical programs. Our recent major sources of working capital have been primarily proceeds from public equity sales of securities and upfront payments pursuant to our U.S. and Japan Distribution Agreements with Nippon Shinyaku. While we pursue our preclinical and clinical programs, we continue to explore potential partnerships for the development of one or more of our product candidates in the US and in other territories across the world.

Our results have included non-cash compensation expense due to the issuance of stock options and warrants, as applicable. We expense the fair value of stock options and warrants over their vesting period as applicable. When more precise pricing data is unavailable, we determine the fair value of stock options using the Black-Scholes option-pricing model. The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based conditions. Stock-based compensation expense is included in the consolidated statements of operations under general and administrative ("G&A") or research and development ("R&D") expenses, as applicable. We expect to record additional non-cash compensation expense in the future, which may be significant.

Results of Operations for the fiscal years ended December 31, 2023 and 2022

Revenue

Clinical Development Income. Clinical development income for the years ended December 31, 2023 and 2022 was approximately $25.2 million and $2.6 million, respectively. The Company began to recognize the $30.0 million upfront payment received from Nippon Shinyaku related to an Exclusive Commercialization and Distribution Agreement (the "U.S. Distribution Agreement") with Nippon Shinyaku in the third quarter of 2022. The Company began to recognize the $10.0 million milestone payment in connection with the U.S. Distribution Agreement in the fourth quarter of 2023. Revenue is ratably recognized using a proportional performance method in relation to the completion of the HOPE-3 clinical trial (Cohort A).

Operating Expenses

Research and Development Expenses. R&D expenses consist primarily of compensation and other related personnel costs, supplies, clinical trial costs, patient treatment costs, rent for laboratories and manufacturing facilities, consulting fees, costs of personnel and supplies for manufacturing, costs of service providers for preclinical, clinical and manufacturing, certain legal expenses resulting from intellectual property prosecution, stock-based compensation expense and other expenses relating to the design, development, testing and enhancement of our product candidates.

The following table summarizes our R&D expenses by category for each of the periods indicated:

	Year ended December 31,			
	2023	2022	Change ($)	Change (%)
Compensation and other personnel expenses	$ 11,272,356	$ 7,450,879	$ 3,821,477	51 %
Duchenne muscular dystrophy (CAP-1002)	18,667,993	7,470,558	11,197,435	150 %
Exosomes platform research	2,090,999	3,600,916	(1,509,917)	(42)%
Facility expenses	1,457,097	1,070,598	386,499	36 %
Stock-based compensation	1,916,245	805,089	1,111,156	138 %
Depreciation	626,514	420,581	205,933	49 %
Research and other	416,835	998,328	(581,493)	(58)%
Total research and development expenses	$ 36,448,039	$ 21,816,949	$ 14,631,090	67 %

R&D expenses for 2023 increased by approximately $14.6 million, or 67%, compared to 2022. The increase was primarily driven by the following:

- $3.8 million increase in compensation and other personnel expenses primarily due to increases in headcount;
- $11.2 million increase in DMD (CAP-1002) program primarily due to the enrollment of our HOPE-3 clinical program, our HOPE-2 OLE clinical trial and our expanded manufacturing production efforts for CAP-1002;
- $0.4 million increase in facility expenses primarily related to increased lease expenses due to our expansion efforts of our research and manufacturing facility in San Diego;
- $1.1 million increase in stock-based compensation expense primarily due to increases in headcount and risk-free rate, which resulted in an increase in fair value of option issued; and
- $0.2 million increase in depreciation expense primarily related to increased equipment purchases and capital improvements related to expansion efforts of our research and manufacturing facility in San Diego.

This increase was partially offset by a $1.5 million decrease in exosomes research primarily due to reduced expenses related to completion of certain research projects and a $0.6 million decrease in research and other primarily due to the completion of activities related to our INSPIRE clinical program in 2022.

General and Administrative Expenses. G&A expenses consist primarily of compensation and other related personnel expenses for executive, finance and other administrative personnel, stock-based compensation expense, accounting, legal and other professional fees, consulting expenses, rent for corporate offices, business insurance and other corporate expenses.

The following table summarizes our G&A expenses by category for each of the periods indicated:

	Year ended December 31,			
	2023	2022	Change ($)	Change (%)
Stock-based compensation	$ 5,476,151	$ 3,653,489	$ 1,822,662	50 %
Compensation and other personnel expenses	3,702,469	3,283,964	418,505	13 %
Professional services	1,700,852	1,958,666	(257,814)	(13)%
Facility expenses	294,841	355,318	(60,477)	(17)%
Depreciation	442,368	112,550	329,818	293 %
Other corporate expenses	1,191,205	1,067,916	123,289	12 %
Total general and administrative expenses	$ 12,807,886	$ 10,431,903	$ 2,375,983	23 %

G&A expenses for 2023 increased by approximately $2.4 million, or 23%, compared to 2022. The increase was primarily driven by the following:

- $1.8 million increase in stock-based compensation expense primarily due to increases in headcount;
- $0.4 million increase in compensation and other personnel expenses primarily due to increases in headcount and recruiting costs;
- $0.3 million increase in depreciation related to leasehold improvements to our San Diego corporate headquarters; and

- $0.1 million increase in other corporate expenses primarily related to increased travel and payroll processing costs due to increased headcount.

This increase was partially offset by a $0.3 million decrease in professional service expenses primarily due to a decrease in business development related expenses.

Other Income

Other Income. Other income for the years ended December 31, 2023 and 2022 was approximately $0.1 million and $0.2 million, respectively. Other income in 2022 was related to the Employer Retention Credit under the CARES Act.

Investment Income. Investment income for the years ended December 31, 2023 and 2022 was approximately $1.7 million and $0.5 million, respectively. The increase in investment income in 2023 as compared to 2022 is due to increased interest rates and the higher principal balance in our marketable securities, savings and money market fund accounts.

Products Under Active Development

CAP-1002 for the treatment of DMD – We are currently conducting our HOPE-3, Phase 3 study for DMD and our ongoing OLE study of the HOPE-2 trial for which we expect to spend approximately $25.0 million to $35.0 million in 2024. The expenses for our DMD program will include costs for personnel, clinical, regulatory and manufacturing-related expenses, including expenses related to the scale-up for potential commercial scale manufacturing if our CAP-1002 product is approved.

Exosome-Based Therapeutics and Vaccines – Our exosome platform is in early-stage preclinical development. We expect to spend approximately $3.0 million to $5.0 million during 2024 on development expenses related to our exosomes program, which includes personnel, preclinical studies and manufacturing related expenses for these technologies. Our expenses for this program are primarily focused on the expansion of our engineered exosomes platform including the manufacturing of our StealthX™ vaccine to be used in connection with our collaboration with NIAID.

Our expenditures on current and future clinical development programs, particularly our CAP-1002 and exosomes programs, cannot be predicted with any significant degree of certainty as they are dependent on the results of our current trials and our ability to secure additional funding and a strategic partner. Further, we cannot predict with any significant degree of certainty the amount of time which will be required to complete our clinical trials, the costs of completing research and development projects or whether, when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during manufacturing and clinical development and as a result of a variety of other factors, including:

- the number of trials and studies in a clinical program;
- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the rates of patient recruitment and enrollment;
- the duration of patient treatment and follow-up;
- the costs of manufacturing our product candidates;
- the availability of necessary materials required to make our product candidates; and
- the costs, requirements and timing of, and the ability to secure, regulatory approvals.

Liquidity and Capital Resources for the fiscal years ended December 31, 2023 and 2022

The following table summarizes our liquidity and capital resources as of and for each of our last two fiscal years, and our net increase (decrease) in cash, cash equivalents, and marketable securities as of and for each of our last two fiscal years and is intended to supplement the more detailed discussion that follows. The amounts stated in the tables below are expressed in thousands.

	As of December 31,	
Liquidity and capital resources	**2023**	**2022**
Cash and cash equivalents	$ 14,695	$ 9,603
Marketable securities	$ 24,793	$ 31,818
Working capital	$ 19,586	$ 19,302
Stockholders' equity	$ 22,601	$ 11,786

	Year ended December 31,	
Cash flow data	**2023**	**2022**
Cash provided by (used in):		
Operating activities	$ (25,596)	$ 4,917
Investing activities	5,108	(35,073)
Financing activities	25,580	4,874
Net increase (decrease) in cash and cash equivalents	$ 5,092	$ (25,282)

Our total cash, cash equivalents, and marketable securities as of December 31, 2023 were approximately $39.5 million compared to approximately $41.4 million as of December 31, 2022. The decrease in cash, cash equivalents and marketable securities from December 31, 2023 as compared to December 31, 2022 is due to a net loss of approximately $22.3 million for the year ended December 31, 2023, receipt of $12.0 million upfront from Nippon Shinyaku related to the Japan Distribution Agreement in the first quarter of 2023, and approximately $23.0 million raised in October 2023 through a registered direct offering. The net loss of approximately $22.3 million for the year ended December 31, 2023 was driven by the increased R&D expenses in connection with our clinical program in DMD. As of December 31, 2023, we had approximately $36.1 million in total liabilities, of which approximately $24.3 million relates to deferred revenue and approximately $2.2 million related to lease liabilities in connection with our operating lease right-of-use assets. As of December 31, 2023, we had approximately $19.6 million in net working capital.

Cash used in operating activities was approximately $25.6 million for the year ended December 31, 2023 and cash provided by operating activities was approximately $4.9 million for the year ended December 31, 2022. The net change of approximately $30.5 million in cash from operating activities is due to the milestone payment of $10.0 million from Nippon Shinyaku and deferred revenue. Furthermore, there was an increase of approximately $2.9 million in stock-based compensation and a decrease in net loss of approximately $6.7 million for the year ended December 31, 2023 as compared to the same period in 2022. Furthermore, there was a net change of approximately $0.1 million in accounts payable and accrued expenses, which includes related party accounts payable and accrued expenses. To the extent we obtain sufficient capital and/or long-term debt funding and are able to continue developing our product candidates, including if we expand our platform technology portfolio, engage in further research and development activities, and, in particular, conduct preclinical studies and clinical trials, we expect to continue incurring substantial losses, which will generate negative net cash flows from operating activities.

We had cash flow provided by investing activity of approximately $5.1 million for the year ended December 31, 2023 and cash flow used in investing activities of approximately $35.1 million for the year ended December 31, 2022. The change in cash flow by investing activities for the year ended December 31, 2023 as compared to the same period of 2022 is due to the net effect from purchases, sales, and maturities of marketable securities as well as purchases of property and equipment and leasehold improvements.

We had cash flow provided by financing activities of approximately $25.6 million and $4.9 million for the years ended December 31, 2023 and 2022, respectively. The increase in cash provided by financing activities for the year ended December 31, 2023 as compared to the same period of 2022 is primarily due to the net proceeds from the sale of common stock. During 2023 we received net proceeds from the sale of stock of approximately $25.5 million compared to approximately $4.8 million over the same period of 2022.

From inception through December 31, 2023, we financed our operations primarily through private and public sales of our equity securities, government grants, and payments from distribution agreements and collaboration partners. As we have not generated any revenue from the commercial sale of our products to date, and we do not expect to generate revenue for several years, if ever, we will need to raise substantial additional capital to fund our research and development, including our long-term plans for clinical trials and new product development. We may seek to raise additional funds through various potential sources, such as equity and debt financings, government grants, or through strategic collaborations and license agreements or other distribution agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations, complete our clinical trials or if such funds become available to us, that such additional financing will be sufficient to meet our needs. Moreover, to the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that may not be favorable to us.

Our estimates regarding the sufficiency of our financial resources are based on assumptions that may prove to be wrong. We may need to obtain additional funds sooner than planned or in greater amounts than we currently anticipate. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the progress of our clinical and research activities;
- the number and scope of our clinical and research programs;
- the progress and success of our preclinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our ability to successfully manufacture product for our clinical trials and potential commercial use;
- the availability of materials necessary to manufacture our product candidates;
- the costs of manufacturing our product candidates, and the progress of efforts with parties with whom we may enter into commercial manufacturing agreements, if necessary;
- our ability to maintain current research and development programs and to establish new research and development and licensing arrangements;
- additional costs associated with maintaining licenses and insurance;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

Collaborations

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: United States)

On January 24, 2022, Capricor entered into a Commercialization and Distribution Agreement (the "U.S. Distribution Agreement") with Nippon Shinyaku, a Japanese corporation. Under the terms of the U.S. Distribution Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in the United States of CAP-1002 for the treatment of DMD.

Under the terms of the U.S. Distribution Agreement, Capricor will be responsible for the conduct of the HOPE-3 trial as well as the manufacturing of CAP-1002. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in the United States. Pursuant to the U.S Distribution Agreement, Capricor received an upfront payment of $30.0 million in the first quarter of 2022. The first milestone payment of $10.0 million was paid upon completion of the interim futility analysis of the HOPE-3 trial whereby the outcome was determined to be not futile. Capricor received this milestone payment from Nippon Shinyaku in January 2024. Additionally, there are potential milestones totaling up to $90.0 million leading up to and including the BLA approval. Further, there are various potential sales-based milestones, if commercialized, tied to the achievement of certain sales thresholds for annual net sales of CAP-1002 of up to $605.0 million. Further, pursuant to the U.S. Distribution Agreement, Capricor has the obligation to sell commercial product to Nippon Shinyaku, subject to regulatory approval, and Capricor will have the right to receive a meaningful mid-range double-digit share of product revenue.

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: Japan)

On February 10, 2023, Capricor entered into a Commercialization and Distribution Agreement (the "Japan Distribution Agreement") with Nippon Shinyaku. Under the terms of the Japan Distribution Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in Japan of CAP-1002 for the treatment of DMD.

Under the terms of the Japan Distribution Agreement, Capricor received an upfront payment of $12.0 million in the first quarter of 2023 and in addition, Capricor will potentially receive additional development and sales-based milestone payments of up to approximately $89.0 million, subject to foreign currency exchange rates, and a meaningful double-digit share of product revenue. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in Japan. Capricor will be responsible for the conduct of clinical development in Japan, as may be required, as well as the manufacturing of CAP-1002. Subject to regulatory approval, Capricor will sell commercial product to Nippon Shinyaku in Japan. In addition, Capricor or its designee will hold the Marketing Authorization in Japan if the product is approved in that territory.

Financing Activities by the Company

October 2023 Financing

On October 3, 2023, the Company entered into Securities Purchase Agreements with its commercial partner, Nippon Shinyaku and funds associated with Highbridge Capital Management, LLC (the "Investors"), pursuant to which the Company agreed to issue and sell to the Investors, in a registered direct offering (the "Registered Direct Offering"), an aggregate of 4,935,621 shares of its common stock, par value $0.001 per share, at a price per share of $4.66 for an aggregate purchase price of approximately $23.0 million. Each share of common stock offered was sold with a warrant to purchase one share of common stock at an exercise price of $5.70 per share. Each warrant will be exercisable beginning six months after issuance and will expire seven years from the date of issuance. As part of the Registered Direct Offering, the Company agreed not to issue or sell shares (subject to customary exceptions for employee stock option issuances and other customary exceptions) for a period of 30 days following the date of the prospectus supplement that was used in the Registered Direct Offering. That prospectus was dated September 29, 2023, and the Company "lock-up" expired on October 29, 2023. The Company's directors and executive officers also entered into "lock-up" agreements with the placement agent in the Registered Direct Offering, which agreements expired on the 60th day following the date of the Securities Purchase Agreements, or December 2, 2023.

ATM Program

On June 21, 2021, the Company initiated an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $75.0 million (the "ATM Program"), with the common stock to be distributed at the market prices prevailing at the time of sale. The ATM Program was established under a Common Stock Sales Agreement (the "Sales Agreement,"), with Wainwright, under which we may, from time to time, issue and sell shares of our common stock through Wainwright as sales agent. The Sales Agreement provides that Wainwright will be entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold. All shares issued pursuant to the ATM Program were issued pursuant to our shelf registration statement on Form S-3 (File No. 333-254363), which was initially filed with the SEC on March 16, 2021, amended on June 15, 2021 and declared effective by the SEC on June 16, 2021. From June 21, 2021 through March 7, 2024, the Company sold an aggregate of 3,227,501 shares of common stock under the ATM Program at an average price of approximately $5.50 per share for gross proceeds of approximately $17.8 million. Approximately $57.2 million of common stock may still be sold pursuant to the ATM Program. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses to Wainwright, as well as legal and accounting fees in the aggregate amount of approximately $0.6 million.

CIRM Grant Award

On June 16, 2016, Capricor entered into an award (the "CIRM Award") with the California Institute for Regenerative Medicine ("CIRM") in the amount of approximately $3.4 million to fund, in part, Capricor's Phase 1/2 HOPE-Duchenne clinical trial investigating CAP-1002 for the treatment of Duchenne muscular dystrophy-associated cardiomyopathy. Pursuant to terms of the CIRM Award, the disbursements were tied to the achievement of specified operational milestones. In addition, the terms of the CIRM Award included a co-funding requirement pursuant to which Capricor was required to spend approximately $2.3 million of its own capital to fund the CIRM funded research project. The CIRM Award is further subject to the conditions and requirements set forth in the CIRM Grants Administration Policy

for Clinical Stage Projects. Such requirements include, without limitation, the filing of quarterly and annual reports with CIRM, the sharing of intellectual property pursuant to Title 17, California Code of Regulations (CCR) Sections 100600-100612, and the sharing with the State of California of a fraction of licensing revenue received from a CIRM funded research project and net commercial revenue from a commercialized product which resulted from the CIRM funded research as set forth in Title 17, CCR Section 100608. The maximum royalty on net commercial revenue that Capricor may be required to pay to CIRM is equal to nine times the total amount awarded and paid to Capricor.

After completing the CIRM funded research project and at any time after the award period end date (but no later than the ten-year anniversary of the date of the award), Capricor has the right to convert the CIRM Award into a loan, the terms of which will be determined based on various factors, including the stage of the research and development of the program at the time the election is made. On June 20, 2016, Capricor entered into a Loan Election Agreement with CIRM whereby, among other things, CIRM and Capricor agreed that if Capricor elects to convert the grant into a loan, the term of the loan could be up to five years from the date of execution of the applicable loan agreement; provided that the maturity date of the loan will not surpass the ten-year anniversary of the grant date of the CIRM Award. Beginning on the date of the loan, the loan shall bear interest on the unpaid principal balance, plus the interest that has accrued prior to the election point according to the terms set forth in the CIRM Loan Policy and CIRM Grants Administration Policy for Clinical Stage Projects (the "New Loan Balance"), at a per annum rate equal to the LIBOR rate for a three-month deposit in U.S. dollars, as published by the Wall Street Journal on the loan date, plus one percent. Interest shall be compounded annually on the outstanding New Loan Balance commencing with the loan date and the interest shall be payable, together with the New Loan Balance, upon the due date of the loan. Depending on the timing of our election, additional funds may be owed. If Capricor elects to convert the CIRM Award into a loan, certain requirements of the CIRM Award will no longer be applicable, including the revenue sharing requirements. Capricor has not yet made its decision as to whether it will elect to convert the CIRM Award into a loan. If we elect to do so, Capricor would be required to repay the amounts awarded by CIRM, therefore the Company accounts for this award as a liability rather than income.

In 2019, Capricor completed all milestones and close-out activities associated with the CIRM Award and expended all funds received. As of December 31, 2023, Capricor's liability balance for the CIRM Award was approximately $3.4 million.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. We evaluate our estimates and assumptions on an ongoing basis, including research and development and clinical trial accruals, and stock-based compensation estimates. Our estimates are based on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Our actual results could differ from these estimates. We believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our financial statements and accompanying notes.

Leases

ASC Topic 842, *Leases* ("ASC 842"), requires lessees to recognize most leases on the balance sheet with a corresponding right-to-use ("ROU") asset. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The assets and lease liabilities are recognized at the lease commencement date based on the estimated present value of fixed lease payments over the lease term. ROU assets are evaluated for impairment using the long-lived assets impairment guidance.

Leases will be classified as financing or operating, which will drive the expense recognition pattern. The Company elects to exclude short-term leases if and when the Company has them.

The Company leases office and laboratory space, all of which are operating leases. Most leases include the option to renew and the exercise of the renewal options is at the Company's sole discretion. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. In addition, the Company's lease agreements generally do not contain any residual value guarantees or restrictive covenants.

The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

For real estate leases, the Company has elected the practical expedient under ASC 842 to account for the lease and non-lease components together for existing classes of underlying assets and allocates the contract consideration to the lease component only. This practical expedient is not elected for manufacturing facilities and equipment embedded in product supply arrangements.

Revenue Recognition

The Company applies ASU 606, *Revenue for Contracts from Customers*, which amended revenue recognition principles and provides a single, comprehensive set of criteria for revenue recognition within and across all industries. The Company has not yet achieved commercial sales of its drug candidates to date, however, the new standard is applicable to its distribution agreements.

The revenue standard provides a five-step framework for recognizing revenue as control of promised goods or services is transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that it determines are within the scope of the revenue standard, the Company performs the following five steps: (i) identify the contract; (ii) identify the performance obligations; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. At contract inception, the Company assesses whether the goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation, or whether they are not distinct and are combined with other goods and services until a distinct bundle is identified. The Company then determines the transaction price, which typically includes upfront payments and any variable consideration that the Company determines is probable to not cause a significant reversal in the amount of cumulative revenue recognized when the uncertainty associated with the variable consideration is resolved. The Company then allocates the transaction price to each performance obligation and recognizes the associated revenue when, or as, each performance obligation is satisfied.

The Company's distribution agreements may entitle it to additional payments upon the achievement of milestones or shares of product revenue. The milestones are generally categorized into three types: development milestones, regulatory milestones and sales-based milestones. The Company evaluates whether it is probable that the consideration associated with each milestone or shared revenue payments will not be subject to a significant reversal in the cumulative amount of revenue recognized. Amounts that meet this threshold are included in the transaction price using the most likely amount method, whereas amounts that do not meet this threshold are excluded from the transaction price until they meet this threshold. At the end of each subsequent reporting period, the Company re-evaluates the probability of a significant reversal of the cumulative revenue recognized for its milestones and shared revenue payments, and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and net income (loss) in the Company's consolidated statements of operation and comprehensive loss. Typically, milestone payments and shared revenue payments are achieved after the Company's performance obligations associated with the distribution agreements have been completed and after the customer has assumed responsibility for the respective clinical program. Milestones or shared revenue payments achieved after the Company's performance obligations have been completed are recognized as revenue in the period the milestone or shared revenue payments was achieved. If a milestone payment is achieved during the performance period, the milestone payment would be recognized as revenue to the extent performance had been completed at that point, and the remaining balance would be recorded as deferred revenue.

The revenue standard requires the Company to assess whether a significant financing component exists in determining the transaction price. The Company performs this assessment at the onset of its distribution agreements. Typically, a significant financing component does not exist because the customer is paying for services in advance with

an upfront payment. Additionally, future shared revenue payments are not substantially within the control of the Company or the customer.

Whenever the Company determines that goods or services promised in a contract should be accounted for as a combined performance obligation over time, the Company determines the period over which the performance obligations will be performed and revenue will be recognized. Revenue is recognized using either the proportional performance method or on a straight-line basis if efforts will be expended evenly over time. Percentage of completion of patient visits in clinical trials are used as the measure of performance. The Company feels this method of measurement to be the best depiction of the transfer of services and recognition of revenue. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations. If the Company determines that the performance obligation is satisfied over time, any upfront payment received is initially recorded as deferred revenue on its consolidated balance sheets.

Certain judgments affect the application of the Company's revenue recognition policy. For example, the Company records short-term (less than one year) and long-term (over one year) deferred revenue based on its best estimate of when such revenue will be recognized. This estimate is based on the Company's current operating plan and, the Company may recognize a different amount of deferred revenue over the next 12-month period if its plan changes in the future.

Grant Income

The determination as to when income is earned is dependent on the language in each specific grant. Generally, we recognize grant income in the period in which the expense is incurred for those expenses that are deemed reimbursable under the terms of the grant. Grant income is due upon submission of reimbursement request. The transaction price varies for grant income based on the expenses incurred under the awards.

CIRM Grant Award

Capricor accounts for the disbursements under its CIRM Award as long-term liabilities. Capricor recognizes the CIRM grant disbursements as a liability as the principal is disbursed rather than recognizing the full amount of the grant award. After completing the CIRM funded research project and after the award period end date, Capricor has the right to convert the CIRM Award into a loan, the terms of which will be determined based on various factors, including the stage of the research and the stage of development at the time the election is made. In June, 2016, Capricor entered into a Loan Election Agreement with CIRM whereby, among other things, CIRM and Capricor agreed that if Capricor elects to convert the grant into a loan, the term of the loan could be up to five years from the date of execution of the applicable loan agreement; provided that the maturity date of the loan will not surpass the ten-year anniversary of the grant date of the CIRM Award. Since Capricor may be required to repay some or all of the amounts awarded by CIRM, the Company accounts for this award as a liability rather than income.

Research and Development Expenses and Accruals

R&D expenses consist primarily of salaries and related personnel costs, supplies, clinical trial costs, patient treatment costs, rent for laboratories and manufacturing facilities, consulting fees, costs of personnel and supplies for manufacturing, costs of service providers for preclinical, clinical and manufacturing, and certain legal expenses resulting from intellectual property prosecution, stock compensation expense and other expenses relating to the design, development, testing and enhancement of our product candidates. Except for certain capitalized intangible assets, R&D costs are expensed as incurred.

Our cost accruals for clinical trials and other R&D activities are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and contract research organizations ("CROs"), clinical study sites, laboratories, consultants or other clinical trial vendors that perform activities in connection with a trial. Related contracts vary significantly in length and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of fixed, variable and capped amounts. Activity levels are monitored through close communication with the CROs and other clinical trial vendors, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, analysis of work performed against approved contract budgets and payment schedules, and recognition of any changes in scope of the services to be performed. Certain CRO and significant clinical trial vendors provide an estimate of costs incurred but not invoiced at the end of each quarter

for each individual trial. These estimates are reviewed and discussed with the CRO or vendor as necessary, and are included in R&D expenses for the related period. For clinical study sites which are paid periodically on a per-subject basis to the institutions performing the clinical study, we accrue an estimated amount based on subject screening and enrollment in each quarter. All estimates may differ significantly from the actual amount subsequently invoiced, which may occur several months after the related services were performed.

In the normal course of business, we contract with third parties to perform various R&D activities in the on-going development of our product candidates. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of the accrual policy is to match the recording of expenses in the financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials and other R&D activities are recognized based on our estimates of the degree of completion of the event or events specified in the applicable contract.

No adjustments for material changes in estimates have been recognized in any period presented.

Stock-Based Compensation

Our results include non-cash compensation expense as a result of the issuance of stock, stock options and warrants, as applicable. We have issued stock options to employees, directors and consultants under our five stock option plans: (i) the 2006 Stock Option Plan, (ii) the 2012 Restated Equity Incentive Plan (which superseded the 2006 Stock Option Plan) (the "2012 Plan"), (iii) the 2012 Non-Employee Director Stock Option Plan (the "2012 Non-Employee Director Plan"), (iv) the 2020 Equity Incentive Plan (the "2020 Plan"), and (v) the 2021 Equity Incentive Plan (the "2021 Plan"). At this time, the Company only issues options under the 2020 Plan and the 2021 Plan and no longer issues options under the 2006 Stock Option Plan, the 2012 Plan, or the 2012 Non-Employee Director Plan.

We expense the fair value of stock-based compensation over the vesting period. When more precise pricing data is unavailable, we determine the fair value of stock options using the Black-Scholes option-pricing model. This valuation model requires us to make assumptions and judgments about the variables used in the calculation. These variables and assumptions include the weighted-average period of time that the options granted are expected to be outstanding, the volatility of our common stock, and the risk-free interest rate. We account for forfeitures upon occurrence.

Stock options or other equity instruments to non-employees (including consultants) issued as consideration for goods or services received by us are accounted for based on the fair value of the equity instruments issued. The fair value of stock options is determined using the Black-Scholes option-pricing model. The Company calculates the fair value for non-qualified options as of the date of grant and expenses over the applicable vesting periods.

The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based conditions. Stock-based compensation expense is included in general and administrative expense or research and development expense, as applicable, in the Statements of Operations and Comprehensive Income (Loss). We expect to record additional non-cash compensation expense in the future, which may be significant.

Clinical Trial Expense

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses. Our clinical trial accrual process is designed to account for expenses resulting from our obligations under contracts with vendors, consultants, CROs and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our objective is to reflect the appropriate clinical trial expenses in our consolidated financial statements by matching the appropriate expenses with the period in which services are provided and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through financial models that take into account discussions with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates. We make

estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on the facts and circumstances known to us at that time. Our clinical trial accrual and prepaid assets are dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Although we do not expect our estimates to be materially different from amounts actually incurred, 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 us reporting amounts that are too high or too low for any particular period.

Recently Issued or Newly Adopted Accounting Pronouncements

In October 2023, the Financial Accounting Standards Board ("FASB") issued ASU 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*. This standard was issued in response to the SEC's disclosure update and simplification initiative, which affects a variety of topics within the Accounting Standards Codification. The amendments apply to all reporting entities within the scope of the affected topics unless otherwise indicated. The effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. The Company is currently evaluating the impact this guidance will have on its financial statement disclosures.

Other recent accounting pronouncements issued by the Financial Accounting Standards Board, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the SEC, did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statement presentation or disclosures.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Sensitivity

Our exposure to market risk for changes in interest rates relates primarily to our marketable securities and cash and cash equivalents. As of December 31, 2023, the fair value of our cash, cash equivalents, and marketable securities was approximately $39.5 million. Additionally, as of December 31, 2023, Capricor's investment portfolio was classified as cash, cash equivalents and marketable securities which consisted primarily of money market funds and bank money market accounts, which included short term U.S. treasuries, bank savings and checking accounts.

The goal of our investment policy is to place our investments with highly rated credit issuers and limit the amount of credit exposure. We seek to improve the safety and likelihood of preservation of our invested funds by limiting default risk and market risk. Our investments may be exposed to market risk due to fluctuation in interest rates, which may affect our interest income and the fair market value of our investments, if any. We will manage this exposure by performing ongoing evaluations of our investments. Due to the short-term maturities, if any, of our investments to date, their carrying value has always approximated their fair value. Our policy is to mitigate default risk by investing in high credit quality securities, and we currently do not hedge interest rate exposure. Due to our policy of making investments in U.S. treasury securities with primarily short-term maturities, we believe that the fair value of our investment portfolio would not be materially impacted by a hypothetical 100 basis point increase or decrease in interest rates.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CAPRICOR THERAPEUTICS, INC.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Capricor Therapeutics, Inc. and Subsidiary

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Capricor Therapeutics, Inc. and Subsidiary (the Company) as of December 31, 2023 and 2022, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2023, 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 consolidated financial position of the Company as of December 31, 2023 and 2022, and the consolidated results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has continued to incur significant operating losses and negative cash flows from operations, during the year ended December 31, 2023. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Revenue Recognition – Revenue Recognized Over Time

Description of the Matter

As discussed in Note 1 and Note 7 to the Consolidated Financial Statements, the Company earns its revenue through an exclusive commercialization and distribution agreement. For performance obligations related to services that are required to be recognized over time, the Company generally measures its progress to completion using an input measure of total costs for patient visits incurred divided by total costs expected to be incurred for all patient visits.

Auditing revenue recognition is complex and highly judgmental due to the variability and uncertainty associated with the Company's assessment of measure of progress. Changes in these estimates would have a significant effect on the amount of revenue recognized.

How We Addressed the Matter in Our Audit

To test the measures of progress used for performance obligations related to services that are required to be recognized over time, our audit procedures included, among others, evaluating the appropriateness of the Company's accounting policy for each type of arrangement, testing the identified measure of performance by reading contracts with customers, including all amendments, and reviewing the contract analyses prepared by management. We evaluated whether the selected measures of progress towards satisfaction of performance obligations were applied consistently. We also tested the completeness and accuracy of the underlying data used for the measure of progress by testing and or analyzing the underlying data and conducting interviews of project personnel.

/s/ Rose, Snyder & Jacobs LLP
Rose, Snyder & Jacobs LLP

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

Encino, California
March 8, 2024

CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2023 AND 2022

ASSETS

	December 31, 2023	December 31, 2022
CURRENT ASSETS		
Cash and cash equivalents	$ 14,694,857	$ 9,603,242
Marketable securities	24,792,846	31,818,020
Receivables	10,371,993	547,580
Prepaid expenses and other current assets	995,776	919,892
TOTAL CURRENT ASSETS	50,855,472	42,888,734
PROPERTY AND EQUIPMENT, net	5,560,641	4,588,030
OTHER ASSETS		
Lease right-of-use assets, net	2,050,042	2,349,974
Other assets	268,172	268,172
TOTAL ASSETS	$ 58,734,327	$ 50,094,910
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 6,222,762	$ 4,834,683
Accounts payable and accrued expenses, related party	27,479	89,234
Lease liabilities, current	749,112	682,039
Deferred revenue, current	24,270,465	17,980,599
TOTAL CURRENT LIABILITIES	31,269,818	23,586,555
LONG-TERM LIABILITIES		
CIRM liability	3,376,259	3,376,259
Lease liabilities, net of current	1,486,783	1,878,070
Deferred revenue, net of current	—	9,467,932
TOTAL LONG-TERM LIABILITIES	4,863,042	14,722,261
TOTAL LIABILITIES	36,132,860	38,308,816
COMMITMENTS AND CONTINGENCIES (NOTE 6)		
STOCKHOLDERS' EQUITY		
Preferred stock, $0.001 par value, 5,000,000 shares authorized, none issued and outstanding	—	—
Common stock, $0.001 par value, 50,000,000 shares authorized, 31,148,320 and 25,241,402 shares issued and outstanding, respectively	31,148	25,241
Additional paid-in capital	181,701,859	148,735,420
Accumulated other comprehensive income	235,813	105,244
Accumulated deficit	(159,367,353)	(137,079,811)
TOTAL STOCKHOLDERS' EQUITY	22,601,467	11,786,094
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 58,734,327	$ 50,094,910

See accompanying notes to the audited consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
FOR THE YEARS ENDED DECEMBER 31, 2023 AND 2022

	Years ended December 31,	
	2023	**2022**
REVENUE		
Revenue	$ 25,178,066	$ 2,551,469
TOTAL REVENUE	25,178,066	2,551,469
OPERATING EXPENSES		
Research and development	36,448,039	21,816,949
General and administrative	12,807,886	10,431,903
TOTAL OPERATING EXPENSES	49,255,925	32,248,852
LOSS FROM OPERATIONS	(24,077,859)	(29,697,383)
OTHER INCOME (EXPENSE)		
Other income	67,657	190,582
Investment income	1,728,701	521,535
Loss on disposal of fixed assets	(6,041)	(34,266)
TOTAL OTHER INCOME (EXPENSE)	1,790,317	677,851
NET LOSS	(22,287,542)	(29,019,532)
OTHER COMPREHENSIVE INCOME (LOSS)		
Net unrealized gain on marketable securities	130,569	105,244
COMPREHENSIVE LOSS	$ (22,156,973)	$ (28,914,288)
Net loss per share, basic and diluted	$ (0.83)	$ (1.18)
Weighted average number of shares, basic and diluted	26,778,360	24,552,688

See accompanying notes to the audited consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE PERIOD FROM DECEMBER 31, 2021 THROUGH DECEMBER 31, 2023

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	OTHER COMPREHENSIVE INCOME	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
Balance at December 31, 2021	24,185,001	$ 24,185	$ 139,404,060	$ —	$ (108,060,279)	$ 31,367,966
Issuance of common stock, net of fees	830,858	831	4,802,703	—	—	4,803,534
Stock-based compensation	—	—	4,458,578	—	—	4,458,578
Stock options exercised	225,543	225	70,079	—	—	70,304
Unrealized gain on marketable securities	—	—	—	105,244	—	105,244
Net loss	—	—	—	—	(29,019,532)	(29,019,532)
Balance at December 31, 2022	25,241,402	$ 25,241	$ 148,735,420	$ 105,244	$ (137,079,811)	$ 11,786,094
Issuance of common stock, net of fees	5,813,442	5,813	25,509,536	—	—	25,515,349
Stock-based compensation	—	—	7,392,396	—	—	7,392,396
Stock options exercised	93,476	94	64,507	—	—	64,601
Unrealized gain on marketable securities	—	—	—	130,569	—	130,569
Net loss	—	—	—	—	(22,287,542)	$ (22,287,542)
Balance at December 31, 2023	31,148,320	$ 31,148	$ 181,701,859	$ 235,813	$ (159,367,353)	$ 22,601,467

See accompanying notes to the audited consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2023 AND 2022

	Years ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (22,287,542)	$ (29,019,532)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Loss on disposal of fixed assets	6,041	34,266
Depreciation and amortization	1,068,882	533,131
Stock-based compensation	7,392,396	4,458,578
Changes in lease liabilities	(24,282)	161,740
Changes in operating assets and liabilities:		
Receivables	(9,824,413)	(155,830)
Prepaid expenses and other current assets	(75,884)	240,045
Other assets	—	7,550
Accounts payable and accrued expenses	1,388,078	1,718,312
Accounts payable and accrued expenses, related party	(61,755)	(510,154)
Deferred revenue	(3,178,066)	27,448,531
Net cash provided by (used in) operating activities	(25,596,545)	4,916,637
Cash flows from investing activities:		
Purchase of marketable securities	(97,441,506)	(114,218,737)
Proceeds from sales and maturities of marketable securities	104,597,249	82,505,961
Purchases of property and equipment	(1,311,660)	(2,000,243)
Payments for leasehold improvements	(735,873)	(1,359,488)
Net cash provided by (used in) investing activities	5,108,210	(35,072,507)
Cash flows from financing activities:		
Net proceeds from sale of common stock	25,515,349	4,803,534
Proceeds from exercise of stock awards	64,601	70,304
Net cash provided by financing activities	25,579,950	4,873,838
Net increase (decrease) in cash and cash equivalents	5,091,615	(25,282,032)
Cash and cash equivalents balance at beginning of period	9,603,242	34,885,274
Cash and cash equivalents balance at end of period	$ 14,694,857	$ 9,603,242
Supplemental disclosures of cash flow information:		
Interest paid in cash	$ —	$ —
Income taxes paid in cash	$ —	$ —

See accompanying notes to the audited consolidated financial statements.

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Capricor Therapeutics, Inc., a Delaware corporation (referred to herein as "Capricor Therapeutics" or the "Company," "we," "us" or "our"), is a clinical-stage biotechnology company focused on the development of transformative cell and exosome-based therapeutics for treating Duchenne muscular dystrophy ("DMD"), a rare form of muscular dystrophy which results in muscle degeneration and premature death, and other diseases with high unmet medical needs. Capricor, Inc. ("Capricor"), a wholly-owned subsidiary of Capricor Therapeutics, was founded in 2005 as a Delaware corporation based on the innovative work of its founder, Eduardo Marbán, M.D., Ph.D. After completion of a merger between Capricor and a subsidiary of Nile Therapeutics, Inc., a Delaware corporation ("Nile"), on November 20, 2013, Capricor became a wholly-owned subsidiary of Nile and Nile formally changed its name to Capricor Therapeutics, Inc. Capricor Therapeutics, together with its subsidiary, Capricor, has multiple therapeutic drug candidates in various stages of development.

Basis of Consolidation

Our consolidated financial statements include the accounts of the Company and our wholly-owned subsidiary. All intercompany transactions have been eliminated in consolidation.

Reclassification

Certain reclassification of prior period amounts has been made to conform to the current year presentation.

Liquidity and Going Concern

The Company has historically financed its research and development activities as well as operational expenses primarily from equity financings, government grants, and payments from distribution agreements and collaboration partners.

Cash, cash equivalents, and marketable securities as of December 31, 2023 were approximately $39.5 million, compared to approximately $41.4 million as of December 31, 2022. In the first quarter of 2023, the Company received an upfront payment of $12.0 million from Nippon Shinyaku Co., Ltd., a Japanese corporation, ("Nippon Shinyaku"), in accordance with its Japan Exclusive Commercialization and Distribution Agreement (see Note 7 – "License and Distribution Agreements"). In October 2023, the Company completed a registered direct offering for gross proceeds of approximately $23.0 million (see Note 2 – "Stockholder's Equity"). We received our first milestone payment of $10.0 million in the first quarter of 2024, which was triggered upon completion of the interim futility analysis of the HOPE-3 trial whereby the outcome was determined to be not futile. Additionally, the Company has a Common Stock Sales Agreement in place with H.C. Wainwright & Co. LLC ("Wainwright") to create at-the-market equity programs under which the Company, from time to time, sells shares of its common stock (see Note 2 - "Stockholders' Equity").

The Company's principal uses of cash are for research and development expenses, general and administrative expenses, capital expenditures and other working capital requirements.

The Company's future expenditures and capital requirements may be substantial and will depend on many factors, including, but not limited to, the following:

- the timing and costs associated with our research and development activities, clinical trials and preclinical studies, including the enrollment and progress of our ongoing HOPE-3 Phase 3 clinical trial of CAP-1002 in DMD;
- the timing and costs associated with the manufacturing of our product candidates, including the expansion of our manufacturing capacity to support the potential commercialization of CAP-1002 for DMD;
- the timing and costs associated with potential commercialization of our product candidates;
- the number and scope of our research programs, including the expansion of our exosomes program; and
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights.

The Company's options for raising additional capital include potentially seeking additional financing primarily from, but not limited to, the sale and issuance of equity or debt securities, the licensing or sale of its technology and other assets, potential distribution and other partnering opportunities, and from government grants. The Company has incurred significant operating losses and negative cash flows from operations. Based on the Company's available cash resources and based upon the Company's projections for its operations, the Company does not have sufficient cash on hand to support current operations for at least the next twelve months from the date of filing this Annual Report on Form 10-K. Therefore, there is a substantial doubt about the Company's ability to continue as a going concern.

The Company's plan to address its financial position may include potentially seeking additional financing primarily from, but not limited to, the sale and issuance of equity or debt securities, the licensing or sale of its technology and from government grants. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

The Company will require substantial additional capital to fund its operations. The Company cannot provide assurances that financing will be available when and as needed or that, if available, financing will be available on favorable or acceptable terms. If the Company is unable to obtain additional financing when and if required, it would have a material adverse effect on the Company's business and results of operations. The Company would likely need to delay, curtail or terminate portions of its clinical trial and research and development programs. To the extent the Company issues additional equity securities, its existing stockholders would experience substantial dilution.

Business Uncertainty Related to the Coronavirus

The COVID-19 pandemic presented substantial public health and economic challenges around the world. Our business operations and financial condition and results have been impacted to varying degrees.

In light of past uncertainties due to COVID-19 and its economic and other impacts and to uncertainties around the timing and availability of grant disbursements, the loss of revenue from the REGRESS and ALPHA trials as well as any potential equity and debt financings, the Company submitted for the Employee Retention Credit ("ERC"), a credit against certain payroll taxes allowed to an eligible employer for qualifying wages, which was established by the CARES Act. The Company has submitted $738,778 in ERC for applicable 2020 and 2021 periods, receiving $191,199 in 2021 and $191,463 in 2023. As of December 31, 2023, the Company has recorded a receivable for $366,551 for the remainder of funds expected to be received.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. Management uses its historical records and knowledge of its business in making these estimates. Accordingly, actual results may differ from these estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of less than 30 days at the date of purchase to be cash equivalents.

Marketable Securities

The Company determines the appropriate classification of its marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. All of the Company's marketable securities are considered as available-for-sale and carried at estimated fair values. Realized gains and losses on the sale of debt and equity securities are determined using the specific identification method. Unrealized gains and losses on available-for-sale securities are

presented as accumulated other comprehensive income (loss) as a separate component of stockholders' equity. As of December 31, 2023, marketable securities consist primarily of short-term United States treasuries.

Property and Equipment

Property and equipment are stated at cost. Repairs and maintenance costs are expensed in the period incurred. Depreciation is computed using the straight-line method over the related estimated useful life of the asset, which such estimated useful lives range from five to seven years. Leasehold improvements are depreciated on a straight-line basis over the shorter of the useful life of the asset or the lease term. Depreciation was $1,068,882 and $533,131 for the years ended December 31, 2023 and 2022, respectively.

Property and equipment, net consisted of the following:

	December 31, 2023	December 31, 2022
Furniture and fixtures	$ 187,997	$ 139,336
Laboratory equipment	5,449,597	4,237,089
Leasehold improvements	2,129,102	1,393,230
	7,766,696	5,769,655
Less accumulated depreciation	(2,206,055)	(1,181,625)
Property and equipment, net	$ 5,560,641	$ 4,588,030

Long-Lived Assets

The Company accounts for the impairment and disposition of long-live assets in accordance with guidance issued by the Financial Accounting Standards Board ("FASB"). Long-lived assets to be held and used are reviewed for events or changes in circumstances that indicate that their carrying value may not be recoverable, or annually. No impairment related to long-lived assets was recorded for the years ended December 31, 2023 and 2022.

Leases

ASC Topic 842, *Leases* ("ASC 842"), requires lessees to recognize most leases on the balance sheet with a corresponding right-to-use asset ("ROU asset"). ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The assets and lease liabilities are recognized at the lease commencement date based on the estimated present value of fixed lease payments over the lease term. ROU assets are evaluated for impairment using the long-lived assets impairment guidance.

Leases will be classified as financing or operating, which will drive the expense recognition pattern. The Company elects to exclude short-term leases if and when the Company has them.

The Company leases office and laboratory space, all of which are operating leases (see Note 6 - "Commitments and Contingencies"). Most leases include the option to renew and the exercise of the renewal options is at the Company's sole discretion. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. In addition, the Company's lease agreements generally do not contain any residual value guarantees or restrictive covenants.

The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

For real estate leases, the Company has elected the practical expedient under ASC 842 to account for the lease and non-lease components together for existing classes of underlying assets and allocates the contract consideration to the lease component only. This practical expedient is not elected for manufacturing facilities and equipment embedded in product supply arrangements.

Revenue Recognition

The Company adopted ASU 606, *Revenue for Contracts from Customers* ("ASU 606"), which amended revenue recognition principles and provides a single, comprehensive set of criteria for revenue recognition within and across all industries (see Note 7 – "License and Distribution Agreements").

The revenue standard provides a five-step framework for recognizing revenue as control of promised goods or services is transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that it determines are within the scope of the revenue standard, the Company performs the following five steps: (i) identify the contract; (ii) identify the performance obligations; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. At contract inception, the Company assesses whether the goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation, or whether they are not distinct and are combined with other goods and services until a distinct bundle is identified. The Company then determines the transaction price, which typically includes upfront payments and any variable consideration that the Company determines is probable to not cause a significant reversal in the amount of cumulative revenue recognized when the uncertainty associated with the variable consideration is resolved. The Company then allocates the transaction price to each performance obligation and recognizes the associated revenue when, or as, each performance obligation is satisfied.

The Company's distribution agreements may entitle it to additional payments upon the achievement of milestones or shares of product revenue on sales. The milestones are generally categorized into three types: development milestones, regulatory milestones and sales-based milestones. The Company evaluates whether it is probable that the consideration associated with each milestone or shared revenue payments will not be subject to a significant reversal in the cumulative amount of revenue recognized. Amounts that meet this threshold are included in the transaction price using the most likely amount method, whereas amounts that do not meet this threshold are excluded from the transaction price until they meet this threshold. At the end of each subsequent reporting period, the Company re-evaluates the probability of a significant reversal of the cumulative revenue recognized for its milestones and royalties, and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and net income (loss) in the Company's consolidated statements of operation and comprehensive loss. Typically, milestone payments and shared revenue payments are achieved after the Company's performance obligations associated with the distribution agreements have been completed and after the customer has assumed responsibility for the commercialization program. Milestones or shared revenue payments achieved after the Company's performance obligations have been completed are recognized as revenue in the period the milestone or shared revenue payments were achieved. If a milestone payment is achieved during the performance period, the milestone payment would be recognized as revenue to the extent performance had been completed at that point, and the remaining balance would be recorded as deferred revenue.

The revenue standard requires the Company to assess whether a significant financing component exists in determining the transaction price. The Company performs this assessment at the onset of its distribution agreements. Typically, a significant financing component does not exist because the customer is paying for services in advance with an upfront payment. Additionally, future shared revenue payments are not substantially within the control of the Company or the customer.

Whenever the Company determines that goods or services promised in a contract should be accounted for as a combined performance obligation over time, the Company determines the period over which the performance obligations will be performed and revenue will be recognized. Revenue is recognized using either the proportional performance method or on a straight-line basis if efforts will be expended evenly over time. Percentage of completion of patient visits in clinical trials are used as the measure of performance. The Company feels this method of measurement to be the best depiction of the transfer of services and recognition of revenue. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to

complete its performance obligations. If the Company determines that the performance obligation is satisfied over time, any upfront payment received is initially recorded as deferred revenue on its consolidated balance sheets.

Certain judgments affect the application of the Company's revenue recognition policy. For example, the Company records short-term (less than one year) and long-term (over one year) deferred revenue based on its best estimate of when such revenue will be recognized. This estimate is based on the Company's current operating plan and the Company may recognize a different amount of deferred revenue over the next 12-month period if its plan changes in the future.

Under the U.S. Commercialization and Distribution Agreement (the "US Distribution Agreement") with Nippon Shinyaku, the transaction price consists of variable shared revenue payments and fixed components in the form of an upfront payment and milestones. The timing of the fixed component of the transaction price is upfront, however, the performance obligation is satisfied over a period of time, which is the estimated duration of the HOPE-3 clinical trial, Cohort A arm. Therefore, upon receipt of the upfront payment and achievement of milestones, a contract liability is recorded which represents deferred revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the related revenue recognition.

Grant Income

Generally, government research grants that provide funding for research and development activities are recognized as income when the related expenses are incurred, as applicable. Because the terms of the grant award (the "CIRM Award") from the California Institute for Regenerative Medicine ("CIRM") allow Capricor to elect to convert the grant into a loan after the end of the project period, the CIRM Award is being classified as a liability rather than income (see Note 5 - "Government Grant Awards"). Grant income is due upon submission of a reimbursement request. The transaction price varies for grant income based on the expenses incurred under the awards. No grant income was recognized during the years ended December 31, 2023 and 2022.

Income Taxes

Income taxes are recognized for the amount of taxes payable or refundable for the current year and deferred tax liabilities and assets are recognized for the future tax consequences of transactions that have been recognized in the Company's financial statements or tax returns. A valuation allowance is provided when it is more likely than not that some portion or the entire deferred tax asset will not be realized.

The Company uses guidance issued by the FASB that clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold of more likely than not and a measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. In making this assessment, a company must determine whether it is more likely than not that a tax position will be sustained upon examination, based solely on the technical merits of the position, and must assume that the tax position will be examined by taxing authorities.

As of December 31, 2023, the Company had federal net operating loss carryforwards of approximately $106.9 million, available to reduce future taxable income, of which approximately $50.7 million will begin to expire in 2027. The post December 31, 2017 net operating losses generated of approximately $56.2 million will carryforward indefinitely, but may be subject to an 80% limitation upon utilization. As of December 31, 2023, the Company had state net operating loss carryforwards of approximately $147.3 million, available to reduce future taxable income, which will begin to expire in 2028. Utilization of these net operating losses could be limited under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), and similar state laws based on ownership changes and the value of the Company's stock. Additionally, currently, the Company has approximately $6.2 million of federal research and development credits and approximately $3.7 million of federal orphan drug credits, available to offset future taxable income. These federal research and development and orphan drug credits begin to expire in 2027 and 2035, respectively. Additionally, the Company currently has approximately $2.2 million of California research and development credits available to offset future taxable income which will carryforward indefinitely. Utilization of these credits could be limited under Section 383 of the Code and similar state laws based on ownership changes and the value of the Company's stock.

Under Section 382 of the Code, the Company's ability to utilize NOL carryforwards or other tax attributes, such as federal tax credits, in any taxable year may be limited if the Company has experienced an "ownership change." Generally, a Section 382 ownership change occurs if one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Similar rules may apply under state tax laws. We have experienced an ownership change that we believe under Section 382 of the Code will result in limitation in our ability to utilize net operating losses and credits. In addition, the Company may experience future ownership changes as a result of future offerings or other changes in ownership of its stock. As a result, the amount of the NOLs and tax credit carryforward presented in the financial statement could be limited and may expire unutilized. The Company's net operating loss carryforwards are subject to Internal Revenue Service ("IRS") examination until they are fully utilized and such tax years are closed.

The Company's policy is to include interest and penalties related to unrecognized tax benefits in income tax expense. The Company incurred no interest or penalties for the years ended December 31, 2023 and 2022. The Company files income tax returns with the IRS and the California Franchise Tax Board.

Research and Development

Costs relating to the design and development of new products are expensed as research and development as incurred in accordance with FASB ASC 730-10, *Research and Development*. Research and development costs amounted to approximately $36.4 million and $21.8 million for the years ended December 31, 2023 and 2022, respectively.

Comprehensive Income (Loss)

Comprehensive income (loss) generally represents all changes in stockholders' equity during the period except those resulting from investments by, or distributions to, stockholders. The Company's comprehensive loss was approximately $22.2 million and $28.9 million for the years ended December 31, 2023 and 2022, respectively. The Company's other comprehensive income (loss) is related to a net unrealized gain (loss) on marketable securities. For the years ended December 31, 2023 and 2022, the Company's other comprehensive income was $130,569 and $105,244, respectively.

Clinical Trial Expense

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses. Our clinical trial accrual process is designed to account for expenses resulting from our obligations under contracts with vendors, consultants, contract research organizations ("CROs"), and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our objective is to reflect the appropriate clinical trial expenses in our consolidated financial statements by matching the appropriate expenses with the period in which services are provided and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through financial models that take into account discussions with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on the facts and circumstances known to us at that time. Our clinical trial accrual and prepaid assets are dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Although we do not expect our estimates to be materially different from amounts actually incurred, 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 us reporting amounts that are too high or too low for any particular period.

Stock-Based Compensation

The Company accounts for stock-based employee compensation arrangements in accordance with guidance issued by the FASB, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, consultants, and directors based on estimated fair values.

The Company estimates the fair value of stock-based compensation awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in the Company's statements of operations and comprehensive loss. The Company estimates the fair value of stock-based compensation awards using the Black-Scholes model. This model requires the Company to estimate the expected volatility and value of its common stock and the expected term of the stock options, all of which are highly complex and subjective variables. The variables take into consideration, among other things, actual and projected stock option exercise behavior. For employees and directors, the expected life was calculated based on the simplified method as described by the SEC Staff Accounting Bulletin No. 110, Share-Based Payment. For other service providers, the expected life was calculated using the contractual term of the award. The Company's estimate of expected volatility was based on the historical stock price of the Company. The Company has selected a risk-free rate based on the implied yield available on U.S. Treasury securities with a maturity equivalent to the expected term of the options.

Basic and Diluted Loss per Share

The Company reports earnings per share in accordance with FASB ASC 260-10, *Earnings per Share.* Basic earnings (loss) per share is computed by dividing income (loss) available to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share is computed similarly to basic earnings (loss) per share except that the denominator is increased to include the number of additional shares of common stock that would have been outstanding if the potential shares of common stock had been issued and if the additional shares of common stock were dilutive.

For the years ended December 31, 2023 and 2022, warrants and options to purchase 13,268,807 and 5,882,621 shares of common stock, respectively, have been excluded from the computation of potentially dilutive securities. Potentially dilutive shares of common stock, which primarily consist of stock options issued to employees, consultants, and directors as well as warrants issued, have been excluded from the diluted loss per share calculation because their effect is anti-dilutive. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between basic and diluted loss per share for the years ended December 31, 2023 and 2022.

Fair Value Measurements

Assets and liabilities recorded at fair value in the balance sheet are categorized based upon the level of judgment associated with the inputs used to measure their fair value. The categories are as follows:

Level Input:	Input Definition:
Level I	Inputs are unadjusted, quoted prices for identical assets or liabilities in active markets at the measurement date.
Level II	Inputs, other than quoted prices included in Level I, that are observable for the asset or liability through corroboration with market data at the measurement date.
Level III	Unobservable inputs that reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date.

The following table summarizes the fair value measurements by level at December 31, 2023 and 2022 for assets and liabilities measured at fair value on a recurring basis:

	December 31, 2023			
	Level I	Level II	Level III	Total
Marketable Securities	$ 24,792,846	$ —	$ —	$ 24,792,846

	December 31, 2022			
	Level I	Level II	Level III	Total
Marketable Securities	$ 31,818,020	$ —	$ —	$ 31,818,020

Carrying amounts reported in the balance sheet of cash and cash equivalents, receivables, accounts payable and accrued expenses approximate fair value due to their relatively short maturity. The carrying amounts of the Company's marketable securities are based on market quotations from national exchanges at the balance sheet date. Interest and dividend income are recognized separately on the income statement based on classifications provided by the brokerage firm holding the investments. The fair value of borrowings is not considered to be significantly different from its carrying amount because the stated rates for such debt reflect current market rates and conditions.

Recent Accounting Pronouncements

In October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*. This standard was issued in response to the SEC's disclosure update and simplification initiative, which affects a variety of topics within the Accounting Standards Codification. The amendments apply to all reporting entities within the scope of the affected topics unless otherwise indicated. The effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. The Company is currently evaluating the impact this guidance will have on its financial statement disclosures.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the SEC, did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statement presentation or disclosures.

2. STOCKHOLDERS' EQUITY

ATM Program

The Company established an "at-the-market" program (the "ATM Program") on June 21, 2021, with an aggregate offering price of up to $75.0 million, pursuant to a Common Stock Sales Agreement with Wainwright by which Wainwright has sold and may continue to sell our common stock at the market prices prevailing at the time of sale. Wainwright is entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold plus reimbursement of certain expenses.

From June 21, 2021 through December 31, 2023, the Company sold an aggregate of 2,976,154 shares of common stock under the ATM Program at an average price of approximately $5.59 per share for gross proceeds of approximately $16.6 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses to Wainwright, as well as legal and accounting fees in the aggregate amount of approximately $0.6 million. As of the date of this filing, approximately $57.2 million of common stock may still be sold pursuant to the ATM Program. Additionally, subsequent to December 31, 2023, the Company sold shares under the ATM Program (see Note 9 – "Subsequent Events").

October 2023 Financing

On October 3, 2023, the Company entered into Securities Purchase Agreements with its commercial partner, Nippon Shinyaku and funds associated with Highbridge Capital Management, LLC (the "Investors"), pursuant to which the Company agreed to issue and sell to the Investors, in a registered direct offering (the "Registered Direct Offering"), an aggregate of 4,935,621 shares of its common stock, par value $0.001 per share, at a price per share of $4.66 for an aggregate purchase price of approximately $23.0 million. Each share of common stock offered was sold with a warrant to purchase one share of common stock at an exercise price of $5.70 per share. Each warrant will be exercisable beginning six months after issuance and will expire seven years from the date of issuance. As part of the Registered Direct Offering, the Company agreed not to issue or sell shares (subject to customary exceptions for employee stock option issuances and other customary exceptions) for a period of 30 days following the date of the prospectus supplement that was used in the Registered Direct Offering. That prospectus was dated September 29, 2023, and the Company "lock-up" expired on October 29, 2023. The Company's directors and executive officers also entered into "lock-up" agreements with the

placement agent in the Registered Direct Offering, which agreements expired on the 60th day following the date of the Securities Purchase Agreements, or December 2, 2023.

Outstanding Shares

At December 31, 2023, the Company had 31,148,320 shares of common stock issued and outstanding.

3. STOCK AWARDS, WARRANTS AND OPTIONS

Warrants

The following table summarizes all warrant activity for the years ended December 31, 2023 and 2022:

	Warrants	Weighted Average Exercise Price
Outstanding at January 1, 2022	105,782	$ 1.37
Granted	—	—
Exercised	—	—
Outstanding at December 31, 2022	105,782	$ 1.37
Granted	4,935,621	5.70
Exercised	—	—
Outstanding at December 31, 2023	5,041,403	$ 5.61

The following table summarizes all outstanding warrants to purchase shares of the Company's common stock:

		Warrants Outstanding			
Type	Grant Date	December 31, 2023	December 31, 2022	Exercise Price per Share	Expiration Date
Common Warrants	12/19/2019	40,782	40,782	$ 1.10	12/19/2024
Common Warrants	3/27/2020	65,000	65,000	$ 1.5313	3/27/2025
Common Warrants	10/3/2023	4,935,621	—	$ 5.70	10/3/2030
		5,041,403	105,782		

Stock Options

The Company's Board of Directors (the "Board") has approved five stock option plans: (i) the 2006 Stock Option Plan, (ii) the 2012 Restated Equity Incentive Plan (which superseded the 2006 Stock Option Plan) (the "2012 Plan"), (iii) the 2012 Non-Employee Director Stock Option Plan (the "2012 Non-Employee Director Plan"), (iv) the 2020 Equity Incentive Plan (the "2020 Plan"), and (v) the 2021 Equity Incentive Plan (the "2021 Plan"). At this time, the Company only issues options under the 2020 Plan and the 2021 Plan and no longer issues options under the 2006 Stock Option Plan, the 2012 Plan, or the 2012 Non-Employee Director Plan.

In June 2020, the Company's stockholders approved the 2020 Equity Incentive Plan (the "2020 Plan"), which authorized 2,500,000 shares of common stock to be issued and allows for the grant of stock options as well as other forms of equity-based compensation. Pursuant to the "evergreen" provision, on January 1, 2021, 823,084 shares were added under the 2020 Plan. Once the 2021 Plan was approved on June 11, 2021, no new shares were added to the share reserve under the 2020 Plan pursuant to its "evergreen" provisions.

In June 2021, the Company's stockholders approved the 2021 Plan, which authorized 3,500,000 shares of common stock reserved under the 2021 Plan for the issuance of stock awards. The number of shares available for issuance under the 2021 Plan shall be automatically increased on January 1 of each year, commencing with January 1, 2022, by an amount equal to the lesser of 5% of the outstanding shares of Common Stock as of the last day of the immediately preceding

fiscal year or such number of shares determined by the compensation committee of the Board. On January 1, 2024 and 2023, 1,557,416 and 1,262,070 shares were added under the 2021 Plan, respectively.

As of December 31, 2023, 1,232,318 options remain available for issuance under the respective stock option plans.

The Company's stock option plans are administered by the Board, in conjunction with the compensation committee of the Board, which determines the recipients and types of awards to be granted, as well as the number of shares subject to the awards, the exercise price and the vesting schedule. Each stock option granted will be designated in the award agreement as either an incentive stock option or a nonstatutory stock option. Notwithstanding such designation, however, to the extent that the aggregate fair market value of the shares with respect to which incentive stock options are exercisable for the first time by the participant during any calendar year (under all plans of the Company and any parent or subsidiary) exceeds $100,000, such options will be treated as nonstatutory stock options. Stock options are granted with an exercise price not less than equal to the closing price of the Company's common stock on the date of grant, and generally vest over a period of one to four years. The term of stock options granted under each of the plans cannot exceed ten years.

The estimated weighted average fair value of the options granted during 2023 and 2022 were approximately $3.85 and $3.04 per share, respectively.

The Company estimates the fair value of each option award using the Black-Scholes option-pricing model. The company used the following assumptions to estimate the fair value of stock options issued during the year ended December 31, 2023 and 2022:

	Year ended December 31,	
	2023	2022
Expected volatility	111 - 121 %	123 - 124 %
Expected term	5 - 7 years	6 - 7 years
Dividend yield	0 %	0 %
Risk-free interest rates	3.5 - 4.5 %	1.5 - 3.9 %

Employee and non-employee stock-based compensation expense was as follows:

	Year ended December 31,	
	2023	2022
General and administrative	$ 5,476,151	$ 3,653,489
Research and development	1,916,245	805,089
Total	$ 7,392,396	$ 4,458,578

The Company does not recognize an income tax benefit as the Company believes that an actual income tax benefit may not be realized. For non-qualified stock options, the loss creates a timing difference, resulting in a deferred tax asset, which is fully reserved by a valuation allowance.

Common stock, stock options or other equity instruments issued to non-employees (including consultants) as consideration for goods or services received by the Company are accounted for based on the fair value of the equity instruments issued. The fair value of stock options is determined using the Black-Scholes option-pricing model. The Company calculates the fair value for non-qualified options as of the date of grant and expenses over the applicable vesting periods. The Company accounts for forfeitures upon occurrence.

The following table summarizes information about stock options outstanding and exercisable at December 31, 2023:

Options Outstanding			
Range of Ex. Prices	Options Outstanding	Weighted Average Term (yrs.)	Weighted Average Exercise Price
$1.39	1,600,054	5.71	$ 1.39
$2.54 - $3.41	1,889,562	8.14	3.19
$3.61 - $3.85	3,004,621	8.17	3.80
$4.11 - $7.14	1,733,167	9.02	5.08
	8,227,404		$ 3.46

Options Exercisable			
Range of Ex. Prices	Options Exercisable	Weighted Average Term (yrs.)	Weighted Average Exercise Price
$1.39	1,544,732	5.69	$ 1.39
$2.54 - $3.41	845,993	8.00	3.18
$3.61 - $3.85	1,601,850	7.85	3.79
$4.11 - $7.14	255,561	7.49	5.16
	4,248,136		$ 2.88

As of December 31, 2023, the total unrecognized fair value compensation cost related to non-vested stock options was approximately $13.5 million, which is expected to be recognized over a weighted average period of approximately 1.5 years.

The following is a schedule summarizing employee and non-employee stock option activity for the years ended December 31, 2023 and 2022:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at January 1, 2022	3,793,824	$ 2.68	
Granted	2,817,370	3.46	
Exercised	(325,667)	1.37	$ 867,854
Expired/Cancelled	(508,688)	4.55	
Outstanding at December 31, 2022	5,776,839	$ 2.97	
Granted	3,420,979	4.32	
Exercised	(182,405)	2.55	$ 367,422
Expired/Cancelled	(788,009)	3.82	
Outstanding at December 31, 2023	8,227,404	$ 3.46	$ 12,493,414
Exercisable at December 31, 2023	4,248,136	$ 2.88	$ 8,636,326

The aggregate intrinsic value represents the difference between the exercise price of the options and the estimated fair value of the Company's common stock for each of the respective periods.

4. CONCENTRATIONS

Concentration of Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash, cash equivalents, and marketable securities. The Company maintains accounts at three financial institutions. These accounts are insured by the Federal Deposit Insurance Corporation (the "FDIC") for up to $250,000 and/or the Securities Investor Protection Corporation, as applicable. The Company's cash, cash equivalents, and marketable securities in excess of the FDIC insured limits as of December 31, 2023, were approximately $39.2 million. The Company monitors the financial stability of the financial institutions with which it maintains accounts and believes it is not exposed to any significant credit risk in cash and cash equivalents. Historically, the Company has not experienced any significant losses

in such accounts and does not believe it is exposed to any significant credit risk due to the quality nature of the financial instruments in which the money is held.

5. GOVERNMENT GRANT AWARDS

CIRM Grant Award (HOPE)

On June 16, 2016, Capricor entered into the CIRM Award with CIRM in the amount of approximately $3.4 million to fund, in part, Capricor's Phase 1/2 HOPE-Duchenne clinical trial investigating CAP-1002 for the treatment of DMD-associated cardiomyopathy. Pursuant to terms of the CIRM Award, the disbursements were tied to the achievement of specified operational milestones. In addition, the terms of the CIRM Award included a co-funding requirement pursuant to which Capricor was required to spend approximately $2.3 million of its own capital to fund the CIRM funded research project. The CIRM Award is further subject to the conditions and requirements set forth in the CIRM Grants Administration Policy for Clinical Stage Projects. Such requirements include, without limitation, the filing of quarterly and annual reports with CIRM, the sharing of intellectual property pursuant to Title 17, California Code of Regulations (CCR) Sections 100600-100612, and the sharing with the State of California of a fraction of licensing revenue received from a CIRM funded research project and net commercial revenue from a commercialized product which resulted from the CIRM funded research as set forth in Title 17, CCR Section 100608. The maximum royalty on net commercial revenue that Capricor may be required to pay to CIRM is equal to nine times the total amount awarded and paid to Capricor.

After completing the CIRM funded research project and at any time after the award period end date (but no later than the ten-year anniversary of the date of the award), Capricor has the right to convert the CIRM Award into a loan, the terms of which will be determined based on various factors, including the stage of the research and development of the program at the time the election is made. On June 20, 2016, Capricor entered into a Loan Election Agreement with CIRM whereby, among other things, CIRM and Capricor agreed that if Capricor elects to convert the grant into a loan, the term of the loan could be up to five years from the date of execution of the applicable loan agreement; provided that the maturity date of the loan will not surpass the ten-year anniversary of the grant date of the CIRM Award. Beginning on the date of the loan, the loan shall bear interest on the unpaid principal balance, plus the interest that has accrued prior to the election point according to the terms set forth in the CIRM Loan Policy and CIRM Grants Administration Policy for Clinical Stage Projects (the "New Loan Balance"), at a per annum rate equal to the LIBOR rate for a three-month deposit in U.S. dollars, as published by the Wall Street Journal on the loan date, plus one percent. Interest shall be compounded annually on the outstanding New Loan Balance commencing with the loan date and the interest shall be payable, together with the New Loan Balance, upon the due date of the loan. If Capricor elects to convert the CIRM Award into a loan, certain requirements of the CIRM Award will no longer be applicable, including the revenue sharing requirements. Capricor has not yet made its decision as to whether it will elect to convert the CIRM Award into a loan. Depending on the timing of our election, additional funds may be owed. If we elect to do so, Capricor would be required to repay the amounts awarded by CIRM; therefore, the Company accounts for this award as a liability rather than income.

In 2019, Capricor completed all milestones and close-out activities associated with the CIRM Award and expended all funds received. As of December 31, 2023, Capricor's liability balance for the CIRM Award was approximately $3.4 million.

6. COMMITMENTS AND CONTINGENCIES

Short-Term Operating Leases

Capricor leases office space in Beverly Hills, California from The Bubble Real Estate Company, LLC ("Bubble Real Estate") pursuant to a lease beginning in 2013. Capricor subsequently entered into several amendments modifying certain terms of the lease. Effective January 1, 2021, we entered into a month-to-month lease amendment with Bubble Real Estate, which is terminable by either party upon 90 days' written notice to the other party. Commencing in July 2022, the monthly lease payment was $7,869 per month. Effective July 1, 2023, the monthly lease payment was reduced to $7,619 per month.

Expenses incurred under short-term operating leases for the years ended December 31, 2023 and 2022 were $92,928 and $81,735, respectively.

Long-Term Operating Leases

Capricor leases facilities in Los Angeles, California from Cedars-Sinai Medical Center ("CSMC"), a related party (see Note 8 – "Related Party Transactions"), pursuant to a lease (the "Facilities Lease") entered into in 2014. Capricor has subsequently entered into several amendments modifying certain terms of the lease. In July 2022, we entered into an amendment for an additional 24-month period extending the term through July 31, 2024 with a monthly lease payment of $10,707. Additionally, in September 2023, we entered into an amendment pursuant to which Capricor was granted an option to extend the lease for an additional 24-month period extending the term through July 31, 2026 with a monthly lease payment of $11,028 commencing on August 1, 2024.

The Company entered into a lease agreement commencing October 1, 2021 with Altman Investment Co, LLC ("Altman") for 9,396 square feet of office and laboratory space located at 10865 Road to the Cure, Suite 150, in San Diego, California (the "San Diego Lease"). The rent is subject to a 3.0% annual rent increase during the initial lease term of five years, plus certain operating expenses and taxes. The San Diego Lease contains an option for Capricor to renew it for an additional term of five years. The Company has subsequently entered into several amendments to the San Diego Lease increasing the square footage of the premises and effective July 1, 2022, the monthly lease payment was increased to $49,322 per month. Effective December 1, 2022, the monthly lease payment was increased to $51,444 per month. Effective October 1, 2023, the monthly lease payment was increased to $58,409 per month.

Effective November 1, 2021, the Company entered into a vivarium agreement with Explora BioLabs, Inc. ("Explora"), a Charles River Company, for vivarium space and services. Under the terms of the agreement, the Company is obligated to pay a base rent of $4,021 per month for an exclusive large vivarium room located in San Diego, California. The lease term is for one-year and will automatically renew for additional successive one-year renewal terms unless either party provides the other party with 60-day written notice of its election not to renew prior to the end of the then-current term. In December 2022, we were notified by Explora of a monthly rent escalation of 4.5% bringing the base rent to approximately $4,202 per month effective January 1, 2023. For ASC 842 purposes, we applied a lease term of five years.

The long-term real estate operating leases are included in "lease right-of-use assets, net" on the Company's Consolidated Balance Sheet and represent the Company's right-to-use the underlying assets for the lease term. The Company's obligation to make lease payments are included in "lease liabilities, current" and "lease liabilities, net of current" on the Company's Consolidated Balance Sheet.

The table below excludes short-term operating leases. The following table summarizes maturities of lease liabilities and the reconciliation of lease liabilities as of December 31, 2023:

2024	$ 886,672
2025	910,106
2026	676,908
2027	—
2028	—
Total minimum lease payments	2,473,686
Less: imputed interest	(237,791)
Total operating lease liabilities	$ 2,235,895
Included in the consolidated balance sheet:	
Current portion of lease liabilities	$ 749,112
Lease liabilities, net of current	1,486,783
Total operating lease liabilities	$ 2,235,895
Other Information:	
Weighted average remaining lease term	2.73 years
Weighted average discount rate	7.24%

As of December 31, 2023, ROU assets for operating leases were approximately $2.1 million and operating lease liabilities were approximately $2.2 million. The following table contains a summary of the lease costs recognized and lease payments pertaining to the Company's operating leases under ASC 842 for the period indicated:

	Year ended December 31,	
	2023	2022
Lease costs, unrelated parties	$ 663,684	$ 632,689
Lease costs, related parties	129,158	128,478
Lease payments, unrelated parties	684,444	470,950
Lease payments, related parties	117,772	128,478

Legal Contingencies

The Company is not a party to any material legal proceedings at this time. From time to time, the Company may become involved in various legal proceedings that arise in the ordinary course of its business or otherwise. The Company records a loss contingency reserve for a legal proceeding when it considers the potential loss probable and it can reasonably estimate the amount of the loss or determine a probable range of loss. The Company has not recorded any material accruals for loss contingencies as of December 31, 2023. The Company has received a letter from CSMC alleging certain overdue payment obligations and alleged breaches (see Note 7 – "License and Distribution Agreements").

Accounts Payable

During the normal course of business, disputes with vendors may arise. If a vendor disputed payment is probable and able to be estimated, we will record an estimated liability.

Other Funding Commitments

The Company is a party to various agreements, principally relating to licensed technology, that require future payments relating to milestones that may be met in subsequent periods or royalties on future sales of specific products (see Note 7 - "License and Distribution Agreements").

Additionally, the Company is a party to various agreements with contract research, manufacturing and other organizations that generally provide for termination upon notice, with the exact amounts owed in the event of termination to be based on the timing of termination and the terms of the agreement.

Employee Severances

The Board of Directors approves severance packages for specific full-time employees based on their length of service and position ranging up to six months of their base salaries, in the event of termination of their employment, subject to certain conditions. No liability under these severance packages has been recorded as of December 31, 2023.

7. LICENSE AND DISTRIBUTION AGREEMENTS

Intellectual Property Rights for Capricor's Technology - CAP-1002 and Exosomes

Capricor has entered into exclusive license agreements for intellectual property rights related to certain cardiac-derived cells with Università Degli Studi Di Roma La Sapienza (the "University of Rome"), JHU and CSMC. Capricor has also entered into an exclusive license agreement for intellectual property rights related to exosomes with CSMC and JHU. In addition, Capricor has filed patent applications related to the technology developed by its own scientists.

University of Rome License Agreement

Capricor and the University of Rome entered into a License Agreement, dated June 21, 2006 (the "Rome License Agreement"), which provides for the grant of an exclusive, world-wide, royalty-bearing license by the University of Rome

to Capricor (with the right to sublicense) to develop and commercialize licensed products under the licensed patent rights in all fields.

Pursuant to the Rome License Agreement, Capricor paid the University of Rome a license issue fee, is currently paying minimum annual royalties in the amount of 20,000 Euros per year, and is obligated to pay a lower-end of a mid-range double-digit percentage on all royalties received as a result of sublicenses granted, which are net of any royalties paid to third parties under a license agreement from such third-party to Capricor. The minimum annual royalties are creditable against future royalty payments.

The Rome License Agreement will, unless extended or sooner terminated, remain in effect until the later of the last claim of any patent or until any patent application comprising licensed patent rights has expired or been abandoned. Under the terms of the Rome License Agreement, either party may terminate the agreement should the other party become insolvent or file a petition in bankruptcy. Either party may terminate the agreement upon the other party's material breach, provided that the breaching party will have up to 90 days to cure its material breach. Capricor may also terminate for any reason upon 90 days' written notice to the University of Rome.

The Johns Hopkins University License Agreements

License Agreement for CDCs

Capricor and JHU entered into an Exclusive License Agreement, effective June 22, 2006 (the "JHU License Agreement"), which provides for the grant of an exclusive, world-wide, royalty-bearing license by JHU to Capricor (with the right to sublicense) to develop and commercialize licensed products and licensed services under the licensed patent rights in all fields and a nonexclusive right to the know-how. Various amendments were entered into to revise certain provisions of the JHU License Agreement. Under the JHU License Agreement, Capricor is required to exercise commercially reasonable and diligent efforts to develop and commercialize licensed products covered by the licenses from JHU.

Pursuant to the JHU License Agreement, JHU was paid an initial license fee and, thereafter, Capricor is required to pay minimum annual royalties on the anniversary dates of the JHU License Agreement. The minimum annual royalties are creditable against a low single-digit running royalty on net sales of products and net service revenues, which Capricor is also required to pay under the JHU License Agreement, which running royalty may be subject to further reduction in the event that Capricor is required to pay royalties on any patent rights to third parties in order to make or sell a licensed product. In addition, Capricor is required to pay a low double-digit percentage of the consideration received by it from sublicenses granted and is required to pay JHU certain defined development milestone payments upon the successful completion of certain phases of its clinical studies and upon receiving approval from the FDA. The maximum aggregate amount of milestone payments payable under the JHU License Agreement, as amended, is $1,850,000. In March 2022, Capricor paid the $250,000 development milestone related to the Phase 2 study pursuant to the terms of the JHU License Agreement. The next milestone is triggered upon successful completion of a full Phase 3 study for which a payment of $500,000 will be due.

The JHU License Agreement will, unless sooner terminated, continue in effect in each applicable country until the date of expiration of the last to expire patent within the patent rights, or, if no patents are issued, then for twenty years from the effective date. Under the terms of the JHU License Agreement, either party may terminate the agreement should the other party become insolvent or file a petition in bankruptcy or fail to cure a material breach within 30 days after notice. In addition, Capricor may terminate for any reason upon 60 days' written notice.

License Agreement for Exosome-based Vaccines and Therapeutics

Capricor and JHU entered into an Exclusive License Agreement (the "JHU Exosome License Agreement"), effective April 28, 2021 for its co-owned interest in certain intellectual property rights related to exosome-mRNA vaccines and therapeutics. The JHU Exosome License Agreement provided for the grant of an exclusive, world-wide, royalty-bearing license of JHU's co-owned rights by JHU to Capricor, with the right to sublicense, in order to conduct research using the patent rights and know-how and to develop and commercialize products in the field using the patent rights and know-how. The JHU Exosome License Agreement was terminated by Capricor on December 15, 2023.

Cedars-Sinai Medical Center License Agreements

License Agreement for CDCs

On January 4, 2010, Capricor entered into an Exclusive License Agreement with CSMC (the "Original CSMC License Agreement"), for certain intellectual property related to its CDC technology. In 2013, the Original CSMC License Agreement was amended twice resulting in, among other things, a reduction in the percentage of sublicense fees which would have been payable to CSMC. Effective December 30, 2013, Capricor entered into an Amended and Restated Exclusive License Agreement with CSMC (the "Amended CSMC License Agreement"), which amended, restated, and superseded the Original CSMC License Agreement, pursuant to which, among other things, certain definitions were added or amended, the timing of certain obligations was revised and other obligations of the parties were clarified.

The Amended CSMC License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by CSMC to Capricor (with the right to sublicense) to conduct research using the patent rights and know-how and develop and commercialize products in the field using the patent rights and know-how. In addition, Capricor has the exclusive right to negotiate for an exclusive license to any future rights arising from related work conducted by or under the direction of Dr. Eduardo Marbán on behalf of CSMC. In the event the parties fail to agree upon the terms of an exclusive license for any future rights, Capricor will have a non-exclusive license to such future rights, subject to royalty obligations.

Pursuant to the Original CSMC License Agreement, CSMC was paid a license fee and Capricor was obligated to reimburse CSMC for certain fees and costs incurred in connection with the prosecution of certain patent rights. Additionally, Capricor is required to meet certain spending and development milestones.

Pursuant to the Amended CSMC License Agreement, Capricor remains obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a low double-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third-party for patent rights in connection with the royalty-bearing product.

The Amended CSMC License Agreement will, unless sooner terminated, continue in effect on a country by country basis until the last to expire of the patents covering the patent rights or future patent rights. Under the terms of the Amended CSMC License Agreement, unless waived by CSMC, the agreement shall automatically terminate: (i) if Capricor ceases, dissolves or winds up its business operations; (ii) in the event of the insolvency or bankruptcy of Capricor or if Capricor makes an assignment for the benefit of its creditors; (iii) if performance by either party jeopardizes the licensure, accreditation or tax exempt status of CSMC or the agreement is deemed illegal by a governmental body; (iv) within 30 days for non-payment of royalties; (v) after 90 days' notice from CSMC if Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights; (vi) if a material breach has not been cured within 90 days; or (vii) if Capricor challenges any of the CSMC patent rights. If Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights, and fails to cure that breach after 90 days' notice from CSMC, instead of terminating the license, CSMC has the option to convert any exclusive license to Capricor to a non-exclusive or co-exclusive license. Capricor may terminate the agreement if CSMC fails to cure any material breach within 90 days after notice.

Capricor and CSMC have entered into several amendments to the Amended CSMC License Agreement, pursuant to which the parties agreed to add and delete certain patent applications from the list of scheduled patents and extend the timing of certain development milestones, among other things. Capricor reimbursed CSMC for certain attorneys' fees and filing fees incurred in connection with the additional patent applications.

We recently received a letter from CSMC alleging that pursuant to the Amended CSMC License Agreement between CSMC and Capricor, Capricor has certain overdue payment obligations to CSMC arising out of a milestone payment received by Capricor pursuant to the U.S. Distribution Agreement entered into between Capricor and Nippon Shinyaku. Capricor has received a milestone payment of $10.0 million under its U.S. Distribution Agreement with Nippon Shinyaku, which CSMC is claiming 10% of this milestone payment is owed to them. The notice letter requests that Capricor cure the alleged breaches of the Amended CSMC License Agreement, and reserves CMSC's purported right to terminate the Amended CSMC License Agreement if such alleged breaches are not cured. We dispute the allegations in

the letter from CSMC and intend to vigorously defend our position and pursue all available remedies, but there is no guarantee that any disputes that we have with CSMC will be resolved or if resolved, will not result in our incurring certain payment and other obligations.

License Agreement for Exosomes

On May 5, 2014, Capricor entered into an Exclusive License Agreement with CSMC (the "Exosomes License Agreement"), for certain intellectual property rights related to CDC-derived exosomes technology. The Exosomes License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by CSMC to Capricor (with the right to sublicense) in order to conduct research using the patent rights and know-how and to develop and commercialize products in the field using the patent rights and know-how. In addition, Capricor has the exclusive right to negotiate for an exclusive license to any future rights arising from related work conducted by or under the direction of Dr. Eduardo Marbán on behalf of CSMC. In the event the parties fail to agree upon the terms of an exclusive license, Capricor shall have a non-exclusive license to such future rights, subject to royalty obligations.

Pursuant to the Exosomes License Agreement, CSMC was paid a license fee and Capricor reimbursed CSMC for certain fees and costs incurred in connection with the preparation and prosecution of certain patent applications. Additionally, Capricor is required to meet certain non-monetary development milestones and is obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a single-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third-party for patent rights in connection with the royalty bearing product.

The Exosomes License Agreement will, unless sooner terminated, continue in effect on a country by country basis until the last to expire of the patents covering the patent rights or future patent rights. Under the terms of the Exosomes License Agreement, unless waived by CSMC, the agreement shall automatically terminate: (i) if Capricor ceases, dissolves or winds up its business operations; (ii) in the event of the insolvency or bankruptcy of Capricor or if Capricor makes an assignment for the benefit of its creditors; (iii) if performance by either party jeopardizes the licensure, accreditation or tax exempt status of CSMC or the agreement is deemed illegal by a governmental body; (iv) within 30 days for non-payment of royalties; (v) after 90 days if Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights; (vi) if a material breach has not been cured within 90 days; or (vii) if Capricor challenges any of the CSMC patent rights. If Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights and fails to cure that breach after 90 days' notice from CSMC, instead of terminating the license, CSMC has the option to convert any exclusive license to Capricor to a non-exclusive or co-exclusive license. Capricor may terminate the agreement if CSMC fails to cure any material breach within 90 days after notice.

Capricor and CSMC have entered into several amendments to the Exosomes License Agreement. Collectively, these amendments added additional patent applications and patent families to the Exosomes License Agreement, added certain defined product development milestone payments, modified certain milestone deadlines, added certain performance milestones with respect to product candidates covered by certain future patent rights in order to maintain an exclusive license to those future patent rights, and converted certain exclusive rights to co-exclusive rights. These amendments also obligated Capricor to reimburse CSMC for certain attorneys' fees and filing fees in connection with the additional patent applications and patent families.

Cell Line License Agreement with Life Technologies

On March 7, 2022, Capricor entered into a non-exclusive cell line license agreement with Life Technologies Corporation, a subsidiary of Thermo Fisher Scientific, Inc., for the supply of certain cells which we will use in connection with the development of our exosomes platform. An initial license fee payment was made in 2022 and additional milestone fees may become due based on the progress of our development program.

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: United States)

On January 24, 2022, Capricor entered into a Commercialization and Distribution Agreement (the "U.S. Distribution Agreement") with Nippon Shinyaku, a Japanese corporation. Under the terms of the U.S. Distribution

Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in the United States of CAP-1002 for the treatment of DMD.

Under the terms of the U.S. Distribution Agreement, Capricor will be responsible for the conduct of the HOPE-3 trial as well as the manufacturing of CAP-1002. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in the United States. Pursuant to the U.S Distribution Agreement, Capricor received an upfront payment of $30.0 million in the first quarter of 2022. The first milestone payment of $10.0 million was paid upon completion of the interim futility analysis of the HOPE-3 trial whereby the outcome was determined to be not futile. Additionally, there are potential milestones totaling up to $90.0 million leading up to and including the BLA approval. Further, there are various potential sales-based milestones, if commercialized, tied to the achievement of certain sales thresholds for annual net sales of CAP-1002 of up to $605.0 million. Further, pursuant to the U.S. Distribution Agreement, Capricor has the obligation to sell commercial product to Nippon Shinyaku, subject to regulatory approval, and Capricor will have the right to receive a meaningful mid-range double-digit share of product revenue.

The Company has evaluated the U.S. Distribution Agreement in accordance with ASU 606, *Revenue for Contracts from Customers*. At the inception, the Company identified one distinct performance obligation. The Company determined that the performance obligation is the conduct of the HOPE-3, Phase 3 clinical study.

The Company determined the transaction price totaled $40.0 million, which was the upfront payment of $30.0 million and $10.0 million milestone payment. The Company has excluded any future milestone or shared revenue payments from this transaction price to date based on probability. The Company has allocated the $40.0 million transaction price to its one distinct performance obligation. Revenue will be recognized using a proportional performance method in relation to the completion of the HOPE-3 clinical study, Cohort A arm, to determine the extent of progress towards completion. Under this method, the transaction price is recognized over the contract's entire performance period using a cost percentage per patient visit relative to the total estimated cost of patient visits.

For the year ended December 31, 2023, the Company recognized approximately $25.2 million as revenue compared to approximately $2.6 million for the year ended December 31, 2022. In relation to the U.S. Distribution Agreement, as of December 31, 2023, the Company recorded approximately $12.3 million as current deferred revenue on the Company's consolidated balance sheets. As of December 31, 2023, the Company recorded a receivable of $10.0 million in connection with the interim futility milestone, which payment was received in January 2024.

The Company had no opening or closing contract asset balances recognized. The difference between the opening and closing balances of the Company's contract liability results from the Company performance of services in connection to its performance obligation.

The transaction price allocated to remaining performance obligations represents contracted revenue that has not yet been recognized. As of December 31, 2023, remaining performance obligations related to the U.S. Distribution Agreement were approximately $12.3 million. At this time, we estimate 100% of the remaining performance obligations are expected to be recognized over the next 12 months. Remaining performance obligations estimates are subject to change.

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: Japan)

On February 10, 2023, Capricor entered into a Commercialization and Distribution Agreement (the "Japan Distribution Agreement") with Nippon Shinyaku. Under the terms of the Japan Distribution Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in Japan of CAP-1002 for the treatment of DMD.

Under the terms of the Japan Distribution Agreement, Capricor received an upfront payment of $12.0 million in the first quarter of 2023 and in addition, Capricor may potentially receive additional development and sales-based milestone payments of up to approximately $89.0 million, subject to foreign currency exchange rates, and a meaningful double-digit share of product revenue. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in Japan. Capricor will be responsible for the conduct of clinical development in Japan, as may be required, as well as the manufacturing of CAP-1002. Subject to regulatory approval, Capricor will sell commercial product to Nippon Shinyaku in Japan. In addition, Capricor or its designee will hold the Marketing Authorization in Japan if the product is approved in that territory.

The Company has evaluated the Japan Distribution Agreement in accordance with ASU 606, *Revenue for Contracts from Customers*. The Company determined the initial transaction price totaled $12.0 million, which was the upfront payment fee. The Company has excluded any future milestone or shared revenue payments from this transaction price to date based on probability. At this time, the Company is evaluating the regulatory pathway to achieve potential product approval in this territory. Until such time, the Company cannot identify any distinct performance obligation. As such, the Company has recorded the entire upfront payment fee of $12.0 million as current deferred revenue on the Company's consolidated balance sheets as of December 31, 2023.

8. RELATED PARTY TRANSACTIONS

Lease and Sub-Lease Agreement

As noted above, Capricor is a party to lease agreements with CSMC (see Note 6 – "Commitments and Contingencies"), and CSMC has served as an investigative site in Capricor's clinical trials. Additionally, Dr. Eduardo Marbán, who is a stockholder of Capricor Therapeutics and has participated from time to time as an observer at the Company's meetings of the Board of Directors, is the Director of the Cedars-Sinai Smidt Heart Institute, and co-founder of Capricor.

Consulting Agreements

In 2013, Capricor entered into a Consulting Agreement with Dr. Frank Litvack, the Company's Executive Chairman and a member of its Board of Directors, whereby Capricor agreed to pay Dr. Litvack $10,000 per month for consulting services. The agreement is terminable upon 30 days' notice.

In July 2020, Capricor entered into an Advisory Services Agreement with Dr. Eduardo Marbán whereby he was granted an option to purchase 50,000 shares of the Company's common stock. Additionally, in January 2022, Dr. Eduardo Marbán was granted an additional option grant to purchase 50,000 shares of the Company's common stock.

In January 2024, Capricor entered into a Consulting Agreement with Michael Kelliher, a member of its Board of Directors, related to business development services whereby he was granted an option to purchase 30,000 shares of the Company's common stock.

Payables to Related Party

As of December 31, 2023 and 2022, the Company had accounts payable and accrued expenses to related parties totaling $27,479 and $89,234, respectively. CSMC accounts for $17,479 and $79,234 of the total accounts payable and accrued expenses to related parties as of December 31, 2023 and December 31, 2022, respectively. CSMC expenses relate to research and development costs, clinical trial costs, license and patent fees, and facilities rent. During the years ended December 31, 2023 and 2022, the Company paid CSMC approximately $226,400 and approximately $794,000, respectively, for such costs.

9. SUBSEQUENT EVENTS

Additional Sales under ATM Program

Subsequent to December 31, 2023 and through March 7, 2024, the Company sold an aggregate of 251,347 shares of common stock under the ATM Program at an average price of approximate $4.50 per share for gross proceeds of approximately $1.1 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses to the placement agent in the aggregate amount of approximately $35,900.

Stock Option Grants

In January 2024, the Company granted a total of 2,203,726 stock options to its employees, certain non-employee consultants, and directors.

License and Service Agreement

In February 2024, we entered into a License and Services Agreement with Azzur Cleanrooms-on-Demand – San Diego, LLC (the "Azzur License Agreement") pursuant to which we have been granted an exclusive license to use certain space and the non-exclusive right to use certain equipment and property for our early phase clinical and/or pre-clinical manufacturing purposes. Our estimated license fee is approximately $120,500 per month for a term of approximately 6 months.

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

We have adopted and maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognizes that controls and procedures, no matter how well designed and operated, cannot provide absolute assurance of achieving the desired control objectives.

As required by Rule 13a-15(b), under the Securities Exchange Act of 1934, as amended, we carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that as of December 31, 2023, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) and 15d-15(f) of the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is a process designed to provide reasonable assurance to our management and Board of Directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes policies and procedures that: (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, errors or fraud. Also, projections of any evaluations of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023 based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commissions in Internal Control-Integrated Framework. Based on that assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2023.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the SEC that permit smaller reporting companies to provide only management's report in this Annual Report on Form 10-K.

Changes in Internal Controls over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) during the fiscal year ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this item will be set forth in the sections entitled "Information Regarding the Board of Directors and Corporate Governance," "Information Regarding Executive Officers" and "Delinquent Section 16(a) Reports" in our Definitive Proxy Statement for our 2024 Annual Meeting of Stockholders (our "2024 Proxy Statement"), to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023, and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this item will be set forth in the section entitled "2023 Executive Compensation" and "Compensation of Directors" in our 2024 Proxy Statement and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by this item will be set forth in the sections entitled "Securities Authorized for Issuance Under Equity Compensation Plans" and "Security Ownership of Certain Beneficial Owners and Management" in our 2024 Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by this item will be set forth in the sections entitled "Certain Relationships and Related Party Transactions" and "Information Regarding the Board of Directors and Corporate Governance" in our 2024 Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this item will be set forth in the section entitled "Principal Accountant Fees and Services" in our 2023 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

The financial statements required by this item are included in a separate section of this Annual Report on Form 10-K beginning on page 88.

(a)(2) Financial Statement Schedules

Financial Statement Schedules have been omitted because they are either not applicable or the required information is included in the consolidated financial statements or notes thereto listed in (a)(1) above.

(a)(3) Exhibits

The following exhibits are filed herewith or incorporated herein by reference:

3.1	Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 9, 2007).
3.2	Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on November 26, 2013).
3.3	Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 4, 2019).
3.4	Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the SEC on February 9, 2007).
3.5	Certificate of Amendment of the Bylaws of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on August 25, 2020).
4.1	Description of the Company's Common Stock, par value $0.001 per share.*
4.2	Form of Common Warrant (incorporated by reference to Exhibit 4.4 to the Company's Amendment No. 1 to Registration Statement on Form S-1/A, filed with the Commission on December 13, 2019).
4.3	Form of Common Stock Purchase Warrant #2 (incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on May 15, 2020).
10.1	Consulting Agreement between Capricor, Inc. and Frank Litvack, dated March 24, 2014 (incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). †
10.2	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). †
10.3	Capricor, Inc. 2012 Restated Equity Incentive Plan (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.4	First Amendment to Capricor, Inc. 2012 Restated Equity Incentive Plan (incorporated by reference to Exhibit 4.12 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.5	Form of Stock Option Agreement for the Capricor, Inc. 2012 Restated Equity Incentive Plan (incorporated by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.6	Exclusive License Agreement, dated June 21, 2006, between Capricor, Inc. and the Universita Degli Studi Di Roma "La Sapienza" (incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +
10.7	Exclusive License Agreement, dated June 22, 2006, between Capricor, Inc. and the Johns Hopkins University (incorporated by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +
10.8	First Amendment to the Exclusive License Agreement, dated May 13, 2009, between Capricor, Inc. and the Johns Hopkins University (incorporated by reference to Exhibit 10.33 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +

10.9 Second Amendment to the Exclusive License Agreement, dated December 20, 2013, between Capricor, Inc. and the Johns Hopkins University (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +

10.10 Amended and Restated Exclusive License Agreement, dated December 30, 2013, between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +

10.11 Loan Agreement, dated February 1, 2013, between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +

10.12 Notice of Loan Award, dated February 1, 2013, between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.39 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +

10.13 Lease Agreement, dated March 29, 2012, between Capricor, Inc. and The Bubble Real Estate Company, LLC (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 14, 2015).

10.14 First Amendment to the Lease Agreement, dated June 13, 2013, between Capricor, Inc. and The Bubble Real Estate Company, LLC (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 14, 2015). +

10.15 Exclusive License Agreement, dated May 5, 2014 between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.46 to the Company's Amendment No. 1 to Registration Statement on Form S-1, filed with the Commission on May 23, 2014). +

10.16 Facilities Lease, dated June 1, 2014, between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on May 15, 2014).

10.17 First Amendment to Exclusive License Agreement, dated as of February 27, 2015, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.54 to the Company's Registration Statement on Form S-1, filed with the Commission on March 6, 2015). +

10.18 Second Amendment to Lease Agreement, dated March 3, 2015, by and between Capricor, Inc. and The Bubble Real Estate Company, LLC (incorporated by reference to Exhibit 10.55 to the Company's Registration Statement on Form S-1, filed with the Commission on March 6, 2015).

10.19 Second Amendment to Exclusive License Agreement, dated as of June 10, 2015, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 14, 2015). +

10.20 Joinder Agreement, dated as of September 30, 2015, by and among the Company, Capricor, Inc. and the California Institute For Regenerative Medicine (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 13, 2015).

10.21 Amendment to Notice of Loan Award, dated as of May 12, 2016 by and between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 15, 2016). +

10.22 Third Amendment to Lease, dated as of May 25, 2016, by and between Capricor, Inc. and The Bubble Real Estate Company, LLC (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 15, 2016).

10.23 Notice of Award, dated as of June 16, 2016, by and between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 15, 2016). +

10.24 Loan Election Agreement, dated as of June 16, 2016, by and between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 15, 2016).

10.25 Second Amendment to Amended and Restated Exclusive License Agreement, dated as of August 5, 2016, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 14, 2016). +

10.26 Third Amendment to Exclusive License Agreement, dated as of August 5, 2016, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 14, 2016). +

10.27 Second Amendment to Capricor Therapeutics, Inc. 2012 Restated Equity Plan (incorporated by reference to Exhibit 4.14 to the Company's Registration Statement on Form S-8, filed with the Commission on January 11, 2017). †

10.28 Third Amendment to Capricor Therapeutics, Inc. 2012 Restated Equity Plan (incorporated by reference to Exhibit 4.15 to the Company's Registration Statement on Form S-8, filed with the Commission on January 11, 2017). †

10.29 Amendment No. 2 to Notice of Loan Award, dated as of June 7, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on June 13, 2017).

10.30 Amendment No. 1 to Notice of Award, dated as of August 8, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 11, 2017).

10.31 First Amendment to Facilities Lease, dated as of August 1, 2017, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 11, 2017).

10.32 Fourth Amendment to Exclusive License Agreement, dated as of December 26, 2017, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.58 to the Company's Annual Report on Form 10-K, filed with the Commission on March 22, 2018). +

10.33 Third Amendment to Exclusive License Agreement, dated as of December 26, 2017, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.59 to the Company's Annual Report on Form 10-K, filed with the Commission on March 22, 2018). +

10.34 Fourth Amendment to Amended and Restated Exclusive License Agreement, dated as of June 20, 2018, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 13, 2018). +

10.35 Fifth Amendment to Exclusive License Agreement, dated as of June 20, 2018, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 13, 2018). +

10.36 Restated and Amended Employment Agreement by and among Capricor Therapeutics, Inc., Capricor, Inc. and Linda Marbán, dated June 5, 2019 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 8, 2019).†

10.37 Employment Agreement by and among Capricor Therapeutics, Inc., Capricor, Inc. and Anthony J. Bergmann, dated May 14, 2019 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 8, 2019).†

10.38 Employment Agreement by and among Capricor Therapeutics, Inc., Capricor, Inc. and Karen G. Krasney, dated May 14, 2019 (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 8, 2019).†

10.39	Common Stock Sales Agreement, dated July 22, 2019, between Capricor Therapeutics, Inc. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on July 22, 2019).
10.40	Capricor Therapeutics, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-8, filed with the Commission on June 17, 2020). †
10.41	Form of Stock Option Agreement for Capricor Therapeutics, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 4.10 to the Company's Registration Statement on Form S-8, filed with the Commission on June 17, 2020). †
10.42	Seventh Amendment to Exclusive License Agreement, dated as of August 20, 2020, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 11, 2020).+
10.43	Capricor Therapeutics, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 13, 2021). †
10.44	Form of Stock Option Agreement for Capricor Therapeutics, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 13, 2021). †
10.45	Standard Industrial/Commercial Multi-Tenant Lease, dated as of July 16, 2021, by and between Capricor Therapeutics, Inc. and Altman Investment Company, LLC (incorporated by reference to Exhibit 10.54 to the Company's Annual Report on Form 10-K, filed with the Commission on March 11, 2022). +
10.46	U.S. Commercialization and Distribution Agreement, dated as of January 25, 2022, by and among Capricor Therapeutics, Inc., Capricor, Inc. and Nippon Shinyaku Co. Ltd. (incorporated by reference to Exhibit 10.55 to the Company's Annual Report on Form 10-K, filed with the Commission on March 11, 2022). +
10.47	Japan Commercialization and Distribution Agreement, dated as of February 10, 2023, by and among Capricor Therapeutics, Inc., Capricor, Inc. and Nippon Shinyaku Co. Ltd. (incorporated by reference to Exhibit 10.55 to the Company's Annual Report on Form 10-K, filed with the Commission on March 17, 2023). +
21.1	List of Subsidiaries. *
23.1	Consent of Rose Snyder & Jacobs, LLP. *
24.1	Power of Attorney (included on signature page hereof). *
31.1	Certification of Principal Executive Officer. *
31.2	Certification of Principal Financial Officer. *
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
97	Capricor Therapeutics, Inc. Policy on Recoupment of Incentive Compensation. *
101	The following financial information from Capricor Therapeutics, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2023 formatted in Inline eXtensible Business Reporting Language (iXBRL): (i) Consolidated Balance Sheets as of December 31, 2023 and 2022, (ii) Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2023 and 2022, (iii) Consolidated Statement of Stockholders' Equity for the period from December 31, 2021 through December 31, 2023, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2023 and 2022, and (v) Notes to Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101).

* Filed herewith.

† Indicates management contract or compensatory plan or arrangement.
+ Portions of the exhibit have been excluded because it is both not material and is the type of information that the registrant treats as private or confidential.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 8, 2024.

CAPRICOR THERAPEUTICS, INC.

By: /s/ Linda Marbán, Ph.D.
Linda Marbán, Ph.D.
Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that we, the undersigned officers and directors of Capricor Therapeutics, Inc., hereby severally constitute Linda Marbán, Ph.D. and Anthony J. Bergmann and each of them singly, our true and lawful attorneys with full power to them, and each of them singly, to sign for us and in our names in the capacities indicated below, any and all amendments to said Annual Report on Form 10-K, and generally to do all such things in our names and in our capacities as officers and directors to enable Capricor Therapeutics, Inc. to comply with the provisions of the Securities Exchange Act of 1934, and all requirements of the U.S. Securities and Exchange Commission, hereby ratifying and confirming our signatures as they may be signed by our said attorneys, or any of them, to any and all amendments hereto.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Linda Marbán, Ph.D. Linda Marbán, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	March 8, 2024
/s/ Anthony J. Bergmann Anthony J. Bergmann	Chief Financial Officer *(Principal Financial and Principal Accounting Officer)*	March 8, 2024
/s/ Frank Litvack, M.D. Frank Litvack, M.D.	Executive Chairman and Director	March 8, 2024
/s/ Earl M. Collier Earl M. Collier	Director	March 8, 2024
/s/ David B. Musket David B. Musket	Director	March 8, 2024
/s/ George W. Dunbar George W. Dunbar	Director	March 8, 2024
/s/ Karimah Es Sabar Karimah Es Sabar	Director	March 8, 2024
/s/ Paul Auwaerter Paul Auwaerter	Director	March 8, 2024
/s/ Michael Kelliher Michael Kelliher	Director	March 8, 2024
/s/ Philip Gotwals Philip Gotwals	Director	March 8, 2024