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

FORM 10-K

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

For the fiscal year ended December 31, 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: 001-39743

KINNATE BIOPHARMA INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**82-4566526**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
Address Not Applicable[1]	**Zip Code Not Applicable[1]**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 299-4699

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, $0.0001 par value per share	KNTE	**The Nasdaq Stock Market LLC** (The Nasdaq Global Select Market)

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 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, 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 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market on June 30, 2023 (the last day of the Registrant's most recently completed second fiscal quarter) was approximately $76 million.

The number of shares of Registrant's Common Stock outstanding as of March 20, 2024 was 47,225,312.

[1] Kinnate Biopharma Inc. (the "Registrant") terminated its lease agreements for office space. Accordingly, the Registrant does not maintain a headquarters. For purposes of compliance with applicable requirements of the Securities Act of 1933, as amended, and Securities Exchange Act of 1934, as amended, any stockholder communication required to be sent to the Registrant's principal executive offices may be directed to the Registrant at Kinnate Biopharma Inc., 800 West El Camino Real, Suite 180, Mountain View, CA 94040.

Auditor Name: KPMG LLP

Auditor Location: San Diego, California

Auditor Firm ID: 185

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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy, development plans, ongoing and planned future preclinical studies and clinical trials, future results of ongoing and planned clinical trials, expected research and development costs, regulatory strategy, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, investors can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements about:

- our expectations related to the Agreement and Plan of Merger, dated as of February 16, 2024 (the Merger Agreement), among us, XOMA Corporation, a Delaware corporation (XOMA), and XRA 1 Corp., a Delaware corporation and a wholly-owned subsidiary of XOMA (Merger Sub), including regarding the ability of the parties to complete the transactions contemplated by the Merger Agreement, the ability of the parties to satisfy the conditions to the consummation of the tender offer contemplated by the Merger Agreement (the Offer) and the other conditions set forth in the Merger Agreement, the possibility of any termination of the Merger Agreement, our ability to retain key personnel, the expected timetable for completing the transactions contemplated by the Merger Agreement, our and XOMA's beliefs and expectations and statements about the benefits sought to be achieved by XOMA's proposed acquisition of us, the potential effects of the acquisition on both us and XOMA and whether or not the conditions for payment in respect of contingent value rights (CVRs) pursuant to the Contingent Value Rights Agreement that we expect to enter into with a rights agent and a representative, agent and attorney-in-fact of the holders of the CVRs at or prior to the completion of the Offer will be met;
- the timing of and steps to implement our Strategic Plans (as defined below);
- the ability of any future preclinical studies and clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the timing, progress and results of any future preclinical studies and clinical trials for our product candidates, including statements regarding the timing of initiation and completion of preclinical studies or clinical trials and related preparatory work, the period during which the results of the preclinical studies or clinical trials will become available;
- the timing, scope and likelihood of regulatory filings and approvals, including timing of investigational new drug applications (INDs) and final approval by the U.S. Food and Drug Administration (FDA) of our current product candidates and any other future product candidates;
- the timing, scope or likelihood of foreign regulatory filings and approvals;
- our ability to develop and advance any future product candidates and programs into, and successfully complete, clinical trials;
- our manufacturing, commercialization, and marketing capabilities and strategy;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- our competitive position and the success of competing therapies that are or may become available;
- our plans relating to the further development of our product candidates;
- existing regulations, regulatory developments and the outcome of related litigation in the United States, Europe and other jurisdictions;

- our expectations regarding the impact of public health concerns, supply chain disruptions, inflation and other drivers of macroeconomic volatility on our business;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our current product candidates and other future product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- our continued reliance on third parties to conduct any future preclinical studies and clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- our ability to obtain, and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- the impact of laws and regulations;
- our expectations regarding the period during which we will remain an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (JOBS Act); and
- our anticipated use of our existing resources.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, investors should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

Except as otherwise indicated, we have prepared this Annual Report on Form 10-K and the forward-looking statements contained in this Annual Report on Form 10-K as if we were going to remain an independent, standalone company. If the transactions contemplated by the Merger Agreement (as defined below) are consummated, many of the forward-looking statements contained in this Annual Report on Form 10-K would no longer be applicable.

Item 1. Business

Overview

We are a clinical-stage precision oncology company that has focused on the discovery, design and development of small molecule kinase inhibitors for difficult-to-treat, genomically defined cancers.

Proposed Agreement and Plan of Merger

On February 16, 2024, we entered into an Agreement and Plan of Merger (the Merger Agreement) with XOMA Corporation, a Delaware corporation (XOMA), and XRA 1 Corp., a Delaware corporation and a wholly owned subsidiary of XOMA (Merger Sub). The Merger Agreement provides for, among other things: (i) the acquisition of all of our outstanding shares of common stock, par value $0.0001 per share (Common Stock), by XOMA through a cash tender offer (the Offer) by Merger Sub, for a price per share of the Common Stock of (A) $2.3352 (the Base Price Per Share), *plus* (B) an additional amount of cash between $0.00 and $0.2527 per share of Common Stock (such amount as finally determined in accordance with the Merger Agreement, the Additional Price Per Share, and together with the Base Price Per Share, the Cash Amount), *plus* (C) one contingent value right (a CVR, and each CVR together with the Cash Amount, the Offer Price); and (ii) after the completion of the Offer, the satisfaction or waiver of certain conditions set forth in the Merger Agreement and in accordance with the General Corporation Law of the State of Delaware, as amended (the DGCL), the merger of Merger Sub with and into us (the Merger) with us surviving the Merger as a wholly-owned subsidiary of XOMA, without a meeting or vote of our stockholders.

We expect to devote significant time and resources to the completion of the transactions contemplated by the Merger Agreement. However, there can be no assurances that such activities will result in the completion of such transactions. Further, the completion of the transactions contemplated by the Merger Agreement may ultimately not deliver the anticipated benefits or enhance shareholder value. If the transactions contemplated by the Merger Agreement are not completed, we will reconsider our strategic alternatives. We consider one of the following courses of action to be the most likely alternatives if the transactions contemplated by the Merger Agreement are not completed:

- *Pursue another strategic transaction*. We may resume the process of evaluating a potential strategic transaction in order to attempt another strategic transaction like that contemplated by the Merger Agreement.
- *Operate our business.* Our board of directors may elect to seek new product candidates for development.
- *Dissolve and liquidate our assets*. If, for any reason, the transactions contemplated by the Merger Agreement do not close, our board of directors may conclude that it is in the best interest of stockholders to dissolve the company and liquidate our assets. In that event, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims. There would be no assurances as to the amount or timing of available cash remaining to distribute to stockholders after paying our obligations and setting aside funds for reserves.

The tender offer is being made subject to all terms and conditions set forth in the Offer to Purchase, dated March 4, 2024 (as amended or supplemented from time to time, the Offer to Purchase), and in the related Letter of Transmittal (as amended or supplemented from time to time, the Letter of Transmittal, which together with the Offer to Purchase constitutes the Offer).

If the Offer and the Merger are completed, the holders of our Common Stock, Company Options and RSUs will be entitled to receive one CVR per share of Common Stock, share of Common Stock underlying a Company Option, or RSU, as applicable, representing the right to receive, subject to the terms and conditions of the Contingent Value Rights Agreement that we expect to enter into with a rights agent and a representative, agent and attorney in-fact of the holders of the CVRs at or prior to the completion of the Offer (the CVR Agreement). Each CVR will represent a contractual right to receive contingent cash payments equal to (i) 100% of the Net Proceeds (as defined in the CVR Agreement), if any, from any sale, transfer, license or other disposition (each, a Disposition) by us, of all or any part of the rights, intellectual property and other assets related to (A) Exarafenib (as defined below) and/or (B) any other pan-RAF inhibitor entered into prior to the time at which Merger Sub first irrevocably accept for purchase the shares of Common Stock tendered in the Offer (the Offer Closing Time) and (ii) 85% of the Net Proceeds, if any, from any Disposition by XOMA or any of its affiliates, including us after the Merger, of all or any part of the CVR Products (as defined below) effected during the period beginning at the effective time of the Merger (the Effective Time) and ending one year following the date of the closing of the Merger (the Disposition Period), in each case, which Net Proceeds are received within five years of the closing of the Merger (such date, the Expiration Date, and such proceeds, collectively, the CVR Proceeds). Pursuant to the CVR Agreement, CVR Products means, collectively, (a) Exarafenib, an inhibitor for the treatment of patients with lung cancer, melanoma and other solid tumors (Exarafenib), (b) our product candidate known as KIN-3248, an inhibitor for the treatment of patients with intrahepatic cholangiocarcinoma, (c) our product candidate known as KIN-8741, an inhibitor with broad mutational coverage across a variety of solid tumors in which c-MET is overexpressed, (d) any product or product candidate contained in, arising from or related to the foregoing programs or (e) any of our other research program active as of the Effective Time.

In the event that no CVR Proceeds become payable prior to the Expiration Date, holders of the CVRs will not receive any payment pursuant to the CVR Agreement. During the Disposition Period, Merger Sub shall, and shall cause its subsidiaries, licensees and rights transferees to, use commercially reasonable efforts to enter into one or more agreements for a Disposition as promptly as practicable following the Effective Time.

Following the completion of the Offer, subject to the absence of injunctions or other legal restraints preventing or making illegal the consummation of the Merger, Merger Sub will merge with and into us, with the Company surviving as a wholly-owned subsidiary of XOMA, pursuant to the procedure provided for under Section 251(h) of the DGCL, without any additional stockholder approvals. The Merger will be effected as soon as practicable following the closing time of the Offer. Pursuant to the terms of the Merger Agreement, as of the Effective Time, by virtue of the Merger and without any action on the part of the holders, (i) each outstanding share of our Common Stock (other than any shares of Common Stock held in the treasury of us, owned, directly or indirectly, by XOMA, Merger Sub or any subsidiary of XOMA, irrevocably accepted for purchase in the Offer or by any stockholders who are entitled to and who properly exercise appraisal rights under Delaware law) will be converted into the right to receive the Offer Price, (ii) the vesting of each option to purchase shares of Common Stock (the Company Options) shall be accelerated and (A) each of the Company Options that has an exercise price per share that is less than the Cash Amount (each, an In-the-Money Option) that is then outstanding will be cancelled in exchange for the right to receive (1) an amount in cash without any interest, less any applicable tax withholding, equal to the product of (x) the total number of shares of Common Stock underlying such In-the-Money Option as of immediately prior to the Effective Time multiplied by (y) the excess of the Cash Amount over the applicable exercise price per share under such In-the-Money Option and (2) one CVR for each share of Common Stock underlying such In-the-Money Option and (B) each Company Option that has an exercise price per share that is equal to or greater than the Cash Amount (each, an Out-of-the-Money Option) that is then outstanding will be cancelled in exchange for the right to receive one CVR for each share of Common Stock underlying such Out-of-the-Money Option; provided that each such CVR will provide for payment only after amounts otherwise payable under such CVR exceed a threshold equal to the excess of the per share exercise price of such Out-of-the-Money Option over the Cash Amount and (iii) the vesting of each restricted stock unit for shares of Common Stock (RSU) shall be accelerated and each RSU that is then outstanding will be cancelled in exchange for the right to receive (A) an amount in cash without interest, less any applicable tax withholding, equal to the Cash Amount and (B) one (1) CVR.

The obligation of Merger Sub to purchase shares of Common Stock validly tendered pursuant to the Offer and not validly withdrawn prior to the expiration of the Offer is subject to the satisfaction or waiver of a number of conditions set forth in the Merger Agreement, including: (i) that the number of shares of Common Stock validly tendered and not properly withdrawn equals at least one share more than 50% of the number of shares of Common Stock that are then issued and outstanding as of the expiration of the Offer (the Minimum Tender Condition); (ii) that there be no Legal Restraints (as defined in the Merger Agreement) in effect preventing or prohibiting the consummation of the Offer or any of the other transactions contemplated by the Merger Agreement or the CVR Agreement; (iii) the accuracy of representations and warranties we have made in the Merger Agreement, including that, since the date of the Merger Agreement, there shall not have occurred any Company Material Adverse Effect (as defined in the Merger Agreement); (iv) our compliance in all material respects with our obligations under the Merger Agreement; (v) that no termination of the Merger Agreement has occurred; and (vi) that our Closing Net Cash (as defined in and determined in accordance with the Merger Agreement) is at least $120.0 million (the Closing Net Cash Condition) (each of (i) through (vi) individually, an Offer Condition, and collectively, the Offer Conditions). The obligations of the XOMA and the Merger Sub to consummate the Offer and the Merger under the Merger Agreement are not subject to a financing condition. Merger Sub expressly reserves the right, in its sole discretion, to: (i) waive, in whole or in part, any Offer Condition other than the Minimum Tender Condition; and/or (ii) modify the terms of the Offer in a manner not inconsistent with the Merger Agreement, subject to certain exceptions described in the Merger Agreement and the Offer to Purchase.

The Merger Agreement contains customary representations and warranties by XOMA, Merger Sub and us. The Merger Agreement also contains customary covenants and agreements, including with respect to the operations of our business between signing and closing.

The Merger Agreement contains customary non-solicitation restrictions prohibiting our solicitation of alternative business combination transactions and restricts our ability to furnish non-public information to, or participate in any discussions or negotiations with, any third party with respect to any such alternative business combination transaction, subject to customary exceptions in the event of an acquisition proposal that was not solicited in violation of these restrictions and that the board of directors or the Special Committee of the board of directors (the Special Committee) determines constitutes or could reasonably be expected to lead to a Superior Company Proposal (as defined in the Merger Agreement).

The Merger Agreement contains customary termination rights for both XOMA and Merger Sub, on the one hand, and us, on the other hand, including, among others, for failure to consummate the Offer on or before June 16, 2024. If the Merger Agreement is terminated under certain circumstances specified in the Merger Agreement, including in connection with our entry into an agreement with respect to a Superior Company Proposal, we will be required to pay XOMA a termination fee of approximately $3.5 million. If XOMA terminates the Merger Agreement due to us having Closing Net Cash of less than $120.0 million, we will be required to pay to XOMA an expense reimbursement fee up to a maximum amount of $1.25 million.

We anticipate that the Offer and the Merger contemplated under the Merger Agreement will be consummated in the first half of 2024. However, there can be no assurance that the Offer and the Merger contemplated by the Merger Agreement will be completed.

If the Merger is effected, our Common Stock will be delisted from The Nasdaq Stock Market LLC and our obligation to file periodic reports under the Securities Exchange Act of 1934, as amended (the Exchange Act), will terminate, and we will be privately held.

Asset Purchase Agreement

On February 27, 2024, we entered into an Asset Purchase Agreement (the Purchase Agreement) by and among us and Pierre Fabre Médicament, SAS (Pierre Fabre), pursuant to which we sold the global rights to Exarafenib, and other pan-RAF program assets to Pierre Fabre, subject to the terms and conditions of the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, Pierre Fabre purchased Exarafenib and other pan-RAF assets and will assume 100% of the ongoing program and costs associated with these assets. We will receive a total consideration of up to $31.0 million, consisting of $500,000 at closing, and an additional $30.5 million contingent upon the earlier of (i) the dosing of the first patient in the first pivotal trial for Exarafenib or any other acquired asset, (ii) the application for accelerated approval pursuant to the U.S. Food and Drug Administration's Accelerated Approval Program for Exarafenib or any other acquired asset or (iii) the submission of a marketing application for regulatory approval for Exarafenib or any other acquired asset. In addition, Pierre Fabre will assume up to $5.0 million of trade payables for the transferred assets. The transaction is not subject to closing conditions and closed upon signing.

In connection with our transaction with XOMA, our stockholders will receive 100% of the Net Proceeds payable from the $30.5 million contingent payment, assuming the closing of the proposed transaction with XOMA occurs and such proceeds are received prior to the Expiration Date.

Business and Programs

In September 2023, the Company's board of directors, based on a strategic review of the Company's business, approved a reprioritization of the Company's research and development programs and a workforce restructuring (the September 2023 Strategic Plan).

In January 2024, we announced a further workforce restructuring and the exploration of strategic alternatives for the Company in an effort to maximize shareholder value and we subsequently suspended almost all of our research and development activities (the January 2024 Strategic Plan, and together with the September 2023 Strategic Plan, the Strategic Plans). Prior to this announcement, our business focused on expanding on the promise of targeted therapies and developing medicines for known oncogenic drivers where there are no approved targeted drugs and to overcome the limitations of marketed cancer therapies, such as non-responsiveness or acquired and intrinsic resistance.

Exarafenib and other pan-RAF programs

On February 27, 2024, we entered into the Purchase Agreement, pursuant to which we sold the global rights to Exarafenib and our other pan-RAF program assets to Pierre Fabre, as previously described.

Prior to the Purchase Agreement, we conducted a Phase 1 study of Exarafenib for the treatment of patients with lung cancer, melanoma and other solid tumors with BRAF Class I, Class II and Class III alterations, as well as NRAS mutant melanoma. We explored Exarafenib as a monotherapy and in combination with a mitogen-activated protein kinase (MEK) inhibitor binimetinib. In September 2023, we announced results from the monotherapy dose expansion phase of KN-8701. The clinical data support Exarafenib's favorable safety and tolerability profile and favorable pharmacokinetic/pharmacodynamic properties. However, considering these results and our assessment of clinical development timelines for Class II fusion-driven solid tumors, as part of the September 2023 Strategic Plan, we decided not to proceed with further clinical development of Exarafenib as a monotherapy agent. We have ceased further development of the program in light of the January 2024 Strategic Plan and the Purchase Agreement with Pierre Fabre.

KIN-3248

KIN-3248, a Fibroblast Growth Factor Receptors (FGFR) inhibitor, was designed for the treatment of patients with intrahepatic cholangiocarcinoma (ICC), a cancer of the bile ducts in the liver, and urothelial carcinoma (UC), a cancer of the bladder lining, as well as other solid tumors. In the first quarter of 2022, we initiated KN-4802, a Phase 1 clinical trial evaluating KIN-3248. In September 2023, we announced results from the dose escalation phase of KN-4802 and, as part of the September 2023 Strategic Plan we decided not to proceed with further clinical development of KIN-3248 and to instead explore strategic alternatives for the KIN-3248 program.

Other Research Programs

We have developed three additional small molecule programs, a MEK inhibitor (KIN-7136), a c-MET inhibitor (KIN-8741) and a Cyclin-Dependent Kinase 4 (CDK4) inhibitor. In the third quarter of 2023, we announced that the FDA cleared the IND application for KIN-7136. In the fourth quarter of 2023, the FDA cleared the IND application for KIN-8741 and we declared a drug candidate for our CDK4 program (KIN-7324). We have suspended almost all of our research and development activities in light of the January 2024 Strategic Plan.We currently own worldwide development and commercial rights for all our programs.

Kinnjiu Acquisition

In February 2023, we announced that we acquired the ownership stake of Kinnjiu Biopharma Inc. (Kinnjiu), the China joint venture that we established in May 2021, previously held by the Series A investors for $24.0 million, using a combination of $9.1 million in cash and 2.2 million shares of common stock of Kinnate. We retain Kinnjiu's cash, intellectual property and other assets, including its legal entity structure. As part of the September 2023 Strategic Plan, we separated from all Kinnjiu employees.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, the expertise of our team, and our development experience and scientific knowledge provide us with competitive advantages, we face increasing competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market, and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions may result in even more resources being concentrated in our competitors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer or more effective, have fewer or less severe side effects, and are more convenient or less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we can, which could result in our competitors establishing a strong market position before we are able to enter the market or could otherwise make our development more complicated. We believe the key competitive factors affecting the success of all of our programs are likely to be efficacy, including DoR and breadth of coverage, safety and patient convenience.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to our business, including obtaining, maintaining and defending our patent rights. We own the patent applications relating to our lead and planned product candidates. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications and obtaining issued patents in the United States and in markets outside of the United States directed to our proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates and continuing innovation to develop, strengthen and maintain our proprietary position in the field of oncology. We also plan to rely on data exclusivity, market exclusivity and patent term extensions when available. Our commercial success will depend, in part, on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions, improvements and product candidates; to preserve the confidentiality of our trade secrets; to defend and enforce our proprietary rights, including any patents that we may own or license in the future; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

As of March 1, 2024, our patent portfolio consists of issued patents and pending patent applications that we own related to our small molecule kinase inhibitor FGFR, MEK, c-MET, and CDK4 programs. In total, we own 6 issued United States patents, 16 pending United States patent applications, seven international patent applications filed under the Patent Cooperation Treaty (PCT application) and 29 pending patent applications in various markets outside of the United States, including Europe, China and Japan.

We also possess substantial know-how and trade secrets relating to the development and commercialization of our product candidates, including related manufacturing processes and technology.

With respect to our product candidates and processes that we intend to develop and commercialize in the normal course of business, we intend to pursue patent protection covering, when possible, compositions, methods of use, dosing and formulations. We may also pursue patent protection with respect to manufacturing and drug development processes and technologies.

Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In general, patents issued for patent applications filed in the United States can provide exclusionary rights for 20 years from the earliest effective filing date. The term of United States patents may be extended by delays encountered during prosecution that are caused by the USPTO, also known as patent term adjustment. In addition, in certain instances, the term of an issued United States patent that covers or claims an FDA-approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, which is called patent term extension. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The term of patents outside of the United States varies in accordance with the laws of the foreign jurisdiction, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of oncology has emerged in the United States. The relevant patent laws and their interpretation outside of the United States are also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, even our issued patents may not guarantee us the right to practice our technology in relation to the commercialization of our products. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology, and our issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

Commercialization

We retain significant development and commercial rights to our product candidates. We currently have no sales, marketing or commercial product distribution capabilities. Our commercialization plans are dependent on the completion of the Merger and the results of our Strategic Plans.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacturing if any of our product candidates obtain marketing approval. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our investigational product candidates, as well as our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our product candidates.

To date, we have obtained for our current product candidates active pharmaceutical ingredients (API) from Patheon API Services, Inc. and Shanghai STA Pharmaceutical Co. and drug product from BioDuro LLC, some of whom we currently rely on as single-source contract manufacturing organizations (CMOs).

If we resume advancing our product candidates through development, we will explore adding backup suppliers for the API and drug product for each of our product candidates to protect against any potential supply disruptions.

We generally expect to rely on third parties for the manufacture of any companion diagnostics we may develop.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries and jurisdictions, such as the European Union, or EU, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Drug Development

In the United States, the FDA regulates drugs under the Food, Drug, and Cosmetic Act (FDCA). Drugs also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our product candidates are considered small molecule drugs and must be approved by the FDA through the new drug application (NDA) process before they may be legally marketed in the United States. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice (GLP);
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board (IRB), or ethics committee at each clinical trial site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice (GCP) requirements and other clinical trial-related regulations to establish substantial evidence of the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- determination by the FDA within 60 days of its receipt of an NDA to accept the filing for substantive review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements assuring that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the preclinical study and/or clinical trial sites that generated the data in support of the NDA filing;
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, 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.

The data required to support an NDA are generated in two distinct developmental stages: preclinical and clinical. The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for any current and future product candidates will be granted on a timely basis, or at all.

Preclinical Studies and IND

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events, which support subsequent clinical testing, and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature, plans for clinical studies and a proposed clinical protocol, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the clinical trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB must also approve the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA. The FDA will generally accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with the ethical principles contained in the Declaration of Helsinki pursuant to 21 CFR 312.120(c)(4), incorporating the 1989 version of the Declaration, or with the laws and regulations of the foreign regulatory authority where the trial was conducted, such as the European Medicines Agency (EMA), whichever provides greater protection of the human subjects, and with GCP and GMP requirements, and the FDA is able to validate the data through an onsite inspection, if deemed necessary, and the practice of medicine in the foreign country is consistent with the United States.

Clinical trials in the United States generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, tolerability and safety of the drug.

- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose and dosing schedule required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.

- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use and its safety in use, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, are conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. The sponsor is also responsible for submitting written IND safety reports, including reports of serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or *in vitro* testing that suggest a significant risk for human subjects, and any clinically significant increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a clinical trial may move forward at designated check-points based on access to certain data from the clinical trial.

Concurrent with clinical trials, companies usually complete additional animal safety studies and also must develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process, as performed by the manufacturing facility, must be capable of consistently producing quality batches of our product candidates. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that our product candidates do not undergo unacceptable deterioration over their labeled shelf life.

NDA Review Process

Following completion of the clinical trials, data is analyzed to assess whether the safety and efficacy of the investigational product has been demonstrated for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. In short, the NDA is a request for approval to market the drug in the United States for one or more specified indications and must contain proof of safety and efficacy for a drug.

The application must include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of an NDA must be obtained before a drug may be legally marketed in the United States.

Under the Prescription Drug User Fee Act (PDUFA), as amended, each NDA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for each marketed human drug. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted NDAs before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months, from the filing date, in which to complete its initial review of a new molecular-entity NDA and respond to the applicant, and six months from the filing date of a new molecular-entity NDA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies and/or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA's interpretation of data may differ from our interpretation.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA. 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.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. However, competitors may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication for which we are seeking approval, or if a product candidate is determined to be contained within the scope of the competitor's product for the same indication. If one of our products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

In *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with the FDA's longstanding position that orphan drug exclusivity only applies to the approved use or indication within an eligible disease. In particular, the circuit court held that orphan-drug exclusivity for Catalyst's drug blocked FDA approval of another drug for all uses or indications within the same orphan-designated disease, or Lambert-Eaton myasthenic syndrome (LEMS), even though Catalyst's drug was approved at that time only for use in the treatment of LEMS in adults. Accordingly, the court ordered the FDA to set aside the approval of a drug indicated for LEMS in children. This decision created uncertainty in the application of orphan drug exclusivity. On January 24, 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the FDA will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan- designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

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 that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for fast track status any time before receiving NDA approval, but ideally no later than the pre-NDA meeting with the FDA.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies.

A product may also be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM), which is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. The FDA may withdraw drug approval or require changes to the labeled indication of the drug if confirmatory post-market clinical trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions as it deems necessary to assure safe use of the product.

Additionally, a drug may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently-approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or may decide that the time period for FDA review or approval will not be shortened. In December 2022, the Consolidated Appropriations Act, 2023, including the Food and Drug Omnibus Reform Act, or FDORA, was signed into law. FDORA made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements.

FDA Regulation of Companion In Vitro Diagnostics

A therapeutic product may rely upon an in vitro companion diagnostic for use in selecting the patients that will be more likely to respond to that therapy. If an in vitro diagnostic is essential to the safe and effective use of the therapeutic product and if the manufacturer wishes to market or distribute such diagnostic for use as a companion diagnostic, then the FDA will require separate approval or clearance of the diagnostic as a companion diagnostic to the therapeutic product. According to FDA guidance, an unapproved or uncleared companion diagnostic device used to make treatment decisions in clinical trials of a drug generally will be considered an investigational medical device unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption, or IDE, regulations. The sponsor of the diagnostic device will be required to comply with the IDE regulations for clinical studies involving the investigational diagnostic device. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same clinical trial, if the clinical trial meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the clinical trial protocol, the investigational product(s), and subjects involved, a sponsor may seek to submit an IDE alone (e.g., if the drug has already been approved by the FDA and is used consistent with its approved labeling), or both an IND and an IDE.

Pursuing FDA approval/clearance of an in vitro companion diagnostic would require either a pre-market notification, also called 510(k) clearance, or a pre-market approval, or PMA, or a de novo classification for that diagnostic. The review of companion diagnostics involves coordination of review with the FDA's Center for Devices and Radiological Health.

510(k) clearance process

To obtain 510(k) clearance, a pre-market notification is submitted to the FDA demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet required the submission of a PMA application. The FDA's 510(k) clearance process may take three to 12 months from the date the application is submitted and filed with the FDA, but may take longer if the FDA requests additional information, among other reasons. In some cases, the FDA may require clinical data to support substantial equivalence. In reviewing a pre-market notification submission, the FDA may request additional information, which may significantly prolong the review process. Notwithstanding compliance with all these requirements, clearance is never assured.

After a device receives 510(k) clearance, any subsequent modification of the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or require a PMA. In addition, the FDA may make substantial changes to industry requirements, including which devices are eligible for 510(k) clearance, which may significantly affect the process.

De novo classification process

If a new medical device does not qualify for the 510(k) pre-market notification process because no predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. The Food and Drug Administration Modernization Act of 1997 established a different route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the Request for Evaluation of Automatic Class III Designation, or the de novo classification process. This process allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. The FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk and requires PMA or that general controls would be inadequate to control the risks and special controls cannot be developed.

Obtaining FDA marketing authorization, de novo down-classification, or approval for medical devices is expensive and uncertain, and may take several years, and generally requires significant scientific and clinical data.

PMA process

The PMA process, including the gathering of clinical and nonclinical data and the submission to and review by the FDA, can take several years or longer. The applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness, including information about the device and its components regarding, among other things, device design, manufacturing, and labeling. PMA applications are subject to an application fee. In addition, PMAs for medical devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic produces reproducible results. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes extensive testing, control, documentation, and other quality assurance and GMP requirements.

Post-approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping requirements, requirements to report adverse events and comply with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations, known as "off-label promotion," and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for REMS, to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

The FDA may withdraw 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 studies to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications;
- suspension or revocation of product approvals;
- product seizure or detention;
- refusal to permit the import or export of products; and
- 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 label. 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.

Similar to post-approval regulatory requirements that apply to drug products, for any medical devices that we may develop in the future, after a medical device is placed on the market, numerous regulatory requirements apply. These include: the quality manufacturing requirements set forth in the Quality System Regulation, or QSR, labeling regulations, the FDA's general prohibition against promoting products for unapproved or "off label" uses, registration and listing, the Medical Device Reporting, or MDR, regulation (which requires that manufacturers report to the FDA if the device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur), and the Reports of Corrections and Removals regulation (which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act). The FDA enforces these requirements by unannounced inspection, market surveillance and other means. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from an untitled regulatory letter or a warning letter, to more severe sanctions such as fines, injunctions and civil penalties; recall or seizure of products; operating restrictions, partial suspension or total shutdown of production; refusing requests for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMA approvals already granted; and criminal prosecution.

Other U.S. Regulatory Matters

Pharmaceutical manufacturers are subject to various healthcare laws, regulation, and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Our conduct, including those of our employees, as well as our business operations and relationships with third parties, including current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market, and distribute any products for which we obtain marketing approval. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the ACA provides that the government may assert 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 civil False Claims Act.

- The federal false claims, including the civil False Claims Act that can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, and/or impose exclusions from federal health care programs and/or penalties for parties who engage in such prohibited conduct.

- The Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations also impose obligations on covered entities such as health insurance plans, healthcare clearinghouses, and certain health care providers and their respective business associates, including mandatory contractual terms as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

- The federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services (HHS), information regarding certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members;

- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and require the registration of their sales representatives, state laws that require biotechnology companies to report information on the pricing of certain drug products, and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws. In addition, the distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act as well as other applicable consumer safety requirements.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts.

U.S. Patent-term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of any future product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term restoration period is generally one-half the time between the effective date of an IND or the issue date of the patent, whichever is later, and the submission date of an NDA plus the time between the submission date of an NDA or the issue date of the patent, whichever is later, and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

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

European Union Drug Development

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated, it must be approved in each of the EU countries where the clinical trial is to be conducted by two distinct bodies: the National Competent Authority (NCA), and one or more Ethics Committees (ECs). Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014, which entered into application on January 31, 2022, ensures that the rules for conducting clinical trials in the EU will be identical and simplifies the rules for clinical trial authorization and standards of performance.

European Union Drug Review and Approval

In the European Economic Area (EEA), which is comprised of the 27 Member States of the European Union and three European Free Trade Association States (Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization (MA). There are two types of marketing authorizations.

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP), of the EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State (RMS). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics (SmPC), and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above described procedures, before granting the MA, EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. Similar to the U.S. patent term-restoration, Supplementary Protection Certificates (SPCs) serve as an extension to a patent right in Europe for up to five years. SPCs apply to specific pharmaceutical products to offset the loss of patent protection due to the lengthy testing and clinical trials these products require prior to obtaining regulatory marketing approval.

Coverage and Reimbursement

Sales of our products, if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by CMS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union 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 products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Healthcare Reform

The United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the ACA substantially changed the way healthcare is financed by both the government and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. The ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price (AMP), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Additionally, for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. The Bipartisan Budget Act of 2018 (the BBA), among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare Part D drug plans. In June 2021, the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. In January 2021, President Biden issued an Executive Order that initiates a special enrollment period to allow people to obtain health insurance coverage through the ACA marketplace, and instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, among others. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and healthcare measures promulgated by the Biden administration will impact the ACA, our business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2032, with the exception of a temporary suspension implemented under various COVID-19 relief legislation. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, 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. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Additionally, there has 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. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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. For example, a number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the likelihood, nature, or extent of health reform initiatives that may arise from future federal and state legislation or administrative action. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Facilities

We formerly had offices located in San Diego, California and San Francisco, California. In January and February 2024, we assigned our lease agreements in San Diego and San Francisco, respectively, and became a remote-only company. We believe that suitable office space will be available as and when needed.

Employees and Human Capital Resources

As of December 31, 2023, we had 27 employees, all of which were full-time employees, and 17 of which were engaged in research and development. We consider our relationship with our employees to be good. In January 2024, we announced a further reduction in force (RIF) in light of the January 2024 Strategic Plan and in March 2024 we completed another RIF. We currently have 10 remaining full-time employees.

Corporate Information

We were incorporated in Delaware in January 2018. We are a remote-only company and therefore we do not have principal executive offices. For purposes of compliance with applicable requirements of the Securities Act of 1933, as amended (the Securities Act), and Securities Exchange Act of 1934, any stockholder communication required to be sent to the Company's principal executive offices may be sent to Kinnate Biopharma Inc., 800 West El Camino Real, Suite 180, Mountain View, California 94040. Our telephone number is (858) 299-4699. Our website address is www.kinnate.com. Information contained on the website is not incorporated by reference into this Annual Report on Form 10-K or any other filings we make with the SEC.

We may announce material information to the public through filings with the SEC, our website, press releases, public conference calls, and public webcasts. We use these channels, as well as social media, to communicate with the public about Kinnate, its product candidates and other matters. As such, investors, the media and others are encouraged to review the information disclosed through our social media and other channels listed above as such information could be deemed to be material information. Please note that this list may be updated from time to time. We also make available on or through our website certain reports and amendments to those reports that we file with or furnish to the SEC in accordance with the Exchange Act. These include our Annual Reports on Form 10-K, our quarterly reports on Form 10-Q, and our current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC.

We use the Kinnate logo and other marks as trademarks in the United States and other countries. This periodic report contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this periodic report, including logos, artwork and other visual displays, may appear without the TM symbol, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Item 1A. Risk Factors

Investors should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in our other public filings in evaluating our business. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, and growth prospects. In such an event, the market price of our common stock could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock.

Risk Factor Summary

Our business operations are subject to numerous risks and uncertainties, including those outside of our control, that could cause our actual results to be harmed, including risks related to the following:

Risks Related to the Offer and the Merger

- The Offer and the Merger are subject to a number of conditions beyond our control. Failure to complete the Offer and the Merger within the expected time frame, or at all, could have a material adverse effect on our business, operating results, financial condition and our share price.
- The consideration payable to holders of our Common Stock pursuant to the Merger Agreement will be adjusted if our net cash amount exceeds a certain threshold but will not otherwise be adjusted for changes in our business, assets, liabilities, prospects, outlook, financial condition or results of operations, or in the event of any change in our share price.
- Our stockholders may not receive any payment on the CVR and the CVR may expire valueless.
- The Merger Agreement contains provisions that could discourage a potential competing acquirer.
- Stockholder litigation could prevent or delay the consummation of the Offer and the Merger or otherwise negatively impact our business, operating results and financial condition.
- We may become involved in securities class action litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.
- Our executive officers and directors may have interests in the Offer and the Merger that are different from, or in addition to, those of our stockholders generally.
- While the Offer and the Merger are pending, we are subject to business uncertainties and contractual restrictions that could disrupt our business, and the Offer and the Merger may impair our ability to attract and retain qualified employees or retain and maintain relationships with our suppliers and other business partners.
- We have incurred, and will continue to incur, direct and indirect costs as a result of the Offer and the Merger.
- If we are not able to complete the Offer and the Merger, we will likely pursue other strategic alternatives. We may not be successful in identifying and implementing any strategic business combination or other transaction and any strategic transaction that we may consummate in the future could have negative consequences. There can be no assurance that the terms of any such other transaction will be favorable.
- We may not realize any additional value in a strategic transaction.
- If a strategic transaction is not consummated, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.
- Our ability to consummate the Offer and the Merger or complete another strategic transaction or a dissolution and liquidation of the Company depends on our ability to retain our employees and engage other advisors and consultants required to consummate such transactions.
- Our principal stockholders and management, if they choose to act together, will have the ability to significantly influence all matters submitted to stockholders for approval.

Risks Related to our Financial Position and Need for Additional Capital

- We are early in our development efforts and have a limited operating history and no products approved for commercial sale.
- We have incurred significant net losses and expect to continue to incur significant net losses for the foreseeable future.
- If the Merger is not completed, we will reconsider our strategic alternatives, including dissolving and liquidating our assets, pursuing another strategic transaction, or operating our business. Our future capital requirements depend on many factors, and adequate additional financing may not be available to us on acceptable terms, or at all.
- We will require substantial additional capital to finance our operations.

Risks Related to the Discovery, Development and Commercialization of our Product Candidates

- Our preclinical studies and clinical trials may fail to demonstrate the safety and efficacy of our product candidates.
- The outcome of testing and early clinical trials may not be predictive of the success of later clinical trials.
- The regulatory approval processes of regulatory authorities are lengthy, time consuming and unpredictable.
- We have no experience as a company in conducting clinical trials to completion.
- Our product candidates may cause significant adverse events, toxicities or other undesirable side effects.
- Data from our preclinical studies and clinical trials may change as more data become available and are subject to verification.
- We could experience delays or difficulties in the enrollment or maintenance of patients in clinical trials.
- We face substantial competition which may result in others discovering, developing or commercializing products before us.
- Our product candidates may not achieve adequate market acceptance among the medical community.
- The market opportunities for our product candidates may be limited to certain smaller patient subsets.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

- We may be unable to obtain regulatory approval and be unable to commercialize our product candidates.
- Regulatory authorities may not accept data from clinical trials conducted in locations outside of their jurisdiction.
- Obtaining regulatory approval in one jurisdiction does not mean we will be successful in other jurisdictions.
- Any product candidates that receive regulatory approval will be subject to post-marketing regulations.
- Where appropriate, we plan to secure approval from regulatory authorities through accelerated registration pathways. If we are unsuccessful, we may be required to conduct additional preclinical studies or clinical trials.
- We may seek, but not obtain, additional Fast Track designations from the FDA for our product candidates.
- A Breakthrough Therapy designation by the FDA may not lead to a faster review or approval process.
- We may not be able to obtain orphan drug designation or maintain orphan drug exclusivity for one or more of our product candidates.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

- In September 2023, we began implementing the Strategic Plans. If the Strategic Plans are unsuccessful, our business may be harmed.
- Our success is highly dependent on our ability to attract, hire and retain highly skilled executive officers and employees.
- Our operations are vulnerable to interruption by natural disasters, war, terrorist activity, pandemics and other events.

Risks Related to Our Intellectual Property

- Our success depends on our ability to protect our intellectual property and our proprietary technologies.
- The scope of our patent protection may not be sufficiently broad, or we could lose patent protection.
- We may not be successful in obtaining or maintaining rights to our future product candidates.
- We may be involved in lawsuits to protect or enforce our patents or our future licensors' patents.
- The outcome of derivation proceedings may require us to cease using or attempt to license the related technology.
- We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.
- Patent terms may be inadequate to protect our competitive position on our product candidates.
- If we do not obtain patent term extension for our product candidates, our business may be materially harmed.
- We may not be able to protect our intellectual property rights throughout the world.

Risks Related to Our Dependence on Third Parties

- We rely on third parties to conduct our preclinical studies and clinical trials, and they may not perform satisfactorily.
- We contract with third parties for the manufacture of our product candidates for preclinical studies and clinical trials and expect to continue to do so for additional preclinical studies, clinical trials and ultimately for commercialization.

Risks Related to the Securities Markets and Ownership of Our Common Stock

- The market price of our common stock is volatile, which could result in substantial losses for investors.
- If securities analysts do not publish research or reports about our business, or if they publish adverse reports regarding us, our stock price and trading volume could decline.

Risks Related to the Offer and the Merger

The Offer and the Merger are subject to a number of conditions beyond our control. Failure to complete the Offer and the Merger within the expected time frame, or at all, could have a material adverse effect on our business, operating results, financial condition and our share price.

On February 16, 2024, we entered into the Merger Agreement with XOMA and Merger Sub, pursuant to which, and upon the terms and subject to the conditions of, Merger Sub commenced a cash tender offer to purchase our Common Stock. After the completion of the Offer, the satisfaction or waiver of certain conditions set forth in the Merger Agreement and in accordance with the DGCL, Merger Sub will be merged with and into us, with us continuing as the surviving corporation and as a wholly owned subsidiary of XOMA, and pursuant to the Merger, each share of Common Stock that is not validly tendered and irrevocably accepted for purchase pursuant to the Offer, except as provided in the Merger Agreement, will be converted in the Merger into the right to receive an amount equal to the Merger Consideration (as defined in the Merger Agreement). Merger Sub's obligation to accept shares of Common Stock tendered in the Offer is subject to conditions, including: (i) that the number of shares of Common Stock validly tendered and not validly withdrawn, equals one share more than 50% of the number of shares of Common Stock then outstanding; (ii) our Closing Net Cash will be at least $120.0 million as of the expiration of the Offer; (iii) the accuracy of our representations and warranties contained in the Merger Agreement, including that, since the date of the Merger Agreement, there shall not have occurred any Company Material Adverse Effect, (iv) our performance in all material respects of its obligations under the Merger Agreement and (v) the other conditions set forth in Exhibit A to the Merger Agreement. The obligations of XOMA and Merger Sub to consummate the Offer and the Merger under the Merger Agreement are not subject to a financing condition.

We cannot predict whether or when the conditions to the Offer will be satisfied. If one or more of these conditions are not satisfied, and as a result, we do not complete the Offer and the Merger, we would remain liable for significant transaction costs, and the focus of our management would have been diverted from seeking other potential strategic opportunities, in each case without realizing any benefits of the Offer and the Merger. Certain costs associated with the Offer and the Merger have already been incurred or may be payable even if the Offer and the Merger are not consummated. Finally, any disruptions to our business resulting from the announcement and pendency of the Offer and the Merger, including any adverse changes in our relationships with our partners, suppliers and employees, could continue or accelerate in the event that we fail to consummate the Offer and the Merger.

Our share price may also fluctuate significantly based on announcements by XOMA, other third parties, or us regarding the Offer and the Merger or based on market perceptions of the likelihood of the satisfaction of the Minimum Tender Condition or other conditions to the consummation of the Offer and the Merger. Such announcements may lead to perceptions in the market that the Offer and the Merger may not be completed, which could cause our share price to fluctuate or decline. Other factors outside of our control, such as a governmental entity enacting a legal restraint or prohibition that prevents or prohibits the Offer or the Merger, could cause us not to satisfy the closing condition relating to the absence of Legal Restraints (as defined in the Merger Agreement) (the Legal Restraint Condition) and thus the Offer and the Merger would not be consummated. Further, unforeseen and unexpected expenses could cause our net cash to be below the applicable threshold thus causing us to fail to satisfy the Closing Net Cash Condition.

If we do not consummate the Offer and the Merger, the price of our Common Stock may decline significantly from the current market price, which may reflect a market assumption that the Offer and the Merger will be consummated. Any of these events could have a material adverse effect on our business, operating results and financial condition and could cause a decline in the price of our Common Stock.

The consideration payable to holders of our Common Stock, In-the-Money Options and RSUs pursuant to the Merger Agreement will be adjusted if our net cash amount exceeds a certain threshold but will not otherwise be adjusted for changes in our business, assets, liabilities, prospects, outlook, financial condition or results of operations, or in the event of any change in our share price.

The consideration payable to holders of our Common Stock, In-the-Money Options and RSUs will be adjusted based on our Closing Net Cash but will not be otherwise adjusted for changes in our business, assets, liabilities, prospects, outlook, financial condition or results of operations, or changes in the market price of, analyst estimates of, or projections relating to, our shares of Common Stock.

Our stockholders may not receive any payment on the CVR and the CVR may expire valueless.

If the Offer and the Merger are completed, the holders of our Common Stock, Company Options and RSUs will be entitled to receive one CVR per share of Common Stock, share of Common Stock underlying a Company Option, or RSU, as applicable, representing the right to receive, subject to the terms and conditions of the CVR Agreement. Each CVR will represent a contractual right to receive contingent cash payments equal to (i) 100% of the Net Proceeds (as defined in the CVR Agreement), if any, from any Disposition by the Company, of all or any part of the rights, intellectual property and other assets related to (A) Exarafenib and/or (B) any other pan-RAF inhibitor entered into prior to the Offer Closing Time, and (ii) 85% of the Net Proceeds, if any, from any Disposition by XOMA or any of its affiliates, including the Company after the Merger, of all or any part of the CVR Products effected during the Disposition Period, in each case, which Net Proceeds are received prior to the Expiration Date. In the event that no CVR Proceeds become payable prior to the Expiration Date, holders of the CVRs will not receive any payment pursuant to the CVR Agreement. The CVRs will not be transferable, except in the limited circumstances specified in the CVR Agreement, will not have any voting or dividend rights, and will not represent any equity or ownership interest in us or any of our affiliates, and interest will not accrue on any amounts potentially payable on the CVRs. Accordingly, the right of any of our stockholders to receive any future payment on or derive any value from the CVRs will be contingent solely upon the occurrence of a Disposition, as outlined above, and no such Disposition is achieved for any reason within the time periods specified in the CVR Agreement, no payments will be made under the CVRs, and the CVRs will expire valueless.

The Merger Agreement contains provisions that could discourage a potential competing acquirer.

The Merger Agreement provides that, upon the terms and subject to the conditions thereof, we and our representatives cannot directly or indirectly solicit, initiate or knowingly encourage or knowingly facilitate discussions with third parties regarding other proposals to acquire or combine with us and we are subject to restrictions on our ability to respond to any such proposal. In the event that we receive an acquisition proposal from a third party, we must notify XOMA of such proposal and negotiate in good faith with XOMA prior to terminating the Merger Agreement or effecting a change in the recommendation of our board of directors and the Special Committee to our stockholders with respect to the Offer and the Merger. The Merger Agreement also contains certain termination rights for XOMA and us and further provides that, upon termination of the Merger Agreement under specified circumstances, including certain terminations in connection with an alternative business combination transaction as permitted by the terms of the Merger Agreement, we will be required to pay XOMA a termination fee of $3.5 million. These provisions could discourage a potential third-party acquirer that might have an interest in acquiring all or a significant portion of us from considering or proposing that acquisition, even if it were prepared to pay consideration with a higher per share cash or market value than the market value proposed to be received or realized in the transaction. These provisions also might result in a potential third-party acquirer proposing to pay a lower price to our stockholders than it might otherwise have proposed to pay due to the added expense of the termination fee that may become payable in certain circumstances. If the Merger Agreement is terminated and we determine to seek another business combination, we may not be able to negotiate a transaction with another party on terms comparable to, or better than, the terms of the Offer and the Merger.

Stockholder litigation could prevent or delay the consummation of the Offer and the Merger or otherwise negatively impact our business, operating results and financial condition.

We may incur additional costs in connection with the defense or settlement of any future stockholder litigation in connection with the Offer and the Merger. Any such future litigation may adversely affect our ability to complete the Offer and the Merger and may impact our ability to meet the Closing Net Cash Condition. We could incur significant costs in connection with any such litigation, including costs associated with the indemnification of our directors and officers. Furthermore, one of the conditions to the consummation of the Offer and the Merger is the Legal Restraint Condition. Consequently, if a plaintiff were to secure injunctive or other relief prohibiting, delaying or otherwise adversely affecting our ability to complete the consummation of the Offer and the Merger, then such injunctive or other relief may prevent the consummation of the Offer or the Merger within the expected time frames or at all.

We may become involved in securities class action litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action litigation has often followed certain significant business transactions not involving the Company, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in investigations by the SEC. We may be subject to such litigation or investigation even if no wrongdoing has occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate the Offer and the Merger within the expected time frames or at all, or to consummate any alternative strategic transaction, and could adversely impact the ultimate value our stockholders receive in any such transaction.

Our executive officers and directors may have interests in the Offer and the Merger that are different from, or in addition to, those of our stockholders generally.

Our executive officers and directors may have interests in the Offer and the Merger that are different from, or are in addition to, those of our stockholders generally, including the acceleration of equity awards in connection with the Merger, severance payments and retention bonuses. Such interests of our directors and executive officers are set forth in further detail in the Schedule 14D-9 we filed with the SEC on March 4, 2024.

While the Offer and the Merger are pending, we are subject to business uncertainties and contractual restrictions that could disrupt our business, and the Offer and the Merger may impair our ability to attract and retain qualified employees or retain and maintain relationships with our suppliers and other business partners.

Whether or not the Offer and the Merger are consummated, the Offer and the Merger may disrupt our current plans and operations, which could have an adverse effect on our business and financial results. The pendency of the Offer and the Merger may also divert management's attention and our resources from ongoing business and operations and our employees. Other key personnel may have uncertainties about the effect of the Offer and the Merger, and the uncertainties may impact our ability to retain key personnel while the Offer and the Merger are pending or in the event that we are unable to consummate the Offer or the Merger within the expected time frames or at all. If key personnel depart because of such uncertainties, our business and results of operations may be adversely affected.

In addition, pending consummation of the Offer and the Merger, the Merger Agreement generally requires us to operate in the ordinary course of business consistent with past practice and our intent to wind down our activities, and restricts us from taking certain actions with respect to our business and financial affairs without XOMA's consent. Such restrictions will be in place until either the Offer and the Merger are consummated or the Merger Agreement is terminated. These restrictions could restrict our ability to, or prevent us from, pursuing attractive business opportunities (if any) that arise prior to the consummation of the Offer and the Merger. For these and other reasons, the pendency of the Offer and the Merger could adversely affect our business, operating results and financial condition.

We have incurred, and will continue to incur, direct and indirect costs as a result of the Offer and the Merger.

We have incurred, and will continue to incur, significant costs and expenses, including fees for professional services and other transaction costs, in connection with the Offer and the Merger, including costs that we may not currently expect. We must pay substantially all of these costs and expenses whether or not the transaction is completed. If the Merger Agreement is terminated under certain circumstances specified in the Merger Agreement, including in connection with the Company's entry into an agreement with respect to a Superior Company Proposal, the Company will be required to pay XOMA a termination fee of approximately $3.5 million. If XOMA terminates the Merger Agreement due to the Company having Closing Net Cash of less than $120.0 million, the Company will be required to pay to XOMA an expense reimbursement fee up to a maximum amount of $1.25 million. There are a number of factors beyond our control that could affect the total amount or the timing of these costs and expenses.

If we are not able to complete the Offer and the Merger, we will likely pursue other strategic alternatives. We may not be successful in identifying and implementing any strategic business combination or other transaction and any strategic transaction that we may consummate in the future could have negative consequences. There can be no assurance that the terms of any such other transaction will be favorable.

As part of the Strategic Plans, we have undertaken a comprehensive assessment of strategic alternatives to maximize stockholder value. Upon the unanimous recommendation of the Special Committee, the board of directors determined that the terms of the Offer, the Merger and the other transactions contemplated under the Merger Agreement are fair to and in the best interests of the Company and the unaffiliated stockholders, approved the execution of the Merger Agreement and, subject to the terms and conditions of the Merger Agreement, recommended that the stockholders accept the Offer and tender their shares of Common Stock pursuant to the Offer.

If we are not able to consummate the Offer and the Merger and decide to evaluate other strategic alternatives there can be no assurance that this review process will result in us pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms or at all. The process of evaluating other strategic alternatives may be time-consuming and complex, and we may incur significant costs related to this evaluation, such as for financial advisors, as well as legal and accounting fees and expenses and other related charges, in addition to those we have already incurred in connection with the Offer and the Merger. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any alternative strategic transaction is pursued or completed. Any such expenses will decrease the remaining cash available for use in our business and may diminish or delay any future distributions to our stockholders.

In addition, if we are not able to complete the Offer and the Merger and are required to pursue another strategic alternative, such alternative transaction may yield unexpected results that adversely affect our business and decrease the remaining cash available for use in our business or the execution of our Strategic Plans. There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve its anticipated results. Any failure of such potential transaction to achieve its anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders.

We may not realize any additional value in a strategic transaction.

XOMA has placed no value on our assets and intellectual property and may spend only limited resources as provided in the CVR Agreement to potentially monetize our assets. Other potential counterparties in a strategic transaction involving us may likewise place minimal or no value on our assets. Further, the development and any potential commercialization of our product candidates will require substantial additional cash to fund the costs associated with conducting the necessary preclinical and clinical testing and obtaining regulatory approval. Consequently, any potential counterparty in a strategic transaction involving us may choose not to spend additional resources and continue development of our product candidates and may likewise attribute little or no value, in such a transaction, to those assets.

If a strategic transaction is not consummated, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that the Offer and the Merger or any other strategic transaction will be consummated. If a strategic transaction is not consummated, the Special Committee and the board of directors may decide to pursue a dissolution and liquidation of the Company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision, as the amount of cash available for distribution will decline over time as we continue to fund our operations. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution would be uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our Board, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our Common Stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

Our ability to consummate the Offer and the Merger or complete another strategic transaction or our dissolution and liquidation depends on our ability to retain our employees and engage other advisors and consultants required to consummate such transactions.

As part of our Strategic Plans and a subsequent RIF completed in March 2024, we reduced our workforce by approximately 89% to a total of 10 full-time employees. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce, decline in employee productivity and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully consummate the Offer and the Merger or complete another strategic transaction or our dissolution and liquidation depends in large part on our ability to retain certain of our remaining personnel, the loss of whose services may adversely impact our ability to consummate such transaction,and engage other advisors and consultants. Due to our limited employee resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our operations, risks that we may not be able to comply with legal and regulatory requirements.

Our principal stockholders and management, if they choose to act together, will have the ability to significantly influence all matters submitted to stockholders for approval.

As of March 13, 2024, our executive officers, directors and their affiliates, in the aggregate, beneficially owned approximately 46% of our outstanding shares of Common Stock and, as a result, when acting together have the ability to significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control of us, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging another potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

As described elsewhere in this Annual Report on Form 10-K, we implemented reductions in force in September 2023 and January and March 2024, and we have suspended almost all of our research and development activities after announcing the XOMA transaction and sale of Exarafenib. In the event that we do not consummate the Offer and the Merger and remain a stand-alone company and resume our research and development activities, clinical trials and efforts to commercialize any therapeutic products, then the following risk factors would apply except as otherwise noted.

Risks Related to our Financial Position and Need for Additional Capital

We have suspended almost all of our research and development efforts, have a limited operating history, have limited experience initiating and have not completed any clinical trials, have no products approved for commercial sale and have not generated any revenue, which may make it difficult for investors to evaluate our current business and likelihood of success and viability.

We are a clinical-stage precision oncology company and have a limited operating history upon which investors can evaluate our business and prospects. We commenced operations as a company in January 2018. We have never completed any clinical trials, have no products approved for commercial sale and have never generated any revenue. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. Historically, we devoted substantially all of our resources to research and development activities, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these operations.

We have limited experience conducting clinical trials to completion and have not yet demonstrated our ability to successfully complete a clinical trial, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for investors or others to accurately predict our likelihood of success and viability than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields. We have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not adequately address these risks and difficulties, our business will suffer.

In January 2024, we announced that we were exploring strategic alternatives for the Company and subsequently we suspended almost all of our research and development activities.

We have incurred significant net losses in each period since our inception, and we expect to continue to incur net losses for the foreseeable future.

We have incurred significant net losses in each reporting period since our inception, have not generated any revenue to date and have financed our operations principally through issuances of our common stock, including in our initial public offering (IPO), and private placements of our convertible preferred stock. Our consolidated net loss was $112.6 million for the year ended December 31, 2023, and as of December 31, 2023, we had an accumulated deficit of $372.0 million. We have not yet completed any clinical trials, and we are exploring strategic alternatives for the Company. We may never develop a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing a product candidate, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Our announcements regarding the Strategic Plans and the signing of the Merger Agreement are likely to further increase the variability of our operating results in the coming quarters as compared to prior quarters. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and the performance of our stock.

Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve our objectives relating to the discovery, development and commercialization of our product candidates.

We rely on our team's expertise in structure-based drug discovery, translational research and patient-driven precision medicine to develop our product candidates. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives, including:

- successful and timely completion of clinical development of product candidates and preclinical and clinical development of product candidates from our research programs;
- establishing and maintaining relationships with contract research organizations (CROs) and clinical sites for the clinical development of product candidates;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- developing an efficient and scalable manufacturing process for our product candidates, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval of our product candidates;
- commercial acceptance of our product candidates by patients, the medical community and third-party payors;
- satisfying any required post-marketing approval commitments to applicable regulatory authorities;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- defending against third-party interference or infringement claims, if any;
- entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations.

Changing circumstances and market conditions, some of which may be beyond our control, could impair our ability to access our existing cash and cash equivalents and investments and to timely pay key vendors and others.

Changing circumstances and market conditions, some of which may be beyond our control, could impair our ability to access our existing cash and cash equivalents and investments and to timely pay key vendors and others. For example, on March 10, 2023, Silicon Valley Bank (SVB) was placed into receivership with the Federal Deposit Insurance Corporation (FDIC), which resulted in all funds held at SVB, including our funds held at SVB, being temporarily inaccessible by SVB's customers. If other banks and financial institutions with whom we have banking relationships enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, we may be unable to access, and we may lose, some or all of our existing cash and cash equivalents and investments to the extent those funds are not insured or otherwise protected by the FDIC. In addition, in such circumstances we might not be able to timely pay key vendors and others. We regularly maintain cash balances that are not insured or are in excess of the FDIC's insurance limit. Any delay in our ability to access our cash and cash equivalents and investments (or the loss of some or all of such funds) or to timely pay key vendors and others could have a material adverse effect on our operations and cause us to need to seek additional capital sooner than planned.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and drug development programs, future commercialization efforts, product development or other operations.

Since our inception, we have used substantial amounts of cash to fund our operations, and if we continue advancing any clinical or preclinical programs our expenses will increase substantially in connection with such activities. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Even if one or more of our product candidates or any future product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if the FDA, the European Medicines Agency (EMA) or other regulatory authorities require us to perform clinical trials or preclinical studies in addition to those that we anticipate. Other unanticipated costs may also arise. Because the design and outcome of clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any future product candidates that we develop. We are not permitted to market or promote any product candidate before we receive marketing approval from the FDA. We also expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

Based on our current operating plan, we believe that our existing cash and cash equivalents and short-term and long-term investments as of the date of this Annual Report on Form 10-K will be sufficient to fund our operating expenses and capital expenditures through at least the next twelve months from the date this Annual Report on Form 10-K is filed with the SEC. If we continue to advance the development of any of our programs including our c-MET inhibitor KIN-8741 research program and our CDK4 selective research program, we will require a significant amount of capital. Our existing cash and cash equivalents will not be sufficient to fund any of our product candidates through regulatory approval, and we anticipate needing to raise additional capital to complete the development of and commercialize our product candidates. Our estimate as to how long we expect our existing cash and cash equivalents and short-term and long-term investments to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We may be required to obtain further funding through public or private equity financings, debt financings, collaborative agreements, licensing arrangements or other sources of financing, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, investors' ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect their rights as stockholders. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research or drug development programs, clinical trials or future commercialization efforts.

Risks Related to the Discovery, Development and Commercialization of our Product Candidates

We are very early in our development efforts. If we are unable to advance any product candidates, obtain regulatory approval and ultimately commercialize such product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts. We previously initiated a Phase 1 clinical trial for KIN-3248 for our FGFR program and have received FDA clearance of the IND application for KIN-7136 as well as for KIN-8741. In January 2024, we announced the exploration of strategic alternatives for the Company and we subsequently suspended almost all of our research and development activities. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful clinical development and eventual commercialization of one or more of our product candidates. We are not permitted to market or promote any product candidate before we receive marketing approval from the FDA, EMA or any other comparable foreign regulatory authorities, and we may never receive such marketing approvals.

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

- approval of INDs for our planned clinical trials and future clinical trials;
- addressing any potential delays resulting from factors related to public health concerns, such as COVID-19;
- successful initiation and completion of clinical trials;
- successful and timely patient selection and enrollment in and completion of clinical trials;
- maintaining and establishing relationships with CROs and clinical sites for the clinical development of our product candidates both in the United States and internationally;
- the frequency and severity of adverse events in clinical trials;
- demonstrating efficacy, safety and tolerability profiles that are satisfactory to the FDA, EMA or any other comparable foreign regulatory authority for marketing approval;
- the timely receipt of marketing approvals from applicable regulatory authorities;
- the timely identification, development and approval of companion diagnostic tests, if required;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers for clinical development and, if approved, commercialization of our product candidates;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- the protection of our rights in our intellectual property portfolio;
- the successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of preclinical and 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. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize any product candidates from our lead programs, which would materially harm our business. If we do not receive marketing approvals for such product candidates, we may not be able to continue our operations.

Our preclinical studies and clinical trials may fail to adequately demonstrate the safety and efficacy of any of our product candidates, which would prevent or delay development, regulatory approval and commercialization.

Before obtaining marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for the sale of our product candidates, we must demonstrate safety and efficacy of our product candidates for use in each target indication through lengthy, complex and expensive preclinical studies and clinical trials. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. Failure can occur at any time during the preclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products.

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

- failure of our product candidates in preclinical studies or clinical trials to demonstrate safety and efficacy;
- receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain research and/or drug development programs;
- the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated or participants dropping out of these clinical trials at a higher rate than anticipated;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements or a finding that our product candidates have undesirable side effects or other unexpected characteristics or risks;
- the cost of clinical trials of our product candidates being greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate; and
- regulators revising the requirements for approving our product candidates.

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 in a timely manner, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may incur unplanned costs, be delayed in seeking and obtaining marketing approval, if we receive such approval at all, receive more limited or restrictive marketing approval, be subject to additional post-marketing testing requirements or have the drug removed from the market after obtaining marketing approval.

Our discovery and preclinical development activities are focused on the development of targeted therapeutics for patients with genomically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs is novel and may never lead to approved or marketable products.

The discovery and development of targeted therapeutics for patients with genomically defined cancers is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Although we believe, based on our preclinical work, that the genomic alterations targeted by our programs are oncogenic drivers, clinical results may not confirm this hypothesis or may only confirm it for certain alterations or certain tumor types. The patient populations for our product candidates are limited to those with specific target alterations and may not be completely defined but are substantially smaller than the general treated cancer population, and we will need to screen and identify these patients with targeted alterations. Successful identification of patients is dependent on several factors, including achieving certainty as to how specific alterations respond to our product candidates and the ability to identify such alterations. Furthermore, even if we are successful in identifying patients, we cannot be certain that the resulting patient populations for each alteration will be large enough to allow us to successfully obtain approval for each alteration type and commercialize our product candidates and achieve profitability.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.

We will be required to demonstrate the safety and efficacy of our product candidates in a diverse population with substantial evidence through well-controlled clinical trials before we can seek marketing approvals for their commercial sale. Preclinical and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products.

The results of preclinical studies may not be predictive of the results of clinical trials of our product candidates, and the results of early clinical trials may not be predictive of the results of later-stage clinical trials. Although product candidates may demonstrate promising results in preclinical studies and early clinical trials, they may not prove to be safe or effective in subsequent clinical trials. Favorable results from certain animal studies may not accurately predict the results of other animal preclinical studies or of human clinical trials, due to the inherent biologic differences in species, the differences between testing conditions in animal preclinical studies and human clinical trials, and the particular goals, purposes, and designs of the relevant preclinical studies and clinical trials.

There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. Likewise, early, smaller-scale clinical trials may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, insufficient durability of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence preclinical studies and clinical trials are never approved as products. The development of our product candidates and our stock price may also be impacted by inferences, whether correct or not, that are drawn between the success or failure of preclinical studies or clinical trials of our competitors or other companies in the biopharmaceutical industry, in addition to our own preclinical studies and 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 clinical trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

Any preclinical studies or clinical trials that we conduct may not demonstrate the safety and efficacy necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety or efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical 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 approval to market any of our product candidates.

Our prospects depend in part upon discovering, developing and commercializing other product candidates, including our CDK4 selective research program, which may fail in development or suffer delays that adversely affect their commercial viability.

Our future operating results are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates from our research programs, including our CDK4 selective research program. A research candidate can unexpectedly fail at any stage of development. The historical failure rate for research candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate.

The success of other research candidates we may develop will depend on many factors, including the following:

- generating sufficient data to support the initiation or continuation of preclinical studies and clinical trials;
- addressing any potential delays resulting from factors related to public health concerns, such as the COVID-19 pandemic;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of a product candidate for use in clinical trials; and
- adverse events in clinical trials.

Even if we successfully advance any research candidates into preclinical and clinical development, their success will be subject to all of the preclinical, clinical, regulatory and commercial risks described elsewhere in this “Risk Factors” section. Accordingly, there can be no assurance that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from any product candidates.

Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to build a pipeline of product candidates with commercial value.

A key element of our strategy is to build a pipeline of product candidates and progress these product candidates through clinical development. Although our research and development efforts to date have resulted in the discovery, preclinical development and clinical development of product candidates, such product candidates, and any other product candidates we have identified, may not be safe or effective as cancer therapeutics, and we may not be able to develop any other product candidates. In addition, our Strategic Plans may render development of product candidates impossible. Even if we are successful in building a pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be product candidates that will receive marketing approval from the FDA, EMA or other regulatory authorities or achieve market acceptance.

The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval of our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

Obtaining approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. For example, the FDA's Oncology Center of Excellence initiated Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development and Project FrontRunner to help develop and implement strategies to support approvals in the early clinical setting, among other goals. How the FDA plans to implement those goals and their impact on specific clinical programs and the industry are unclear. Even if we eventually complete clinical testing and receive approval for our product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested or may impose other prescribing limitations or warnings that limit the product candidate's commercial potential. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our product candidates will ever obtain regulatory approval. Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that we have not demonstrated the safety and efficacy of our product candidates, or that they have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA, EMA or other comparable regulatory authorities may fail to approve companion diagnostic tests required for our product candidates; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.

We have no experience as a company in conducting clinical trials to completion.

We have no experience as a company in conducting clinical trials to completion and in light of our Strategic Plans may never do so. Large-scale clinical trials would require significant additional financial and management resources and reliance on third-party clinical investigators, CROs, and consultants. Relying on third-party clinical investigators, CROs and consultants may force us to encounter delays that are outside of our control. We may be unable to identify and contract with sufficient investigators, CROs and consultants on a timely basis or at all. There can be no assurance that we will be able to negotiate and enter into any necessary services agreements with CROs on terms that are acceptable to us on a timely basis or at all.

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

In January 2022, the FDA cleared our IND for KIN-3248 and we initiated KN-4802, a Phase 1 clinical trial for KIN-3248 in the first quarter of 2022 and began dosing KIN-3248 in humans in the second quarter of 2022. In the third quarter of 2023, we announced that the FDA cleared the IND application for KIN-7136. In the fourth quarter of 2023, the FDA cleared the IND application for KIN-8741. However, we may not be able to file IND applications for other current or future product candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND enabling studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if the FDA agrees with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that it will not change its requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our ongoing and planned future clinical trials may prevent us from initiating or completing our clinical trials or commercializing our product candidates on a timely basis, if at all.

Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could delay or prevent regulatory approval or market acceptance, or even if approval is received, require them to be taken off the market, include new safety warnings, contraindications or precautions, or otherwise limit their commercial potential or result in significant negative consequences.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the clinical trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly. Moreover, results of our preclinical studies or clinical trials could reveal a high and unacceptable severity and prevalence of these or other side effects or adverse events. In such an event, our clinical trials could be suspended or terminated, and the FDA, EMA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, our product candidates may be used in populations for which safety concerns may be particularly scrutinized by regulatory authorities. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, it is expected that some of the patients to be enrolled in our ongoing and planned future clinical trials will die or experience major clinical events either during the course of our clinical trials or after participating in such clinical trials for non-treatment related reasons.

If significant adverse events or other side effects are observed in any of our ongoing or planned future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our clinical trials, or we may be required to abandon the clinical trials or our development efforts of that product candidate altogether. We, the FDA, EMA, other comparable foreign regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such clinical trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage clinical trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies, resulting in marketing approval with restrictive label warnings or for a limited patient population, or result in potential product liability claims. Any of these developments could materially harm our business, financial condition and prospects. Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates previously not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. No regulatory agency has made any determination that any of our product candidates or discovery programs is safe or effective for use by the general public for any indication. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

Interim, topline and preliminary data from our preclinical studies and clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our preclinical studies and clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular preclinical study or clinical trial. For example, we may report responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same preclinical studies or clinical trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete 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. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is typically selected from a more extensive amount of available information. Investors or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any of our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

Delays or difficulties in the enrollment or maintenance of patients in our clinical trials could result in our regulatory submissions or receipt of necessary marketing approvals being delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these clinical trials to such clinical trial's conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

Our ability to activate our clinical trial sites or enroll patients may also be significantly delayed by public health concerns, such as the COVID-19 pandemic. For example, initial site activation for the KN-8701 clinical trial was slower than expected due to the COVID-19 pandemic. In addition, patients may not be able or willing to visit clinical trial sites for dosing or data collection purposes due to limitations on travel and physical distancing imposed or recommended by federal or state governments or patients' reluctance to visit the clinical trial sites during the pandemic. These factors resulting from public health concerns could delay our clinical trials and our regulatory submissions.

Patient enrollment may be affected if our competitors have ongoing clinical trials for programs that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' programs. Patient enrollment for our current or any future clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the clinical trial in question as defined in the protocol, including biomarker-driven identification and/or certain highly-specific criteria related to stage of disease progression, which may limit the patient populations eligible for our clinical trials to a greater extent than competing clinical trials for the same indication that do not have biomarker-driven patient eligibility criteria;
- perceived risks and benefits of the product candidate under study;

- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved or other product candidates being investigated for the indications we are investigating;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods.

Pandemics or other widespread public health concerns could adversely impact our business, including our ongoing and planned future preclinical studies and clinical trials.

A continued and prolonged public health crisis, such as the COVID-19 pandemic, could have a material negative impact on our business, financial condition and operating results. COVID-19 continues to affect populations around the globe, notwithstanding the availability of vaccines for some people, we may experience challenges or disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in clinical site initiation, such as our experience with our KN-8701 clinical trial, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays or difficulties in enrolling and retaining patients in any clinical trials, particularly elderly subjects, who are at a higher risk of severe illness or death;
- difficulties interpreting data from our clinical trials due to the possible confounding effects on patients;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- interruption or delays in the operations of the FDA, EMA or other regulatory authorities, which may impact review and approval timelines;
- limitations in resources that would otherwise be focused on the conduct of our business, our preclinical studies or our clinical trials, including because of sickness or the desire to avoid contact with large groups of people or as a result of government-imposed "shelter in place" or similar working restrictions;
- interruptions, difficulties or delays arising in our existing operations and company culture as a result of our employees working from home or in a hybrid model;
- delays in receiving approval from regulatory authorities to initiate our clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruptions in preclinical studies due to restricted or limited operations at the CROs conducting such studies;
- interruption in global freight and shipping that may affect the transport of clinical trial materials, such as investigational drug product to be used in our clinical trials;
- changes in regulations in response to public health concerns, which may require us to change the ways in which our clinical trials are to be conducted, or to discontinue the clinical trials altogether, or which may result in unexpected costs;
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and
- refusal of the FDA, EMA or other regulatory authorities to accept data from clinical trials in affected geographies outside of their respective jurisdictions.

Since March 2020, the FDA has issued various COVID-19 related guidance documents for manufacturers and clinical trial sponsors, many of which have expired or were withdrawn with the expiration of the COVID-19 public health emergency declaration on May 11, 2023, although some COVID-19 related guidance documents continue in effect. To the extent the government imposes other policies, restrictions, or changes to regulations, including in response to public health concerns, complying with such changes and regulatory requirements could be time-intensive and expensive, resulting in a material adverse effect on our business.

To the extent a pandemic or another widespread public health concern adversely affects our business, financial condition and operating results, it may also have the effect of heightening many of the risks described in this "Risk Factors" section.

We have limited resources and are currently focusing our efforts on exploring strategic alternatives for the Company. As a result, we may fail to capitalize on developing our programs in indications or advancing product candidates that may ultimately have proven to be more profitable.

We are currently focusing our resources and efforts on exploring strategic alternatives for the Company. As a result, because we have limited resources, we may forgo or delay pursuit of opportunities for indications or product candidates that may have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target markets for our programs, including our c-MET inhibitor, KIN-8741 and our CDK4 selective inhibitor KIN-7324, or the product candidates in these programs, we may relinquish valuable rights to our product candidates or programs through collaboration, licensing or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or program.

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 characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with our product candidates. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of product candidates are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. In addition, our product candidates may need to compete with drugs physicians use off-label to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our product candidates.

In particular, there is intense competition in the field of oncology. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, emerging and start-up companies, universities and other research institutions. We also compete with these organizations to recruit and retain qualified scientific and management personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. We could face competition from existing products and products in development for each of our programs.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market, and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology product candidates. These companies also have significantly greater research and marketing capabilities than we do and may also have product candidates that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA, EMA or other comparable foreign regulatory authorities or in discovering, developing and commercializing product candidates in our field before we do.

Our potential commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, have a broader label, are marketed more effectively, are more widely reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for their products 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 or make our development more complicated. Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness.

Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected. For additional information regarding our competition, see the section of this Annual Report on Form 10-K, titled "Business—Competition."

The manufacture of drugs is complex, and our third-party manufacturers or suppliers may encounter difficulties in production or with their supply chains. If any of our third-party manufacturers or suppliers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, as well as sophisticated quality assurance and quality control procedures. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination.

If our third-party manufacturers or suppliers are unable to produce, or provide us with, sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. For example, we may introduce an alternative formulation of one or more of our product candidates during the course of our ongoing or planned future clinical trials. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of ongoing and planned future clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which a product candidate is approved;
- restrictions on the use of product candidates in the labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or a risk evaluation and mitigation strategy, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- the availability of an approved product candidate for use as a combination therapy;

- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and undergo required diagnostic screening to determine treatment eligibility and of physicians to prescribe these therapies and diagnostic tests;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our product candidates; and
- the approval of other new therapies for the same indications.

If any of our product candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

The market opportunities for any product candidates we develop, if approved, may be limited to certain smaller patient subsets and may be smaller than we estimate them to be.

When cancer is detected early (referred to as localized disease), conventional treatments which include chemotherapy, hormone therapy, surgery and radiation therapy and/or selected targeted therapies, may be adequate to cure the patient in many cases. However, once cancer has spread to other areas (advanced or metastatic disease), cancer treatments may not be sufficient to provide a cure but often can significantly prolong life without curing the cancer. First-line therapies designate treatments that are initially administered to patients with advanced or metastatic disease, while second- and third-line therapies are administered to patients when the prior therapies lose their effectiveness. The FDA, EMA and other comparable regulatory bodies often approve cancer therapies for a particular line of treatment. Typically, drug approvals are initially granted for use in later lines of treatment, but with additional evidence of significant efficacy from clinical trials, biopharmaceutical companies can successfully seek and gain approval for use in earlier lines of treatment.

We plan to initially seek approval of our product candidates in most instances at least as a second- or third-line therapy, for use in patients with advanced or metastatic cancer where at least one prior therapy has limited clinical benefit or has lost its effectiveness. For those product candidates for which we demonstrate safety and efficacy, if any, we would expect to seek approval as a second-line therapy and potentially ultimately as a first line therapy. There is no guarantee that our product candidates, even if approved as a second, third or subsequent line of therapy, would be approved for an earlier line of therapy, and prior to any such approvals we may have to conduct additional clinical trials that may be costly, time-consuming and subject to risk.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of the cancers that we are targeting. The potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Consequently, even if our product candidates are approved, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected. In addition, we have not yet conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each such tumor type. Even if we obtain significant market share for our products, if approved, if the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of such product candidates will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by CMS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

As federal and state governments implement additional health care cost containment measures, including measures to lower prescription drug pricing, we cannot be sure that our products, if approved, will be covered by private or public payors, and if covered, whether the reimbursement will be adequate or competitive with other marketed products. Legislative, executive, administrative and other actions by federal and state governments and health plans may put additional downward pressure on pharmaceutical pricing and health care costs, which could negatively impact coverage and reimbursement for our products if approved, our revenue, and our ability to compete with other marketed products and to recoup the costs of our research and development. For further discussion, please see the risk factor below titled, "*We may face difficulties from changes to current regulations and future legislation. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations*."

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. 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.

In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. Additionally, if any companion diagnostic provider is unable to obtain reimbursement or is inadequately reimbursed, that may limit the availability of such companion diagnostic, which would negatively impact prescriptions for our product candidates, if approved.

Outside the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the EU, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA, EMA or other regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to clinical trial participants or patients. We will need to obtain appropriate levels of product liability insurance prior to advancing our product candidates into clinical trials or marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

We may be unable to obtain U.S. or foreign regulatory approval and, as a result, may be unable to commercialize our product candidates.

Our product candidates are and will continue to be subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be approved for marketing. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. We cannot provide any assurance that any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We have not conducted, managed or completed large-scale or pivotal clinical trials nor managed the regulatory approval process with the FDA, EMA or any other regulatory authority. The time required to obtain approvals from the FDA, EMA and other comparable regulatory authorities is unpredictable and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can, and often does, change during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in applicable FDA, EMA or other regulatory policy during the period of drug development, clinical trials and regulatory review.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that we have not demonstrated the safety and efficacy of our product candidates, or that they have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that our product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from any particular product candidates we are developing and for which we are seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market, promote and advertise the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy (REMS) plan as part of approving a New Drug Application (NDA), or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries, and generally includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

We may develop our current or future product candidates in combination with other therapies, which would expose us to additional risks.

We may develop our current or future product candidates in combination with one or more currently-approved cancer therapies or therapies in development. Even if any of our current or future product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially.

We may also evaluate our current or future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA, EMA or other comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any of our current or future product candidates, we may be unable to obtain approval of or successfully market any one or all of the current or future product candidates we develop. Additionally, if the third-party providers of therapies or therapies in development used in combination with our current or future product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our current or future product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We have never commercialized a product candidate as a company before and currently lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized a product candidate as a company. We may license certain rights with respect to our product candidates to collaborators, and, if so, we will rely on the assistance and guidance of those collaborators. For product candidates for which we retain commercialization rights and marketing approval, we will have to develop our own sales, marketing and supply organization or outsource these activities to one or more third parties.

Factors that may affect our ability to commercialize our product candidates, if approved, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, developing adequate educational and marketing programs to increase public acceptance of our approved product candidates, ensuring regulatory compliance of our company, employees and third parties under applicable healthcare laws, and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates upon approval. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.

The FDA, EMA and other comparable foreign regulatory authorities may not accept data from clinical trials conducted in locations outside of their jurisdiction.

We are initially conducting clinical trials of our product candidates in the United States, and we anticipate we may choose to conduct our clinical trials internationally as well. The acceptance of clinical trial data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from United States clinical trials are intended to serve as the basis for marketing approval in the foreign countries outside the United States, the standards for clinical trials and approval may be different. There can be no assurance that any United States or foreign regulatory authority would accept data from clinical trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA or EMA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential product candidates will be harmed.

Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and on-going surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval clinical trial or risk management requirements and regulatory inspection. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, EMA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with current good manufacturing practices (cGMPs) and good clinical practices (GCPs) for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA, EMA and other comparable regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned clinical trials;

- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions; and
- requirements to conduct additional post-market clinical trials to assess the safety of products.

The FDA, EMA and other comparable regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

We may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from pandemics or other public health concerns. For example, since March 2020, the FDA issued various COVID-19 related guidance documents for manufacturers and clinical trial sponsors, many of which have expired or were withdrawn with the expiration of the COVID-19 public health emergency declaration on May 11, 2023. If new guidance and policies are promulgated by the FDA that require changes in our clinical protocol or clinical development plans, our anticipated timelines and regulatory approval may be delayed or materially impacted. For additional risks related to the potential impact of COVID-19 or other widespread public health concerns, please see the risk factor above titled, "*Pandemics or other widespread public health concerns could adversely impact our business, including our ongoing and planned future preclinical studies and clinical trials*."

Moreover, the FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted in the United States for uses that are not approved by the FDA as reflected in the product's approved labeling, or in other jurisdictions for uses that differ from the labeling or uses approved by the applicable regulatory authorities. While physicians may prescribe products for off-label uses, the FDA, EMA and other comparable regulatory authorities actively enforce laws and regulations that prohibit the promotion of off-label uses by companies, including promotional communications made by companies' sales force with respect to off-label uses that are not consistent with the approved labeling, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates, if approved, and generate revenue.

The FDA, EMA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA, EMA and other comparable regulatory authorities strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

If we are required by the FDA, EMA or comparable regulatory authority to obtain approval of a companion diagnostic test in connection with approval of any of our product candidates or a group of therapeutic products, and we do not obtain or we face delays in obtaining approval of a diagnostic test, we will not be able to commercialize the product candidate and our ability to generate revenue will be materially impaired.

If we are required by the FDA, EMA or comparable regulatory authority to obtain approval of a companion diagnostic test in connection with approval of any of our product candidates, such companion diagnostic test would be used during our more advanced phase clinical trials as well as in connection with the commercialization of our product candidates. To be successful in developing and commercializing product candidates in combination with these companion diagnostics, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared at the same time the product candidate is approved. To date, the FDA has required marketing approval of all companion diagnostic tests for cancer therapies. Various foreign regulatory authorities also regulate *in vitro* companion diagnostics as medical devices and, under those regulatory frameworks, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of our current diagnostics and any future diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization.

The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express certain biomarkers or the specific genomic alteration that the companion diagnostic was developed to detect. If the FDA, EMA or a comparable regulatory authority requires approval of a companion diagnostic for any of our product candidates, whether before or concurrently with approval of the product candidate, we, and/or future collaborators, may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of our related product candidates. In June 2023, the FDA announced a new voluntary pilot program through which drug manufacturers can provide to the FDA the diagnostic test performance information used to enroll patients into clinical trials for drug approval, which can facilitate the development of laboratory-developed tests, or LDTs, and to ensure more consistent performance of these tests for drug selection and improving cancer patient care. In October 2023, FDA published a proposed rule that will phase out the agency's enforcement discretion policy for LDTs. Such proposed rule and future issuances from the FDA, EMA and other comparable regulatory authorities may impact our development of a companion diagnostic for our product candidates and result in delays in regulatory approval. We may be required to conduct additional clinical trials to support a broader claim. Also, to the extent other approved diagnostics are able to broaden their labeling claims to include our approved drug products, we may be forced to abandon our companion diagnostic development plans or we may not be able to compete effectively upon approval, which could adversely impact our ability to generate revenue from the sale of our approved products and our business operations.

Additionally, we may rely on third parties for the design, development and manufacture of companion diagnostic tests for our product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so, the development of our product candidates may be adversely affected, our product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of our product candidates that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

Where appropriate, we plan to secure approval from the FDA, EMA or comparable foreign regulatory authorities through the use of accelerated registration pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, EMA or comparable regulatory authorities, if our confirmatory clinical trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA, EMA or such other regulatory authorities may seek to withdraw accelerated approval.

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for one or more of our product candidates from the FDA, EMA or comparable foreign regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory clinical trials to verify and describe the drug's clinical benefit. If such post-approval clinical trials fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug. Further, in December 2022, the Consolidated Appropriations Act, 2023, including the Food and Drug Omnibus Reform Act (FDORA), was signed into law. FDORA made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements. In March 2023, FDA issued a draft guidance on clinical trial considerations for supporting accelerated approval of oncology therapeutics, noting that although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach for more robust efficacy and safety assessment. To the extent FDA requires us to amend the design of our clinical trials or requires additional trials to meet changes in the data requirements for approval, our clinical timelines and approval will be delayed, which can have an adverse effect on our business and operations.

Prior to seeking accelerated approval, we will seek feedback from the FDA, EMA or comparable foreign regulatory authorities and will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, EMA or comparable foreign regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation (e.g., Fast Track designation, Breakthrough Therapy designation or orphan drug designation), there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA, EMA or other comparable foreign regulatory authorities could also require us to conduct further clinical trials prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We may seek additional Fast Track designations from the FDA for our product candidates. Even if our product candidates receive Fast Track designations, we may be unable to obtain or maintain the benefits associated with such Fast Track designations.

Fast Track designation is designed to facilitate the development and expedite the review of therapies for serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is being studied. If any of our product candidates receive Fast Track designation but do not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation does not change the standards for approval. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

A Breakthrough Therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek Breakthrough Therapy designation for one or more of our current or future product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the clinical trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to candidate products considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we may seek Breakthrough Therapy designation for one or more of our current or future product candidates, there can be no assurance that we will receive Breakthrough Therapy designation.

We may not be able to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA, EMA or other comparable foreign regulatory authorities, from approving competing products.

Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Our target indications may include diseases with large patient populations or may include orphan indications. However, there can be no assurances that we will be able to obtain orphan designations for our product candidates.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product candidate is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances. The applicable exclusivity period is 10 years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug designation for a product candidate, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have obtained orphan drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to ensure that we will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process or entitles the product candidate to priority review.

Further, in a 2021 case, a court disagreed with the FDA's longstanding position that orphan drug exclusivity only applies to the approved use or indication within an eligible orphan disease. Although this court decision created uncertainty in the application of orphan drug exclusivity, in January 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court ruling in that case, the FDA intends to continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of orphan drug exclusivity.

We may face difficulties from changes to current regulations and future legislation. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), was passed, which substantially changed the way healthcare is financed by both the government and private insurers and continues to significantly impact the U.S. pharmaceutical industry. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, including legal and constitutional challenges in the Fifth Circuit Court and the Supreme Court of the United States. In June 2021, the Supreme Court of the United States held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is unclear how this Supreme Court decision, future litigation, or healthcare measures promulgated by the Biden administration will impact our business, financial condition and results of operations. Complying with any new legislation or changes in healthcare regulation could be time consuming and expensive, resulting in a material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2032, with the exception of a temporary suspension under various COVID-19 relief legislation. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, 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. These laws as well as future legislation and executive actions may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Moreover, there has 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. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. Further, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. The HHS has released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and potential legislative policies that Congress could pursue to advance these principles. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including pharmaceutical companies, the U.S. Chamber of Commerce, the National Infusion Center Association, the Global Colon Cancer Association, and the Pharmaceutical Research and Manufacturers of America have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. The impact of these judicial challenges, legislative, executive, and administrative actions and any future agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. Further, uncertainties created by the Inflation Reduction Act, including its long-term impact on drug pricing, may negatively impact investments, company valuation, mergers and acquisitions in the industry. The implementation of cost containment measures, including the prescription drug provisions under the Inflation Reduction Act, as well as other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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. Additionally, a number of states are considering or have recently enacted drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin to commercialize any of our product candidates, if approved.

We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government 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 product candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Additionally, the collection and use of health data in the EU is governed by the General Data Protection Regulation (GDPR), which extends the geographical scope of EU data protection law to non-EU entities under certain conditions and imposes substantial obligations upon companies and new rights for individuals, as discussed in the risk factor below titled, "*Data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.*"

Finally, state and foreign laws may apply generally to the privacy and security of information we maintain, and may differ from each other in significant ways, thus complicating compliance efforts. For example, the California Consumer Privacy Act of 2018 (CCPA), which took effect on January 1, 2020, gives California residents numerous expanded rights and allows enforcement by the California Attorney General, with fines set at $2,500 per violation (i.e., per person) or $7,500 per intentional violation, while authorizing private lawsuits to recover statutory damages for certain data breaches. While it exempts some data regulated by HIPAA and certain clinical trials data, the CCPA, to the extent applicable to our business and operations, may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA was modified significantly by the California Privacy Rights Act (CPRA), which was approved by California voters in November 2020 and which became effective January 1, 2023. Numerous other states have proposed, and in certain cases enacted, legislation relating to privacy and data security, many of which impose obligations similar to the CCPA and CPRA. The U.S. federal government also is contemplating federal privacy legislation. The CPRA and these other laws create further uncertainty and may require us to modify our policies and practices and to incur additional costs and expenses. For additional information on the CCPA and other new and evolving state legislation, please see the discussion in the risk factor below titled, "*Data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.*"

Inadequate funding for the FDA, the SEC and other U.S. government agencies or the EMA or comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA, EMA or comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, disruptions from natural disasters or public health concerns, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions of normal operations at the FDA, EMA and other comparable regulatory authorities, including disruptions due to public health concerns, travel restrictions, or staffing shortages, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown or other disruption to normal operations occurs, including delays or disruptions due to public health concerns, travel restrictions, and staffing shortages, it could significantly impact the ability of the FDA to timely review, provide feedback to our clinical trials and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our relationships with healthcare professionals, clinical investigators, CROs and third-party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to significant losses, including, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, as well as market, sell and distribute our product candidates for which we obtain marketing approval.

The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert 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 False Claims Act (FCA). There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection;
- federal civil and criminal false claims laws, including the FCA, which can be enforced through civil "qui tam" or "whistleblower" actions, and civil monetary penalty laws, impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created 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 the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payments Sunshine Act, created under the ACA and its implementing regulations, which require applicable manufacturers of covered drugs, devices, biologicals or medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to HHS information related to payments or other transfers of value made in the previous year to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; 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 that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

We may also be subject to federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and data privacy laws and regulations will involve on-going substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, our employees, or contractors who conduct business on our behalf or for us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, exclusion, debarment or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

In conducting and/or enrolling patients in our current or future clinical trials, we are subject to restrictions relating to privacy, data protection and data security and may be subject to additional restrictions as our clinical operations expand. For example, the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the GDPR. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches (initially to supervisory authorities and, if the breach is serious enough, to individuals), and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater, for the most serious of violations. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. Certain aspects of cross-border data transfers under the GDPR are uncertain as the result of legal proceedings in the EU, including a July 2020 decision by the Court of Justice for the European Union (CJEU) that invalidated the EU-U.S. Privacy Shield and called into question the efficacy and legality of using standard contractual clauses (SCCs). To address certain concerns of the CJEU, the European Commission issued revised SCCs in June 2021. Regulatory guidance and other developments relating to cross-border personal data transfers, including the necessity of putting in place those revised SCCs and the UK SCCs, as discussed below, may increase the complexity of transferring personal data across borders and may require us to engage in additional contractual negotiations and to modify our policies and practices relating to the transfer and other processing of personal data. The GDPR increased our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries.

Further, the exit of the United Kingdom (UK) from the EU has created uncertainty with regard to data protection regulation in the UK. The Data Protection Act of 2018 implements and complements the GDPR and is effective in the UK along with a version of the GDPR referred to as the UK GDPR. Collectively, the Data Protection Act of 2018 and the UK GDPR authorize significant fines, up to the greater of £17.5 million or 4% of global turnover and expose us to two parallel regimes and other potentially divergent enforcement actions for certain violations. Further, aspects of data protection in the UK remain uncertain. On June 28, 2021, the European Commission issued an adequacy decision under the GDPR and the Law Enforcement Directive, pursuant to which personal data generally may be transferred from the EU to the UK without restriction; however, this adequacy decision is subject to a four-year "sunset" period, after which the European Commission's adequacy decision may be renewed, and this decision may be revoked or modified in the interim. Additionally, on February 2, 2022, the UK's Information Commissioner's Office issued new standard contractual clauses to support personal data transfers out of the UK (UK SCCs), which came into effect March 21, 2022, and we may, in addition to other impacts, experience additional costs associated with increased compliance burdens and be required to engage in new contract negotiations with third parties that aid in processing personal data on our behalf or localize certain personal data.

Other jurisdictions also increasingly maintain laws and regulations addressing privacy, data protection, and information security. For example, on August 20, 2021, the Personal Information Protection Law, or PIPL, was adopted in the PRC and it went into effect on November 1, 2021. The PIPL shares similarities with the GDPR, including extraterritorial application, data minimization, data localization, and purpose limitation requirements, and obligations to provide certain notices and rights to citizens of the PRC. The PIPL allows for fines of up to 50 million renmibi or 5% of a covered company's revenue in the prior year.

We may incur liabilities, expenses, costs, and other operational losses under the GDPR and local laws of applicable EU member states, the UK, and other regions in connection with any measures we take to comply with them. Working to comply with the GDPR and other laws and regulations to which we are subject in Europe and other regions outside the United States relating to privacy, data protection, and information security will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our activities in those regions.

In addition, in California the CCPA created new individual privacy rights for California consumers (as defined in the law) and placed increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action in data breach situations. The CCPA went into effect on January 1, 2020, and was modified significantly by the CPRA, which was approved by California voters in the November 3, 2020 election and became effective January 1, 2023. The CCPA and CPRA could mark the beginning of a trend toward more stringent privacy legislation in the United States. The CCPA has prompted a number of proposals for federal and state privacy legislation. For example, Connecticut, Virginia, and Colorado have enacted legislation similar to the CCPA and CPRA that has taken effect in 2023; Utah has enacted such legislation that will take effect on December 31, 2023; Florida, Montana, Oregon and Texas have enacted similar legislation that becomes effective in 2024; Tennessee, Delaware and Iowa have enacted similar legislation that will take effect in 2025; and Indiana has enacted similar legislation that will become effective in 2026. The CCPA, CPRA, and these other laws, as well as other new laws that may be proposed or enacted, could increase our potential liability, require us to modify our policies and practices, cause us to incur increased costs and expenses, and adversely affect our business.

Compliance with U.S. and international laws and regulations relating to privacy, data protection, and data security could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Any actual or alleged failure to comply with U.S. or international laws and regulations relating to privacy, data protection, and data security could result in governmental investigations, proceedings, and enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity, harm to our reputation, and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information or impose other obligations or restrictions in connection with our use, retention and other processing of information, and we may otherwise face contractual restrictions applicable to our use, retention, and other processing of information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA, EMA or comparable foreign regulatory authority regulations, provide accurate information to the FDA, EMA or comparable foreign regulatory authorities, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, research, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also 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. We have adopted a code of conduct, but it is not always possible to identify and deter misconduct by these parties, 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 comply with these 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 significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act (FCPA) and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. Anti-corruption and anti-bribery laws generally prohibit companies and their employees, agents, representatives, business partners and third-party intermediaries from offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, improper payments or benefits to recipients in the public or private sector. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals are owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. We sometimes leverage third parties to conduct our business abroad. We, our employees, agents, representatives, business partners and third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities and we may be held liable for the corrupt or other illegal activities of these employees, agents, representatives, business partners or third-party intermediaries even if we do not explicitly authorize such activities. Recently, the SEC and DOJ have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies.

While we have policies and procedures to address compliance with such laws, we cannot assure you that none of our employees, agents, representatives, business partners and third-party intermediaries will take actions in violation of our policies or applicable laws and regulations, particularly given the high level of complexity of these laws. Any allegations or violations of these laws and regulations could result in whistleblower complaints, adverse media coverage, investigations, prosecutions, settlements, enforcement actions, fines, damages, severe criminal or civil sanctions, disgorgement, loss of export privileges, suspension or debarment from government contracts and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such allegations or violations could have an adverse impact on our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition. Responding to any investigation or action will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees.

In addition, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international or domestic sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

If we fail to comply with Nasdaq rules governing the diversity of our board of directors, we could suffer reputational harm.

In August 2021, the SEC announced that it had approved Nasdaq's proposed rule change to advance board diversity and enhance transparency of board diversity statistics through new listing requirements. Under these listing rules, Nasdaq-listed companies are required, subject to certain exceptions, to annually disclose diversity statistics regarding their directors' voluntary self-identified characteristics and include on their boards of directors at least two "Diverse" directors or publicly disclose why their boards do not include such "Diverse" directors. Under the phase-in period for these new listing rules, for companies listed on the Nasdaq Global Select Market, this disclosure requirement regarding the existence of at least one "Diverse" director applies starting on the later of August 7, 2023, or the date that the company files its proxy statement for its annual shareholder meeting during 2023, and regarding the existence of at least two "Diverse" directors applies starting on the later of August 6, 2025, or the date that the company files its proxy statement for its annual shareholder meeting during 2025. Under these listing rules, a "Diverse" director is someone who self-identifies either as (i) female or (ii) Black or African American, Hispanic or Latinx, Asian, Native American or Alaska Native, Native Hawaiian or Pacific Islander, or two or more races or ethnicities, or (iii) lesbian, gay, bisexual, transgender or a member of the queer community. The SEC's approval of Nasdaq's rule change is subject to ongoing litigation, the outcome of which remains uncertain.

Our board of directors currently includes four female directors and two diverse directors. We are in compliance with the Nasdaq rules. However, if our current or future female or other "Diverse" directors no longer serve on our board of directors prior to the applicable dates under the phase-in period for the new Nasdaq listing rules, we could be out of compliance with these new Nasdaq listing rules. We cannot assure that we can recruit, attract and/or retain qualified members of the board and meet gender and diversity requirements under Nasdaq listing rules, which may expose us to financial penalties and adversely affect our reputation.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

The Strategic Plans may be unsuccessful, lead to additional costs, disrupt our operations, create unintended problems in our workforce, or increase litigation, in which case our business could be harmed.

In September 2023, we began implementing our September 2023 Strategic Plan to: (i) prioritize our Exarafenib combination with binimetinib, our c-MET inhibitor KIN-8741, and our discovery efforts around our CDK4 selective program; (ii) explore strategic alternatives for our Exarafenib monotherapy and KIN-3248 FGFR inhibitor programs; (iii) pause development of our MEK inhibitor KIN-7136; and (iv) implement a workforce restructuring.

In January 2024, we announced our January 2024 Strategic Plan to: (i) further restructure the workforce; (ii) explore strategic alternatives for the Company; and (iii) cease development of our programs.

As part of the Strategic Plans and a subsequent RIF we completed in March 2024, we reduced our workforce by approximately 89% to a total of 10 full-time employees and took related measures to reduce operating expenses. In addition, we separated from all employees of our wholly-owned subsidiary in China, Kinnjiu Biopharma.

Despite our efforts, the Strategic Plans may be unsuccessful, lead to additional costs, disrupt our operations, create unintended problems in our workforce, and increase litigation, which could harm our business and results of operations. We may incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the Strategic Plans. We may not realize, in full or in part, the anticipated benefits and savings from the workforce restructuring due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the Strategic Plans, our operating results and financial condition would be adversely affected. In addition, we may need to undertake additional workforce reductions or restructuring activities in the future. Furthermore, the Strategic Plans could yield unanticipated consequences, such as increased difficulties in our day-to-day operations, attrition beyond planned workforce reductions, reduced employee morale, and difficulty attracting and retaining qualified management, scientific, and other personnel critical to our business. If employees who were not affected by the workforce reduction pursue alternative employment, we may need to seek contractor support, which could harm our productivity and add unplanned expense. The implementation of the workforce restructuring could also lead to litigation brought by or on behalf of our former employees.

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

We currently have a small team focused on the process of exploring strategic alternatives for the Company. If we decide to further develop any of our programs, we must recruit, hire, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. Under the Strategic Plans and a subsequent RIF we completed in March 2024, we reduced our workforce by approximately 89% to a total of 10 full-time employees. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide higher compensation, more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

Additionally, we rely on our scientific experts and other scientific and clinical advisors and consultants to assist us in formulating our research, development and clinical strategies. These advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these advisors and consultants typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. In particular, if we are unable to maintain consulting or employment relationships with our scientific experts and other scientific and clinical advisors and consultants, or if they provide services to our competitors, our development and commercialization efforts will be impaired and our business will be significantly harmed.

Furthermore, our workforce restructuring in connection with the Strategic Plans may result in increased attrition beyond our intended reduction-in-force, reduce employee morale, and negatively impact employee recruiting and retention. If we fail to attract new personnel, or fail to retain and motivate our current personnel, our business and growth prospects could be harmed.

We may need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

Under the Strategic Plans and a subsequent RIF we completed in March 2024, we reduced our workforce by approximately 89% to a total of 10 full-time employees, but in order to successfully implement any development and commercialization plans and strategies, and as we continue operating as a public company, we may need significant additional managerial, operational, sales, marketing, financial and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, retaining and motivating our current and additional employees;

- managing our internal development efforts effectively, including the preclinical, clinical, FDA, EMA and other comparable foreign regulatory authorities' review process for our product candidates, while complying with any contractual obligations to contractors and other third parties;
- managing increasing operational and managerial complexity; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize product candidates developed from programs including our c-MET inhibitor KIN-8741 and CDK4 selective inhibitor KIN-7324 will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of research, clinical development and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our preclinical studies and clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval for any of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates in our c-MET inhibitor KIN-8741 and CDK4 selective research program and, accordingly, may not achieve our research, development and commercialization goals.

Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer actual or suspected security or data privacy breaches or incidents or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations, and potentially significant delays in our delivery to market.

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and external processing and storage systems (e.g., cloud), and those of our third-party CROs, other contractors (including sites performing our current or future clinical trials) and consultants and other third-party service providers, these systems are potentially vulnerable to breakdown or other damage or interruption. Our systems and the systems of third parties who support our operations are vulnerable to service interruptions, system malfunction, natural disasters, terrorism, war (such as the ongoing conflicts in the Middle East and between Ukraine and Russia) and telecommunication and electrical failures, as well as security breaches and incidents arising from or caused by inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to unauthorized access to or disruption of our or third-party systems used in our business and the unauthorized access to, misuse, disclosure, loss, destruction, alteration or dissemination of, or damage to, our data, including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information. For example, companies have experienced an increase in phishing and social engineering attacks from third parties in recent years. Our employees generally work in a hybrid model in our offices and from home. Depending on public health concerns, we may need to adjust our working model from time to time. As a result, we have increased cybersecurity and data security risks, due to increased use of home wi-fi networks and virtual private networks, as well as increased disbursement of physical machines. While we implement controls to reduce the risk of a resulting cybersecurity or data security incident or breach, we may experience data security incidents, and there is no guarantee that the measures we have implemented will be adequate to safeguard all systems and data, especially with an increased number of employees working from home or in a hybrid model where it is more difficult for us to monitor our employees.

Any disruption, security incident, or security breach resulting in any loss, destruction, unavailability, alteration or dissemination of, or damage to, our data (including confidential information) or other data we or any of our CROs, other contractors or consultants or potential future collaborators or other third-party service providers maintain or otherwise process, or our applications, or for it to be believed or reported that any of these occurred, could result in us incurring liability and reputational damage and the development and commercialization of our product candidates could be delayed. For example, if a security incident were to cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss or unavailability of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, disruptions of our internal information technology systems or those of third parties used in our business, or security breaches or incidents impacting us or any of our CROs, other contractors or consultants or potential future collaborators or other third-party service providers, could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the inability to access, data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. Unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to notify individuals or regulators under data breach notification laws, cause us to incur costs related to investigation of the incident (including legal expenses, forensic examination costs, and remediation costs), subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. Our preclinical studies in China could increase our risk to such disruptions.

We expect to incur significant costs in an effort to detect, prevent, and respond to security incidents. We also rely on third parties to manufacture our product candidates, and similar events relating to their systems could also have a material adverse effect on our business. There have been and may continue to be significant supply chain attacks and operational technology attacks globally, and we cannot guarantee that our systems or those of third-party service providers or other third parties that support us or our operations have not been breached or that they do not contain exploitable defects or bugs that could result in a security incident or breach of, or other disruption to, our systems and the systems of third parties that support us and our operations. To the extent that any disruption or security incident were to result in a loss, destruction or alteration of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international laws relating to privacy, data protection, and information security. Litigation and governmental investigations could force us to spend money in defense or settlement, divert management's time and attention, increase our costs of doing business, and/or adversely affect our reputation. We could be required to fundamentally change our business activities and practices in response to such litigation or investigations, which could have an adverse effect on our business. Any actual or perceived inability to adequately protect data in our possession, custody or control could have a material adverse effect upon our reputation, business, operations, or financial condition.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in or, failure or security breach of, or incident impacting, our systems or third-party systems where information important to our business operations or commercial development is stored. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

Our operations are vulnerable to interruption by flood, fire, earthquakes, power loss, telecommunications failure, terrorist activity, pandemics and other events beyond our control, which could harm our business.

Although our employees currently work remotely, we previously had office facilities located in California. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major flood, fire, earthquake, power loss, telecommunications failure, terrorist activity, pandemics or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

We currently do not have and have never had a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration and such arrangements may prove to be less profitable than commercializing the product on our own. If we are unable to enter into such arrangements when needed, on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We may seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in foreign countries, such as the lack of pathways for accelerated drug approval, may result in foreign regulatory approvals taking longer and being more costly than obtaining approval in the United States;
- foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials or our interpretation of data from preclinical studies or clinical trials;
- approval policies or regulations of foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with legal requirements applicable to privacy, data protection, information security and other matters;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes and government payors in foreign countries;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad (such as the ongoing conflicts in the Middle East and between Ukraine and Russia, including the sanctions imposed by the United States, the European Union and others on Russia and other related parties); and
- business interruptions resulting from geo-political actions, including war and terrorism, trade policies, treaties and tariffs.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be limited.

Our federal net operating loss (NOL) carryforwards may be unavailable to offset future taxable income because of restrictions under U.S. tax law. Under tax legislation commonly referred to as the Tax Cuts and Jobs Act of 2017 (Tax Act) as amended by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), our federal NOL carryforwards may be carried forward indefinitely, but for taxable years beginning after December 31, 2020, the deductibility of federal NOL carryforwards generated in tax years beginning after December 31, 2017 is limited to 80% of our current year taxable income. This may require us to pay U.S. federal income taxes in future years despite generating a loss for U.S. federal income tax purposes in prior years. Limitations under state law may differ. As of December 31, 2023, we had available federal NOL carryforwards of $185.7 million. We also have available California NOL carryforwards of approximately $25.1 million as of December 31, 2023, which begin to expire in 2038. We have established a valuation allowance against the carrying value of these deferred tax assets.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (Code), if a corporation undergoes an "ownership change" (generally defined as a cumulative change in the corporation's ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOL carryforwards and certain other pre-change tax attributes to offset its post-change taxable income may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and the Merger, if completed, will result in such an ownership change. We may experience additional ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in ownership. There is also a risk that due to regulatory changes, such as suspensions on the use of NOL carryforwards, or other unforeseen reasons, our existing NOL carryforwards, including state NOL carryforwards, could expire or otherwise be unavailable to offset future income tax liabilities. Because our ability to utilize our NOL carryforwards and certain other tax attributes could be limited as described above, we may not be able to utilize a material portion of our NOL carryforwards and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations.

The stock-based compensation expense related to our RSUs and other outstanding equity awards will result in increases in our expenses in future periods and we may also expend substantial funds to satisfy a portion of our tax withholding and remittance obligations that arise upon the vesting and/or settlement of certain of our RSUs, which may have an adverse effect on our financial condition and results of operations.

We have granted RSUs to our employees, which vest upon the satisfaction of service-based vesting conditions occurring before the award's expiration date. The service-based vesting period is generally satisfied by the award holder providing services to us over a four-year period. As of September 1, 2022, we began recognizing stock-based compensation expense for such RSUs.

Additionally, we may expend substantial funds in connection with the tax withholding and remittance obligations that arise upon the vesting and/or settlement of our outstanding RSUs. Under U.S. tax laws, employment and income tax withholding and remittance obligations for RSUs arise in connection with the vesting and settlement of the RSUs. To fund the employment and income tax withholding and remittance obligations arising in connection with the vesting and settlement of vested RSUs, we will either (i) withhold shares of our common stock that would otherwise be issued with respect to such vested RSUs and pay the relevant tax authorities in cash to satisfy such tax obligations or (ii) have the holders of such vested RSUs use a broker or brokers to sell a portion of such shares into the market, with the proceeds of such sales to be delivered to us for us to remit to the relevant taxing authorities, in order to satisfy such employment and income tax withholding and remittance obligations. Any such expenditures by us of substantial funds to satisfy a portion of our tax withholding and remittance obligations that arise upon the vesting and/or settlement of RSUs may have an adverse effect on our financial condition and results of operations.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

We are or may become subject to income- and non-income-based taxes in the United States under federal, state and local jurisdictions and in certain foreign jurisdictions in which we operate. Tax laws, regulations and administrative practices in these jurisdictions may be subject to significant change, with or without advance notice. For example, on January 1, 2022, a provision of the Tax Act went into effect that eliminates the option to deduct U.S. research and experimental costs in the year incurred and instead requires U.S. research and experimental costs to be capitalized and amortized ratably over a five-year period. Any such costs attributable to research conducted outside the U.S. must be capitalized and amortized over a 15-year period. In addition, the Inflation Reduction Act of 2022, enacted in August 2022, includes a 1% excise tax on stock buybacks and the imposition of a 15% alternative minimum tax on global adjusted financial statement income. Further, many countries, and organizations such as the Organization for Economic Cooperation and Development, have proposed implementing changes to existing tax laws, including a proposed 15% global minimum tax that has been implemented into the laws of some jurisdictions, effective for fiscal years beginning on or after December 31, 2023. Such changes may adversely affect our effective tax rates, cash flows, business and financial condition.

Inflation could negatively impact our business and results of operations.

Inflation in the U.S. and other geographies has risen beyond levels experienced in recent decades. Although inflation rates have begun trending lower, inflation in the prices for our clinical trial drug supply, costs of CROs and CMOs, and rising salaries could still negatively impact our business by increasing our operating expenses. The U.S. Federal Reserve also raised the federal funds rate several times throughout 2022 and 2023 in an effort to control inflationary pressures, and could do so again, which may have additional adverse effects on the economy, and may adversely affect our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or the patent applications of our future licensors will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our and our licensors' proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

We cannot be certain that the claims in our U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign territories, or those of our future licensors, will be considered patentable by the United States Patent and Trademark Office (USPTO), courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our future issued patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive and time-consuming, and we and any future licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we or any future licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of our future licensors may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or in-license in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents or the patents of our future licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents or the patents of our future licensors may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review (PGR) and inter partes review (IPR), or other similar proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could jeopardize patent term adjustment or otherwise reduce patent term, reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, our patents or the patents of our future licensors may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications and those of our future licensors. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our future licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- we or our future licensors or collaborators might not have been the first to make the inventions covered by the issued patents or patent application that we own or license;
- we or our future licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we own or license will not lead to issued patents;
- issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, it could significantly harm our business, results of operations and prospects.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of the date of this Annual Report on Form 10-K, others may hold proprietary rights that could prevent our product candidates from being marketed. It is possible that a third party may assert a claim of patent infringement directed at any of our product candidates. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates, treatment indications, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates, treatment indications, or processes to avoid infringement, if necessary.

Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure.

In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be involved in lawsuits to protect or enforce our patents or our future licensors' patents, which could be expensive, time consuming and unsuccessful. Further, our issued patents or our future licensors' patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent or the patent of our future licensors is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of sufficient written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, PGR, IPR, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and/or unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our future licensors, and the patent examiners are unaware during prosecution. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or the patents and patent applications of our future licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our future licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common stock to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings or developments in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing product candidates, approved products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our future licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our development programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of our future licensors and the enforcement or defense of our issued patents or those of our future licensors.

On September 16, 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 inventor to file” system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we may not be certain that we or our future licensors are the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in the patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of our future licensors and the enforcement or defense of our issued patents or those of our future licensors, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in U.S. patent law, or laws in other countries, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, or could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

The Supreme Court of the United States has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. We cannot predict how decisions by the federal courts, the U.S. Congress or the USPTO may impact the value of our patent rights. For example, the Supreme Court of the United States held in *Amgen v. Sanofi* (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. In addition, the Federal Circuit recently issued a decision involving the interaction of patent term adjustment, terminal disclaimers, and obvious-type double patenting. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patent and the patents we might obtain or license in the future.

As a further example, as of June 1, 2023, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court (UPC). In 2012, the European Union Patent Package (The EU Patent Package) regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European UPC for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. European patent applications will have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the UPC. The UPC and Unitary Patent are significant changes in European patent practice. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC. As a single court system can invalidate a European patent, we, where applicable, may opt out of the UPC and as such, each European patent would need to be challenged in each individual country. We may decide to opt our future European patents out of the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates due to increased competition and, resultantly, on our business, financial condition, prospects and results of operations.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our U.S. patents or those of our future licensors may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We may not be able to protect our intellectual property rights throughout the world.

Although we have pending patent applications in the United States and other countries, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents, the patents of our future licensors, or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or our future licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our future licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our future licensors at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have a predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by regulations and governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications and those of our future licensors. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, and other third parties. We may become subject to litigation where a third party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition and prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of licenses granted to us by others.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce, and defend such patents or patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our future product candidates that are subject of such licensed rights could be adversely affected.

Our future licensors may rely on third-party consultants or collaborators or on funds from third parties such that our future licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our future in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our future licensors, we could lose license rights that are important to our business.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other 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 patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

The patent protection and patent prosecution for some of our product candidates may be dependent on third parties.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates are controlled by our future licensors or collaboration partners. If any of our future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Although we do not currently own issued patents or pending patent applications that have been generated through the use of U.S. government funding, we may acquire or license in the future intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). If the U.S. government exercised its march-in rights in our future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our ongoing preclinical studies and clinical trials, and plan to rely on third parties to conduct additional planned clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such preclinical studies and clinical trials.

We utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs, and strategic partners to conduct and support our ongoing preclinical studies and clinical trials under agreements with us and plan to continue to do so for our future clinical trials. These third parties have had and will continue to have a significant role in the conduct of our preclinical studies and ongoing and planned future clinical trials and the subsequent collection and analysis of data. For example, our academic and industrial partners contribute highly enabling technologies and services that include: (i) medicinal chemists at leading CROs, (ii) bioinformatics support for our translational research efforts, (iii) crystallography and biophysical assay platforms to enable structure-based drug discovery, (iv) biochemical and cell-based assays to guide lead generation and optimization, and (v) patient-derived organoid and xenograft models to translate our findings to the clinical setting.

These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we have limited ability to control the amount or timing of resources that any such third party will devote to our preclinical studies or our ongoing or planned future clinical trials. The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. Some of these third parties may terminate their engagements with us at any time. We also expect to have to negotiate budgets and contracts with CROs, clinical trial sites and CMOs and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. If we need to enter into alternative arrangements with, or replace or add any third parties, it would involve substantial cost and require extensive management time and focus, or involve a transition period, and may delay our drug development activities, as well as materially impact our ability to meet our desired clinical development timelines.

Our heavy reliance on these third parties for such drug development activities will reduce our control over these activities. As a result, we will have less direct control over the conduct, timing and completion of preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the clinical trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are reliable and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current cGMP regulations and will require a large number of test patients. 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.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, or if these third parties need to be replaced, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, 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.

We contract with third parties for the manufacture of our product candidates for preclinical studies and clinical trials and expect to continue to do so for additional preclinical studies, clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quality and quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. We do not have long-term supply agreements, and we purchase our required drug product on a purchase order basis, which means that aside from any binding purchase orders we have from time to time, our supplier could cease supplying to us or change the terms on which it is willing to continue supplying to us at any time. In addition, the ongoing conflicts in the Middle East and between Ukraine and Russia, including the sanctions imposed by the United States, the European Union and others on Russia and other related parties, could negatively impact supply chains that directly or indirectly affect manufacturing processes necessary for the continued development and potential commercialization of our product candidates. If we were to experience an unexpected loss of supply of any of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing preclinical studies or clinical trials.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule and specifications, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising or prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;

- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements, including cGMPs;
- the breach by the third-party contractors of our agreements with them;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of our contract manufacturing partners and are dependent on these contract manufacturing partners for compliance with cGMP regulations for manufacturing both API and finished drug products. To date, we have obtained API and drug product for our product candidates from single-source third party contract manufacturers. We are in the process of developing our supply chain for each of our product candidates and intend to put in place framework agreements under which third-party contract manufacturers will generally provide us with necessary quantities of API and drug product on a project-by-project basis based on our development needs. As we advance our product candidates through development, we will consider our lack of redundant supply for the API and drug product for each of our product candidates to protect against any potential supply disruptions. However, we may be unsuccessful in putting in place such framework agreements or protecting against potential supply disruptions.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable regulatory authorities, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we will need to find alternative manufacturing facilities, and those new facilities would need to be inspected and approved by the FDA, EMA or comparable regulatory authority prior to commencing manufacturing, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals.

In order to commercially produce our products either at a third party's facility or in any facility of ours, we will need to comply with the FDA's cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our precision medicines as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our precision medicines for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, product candidates, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products, product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

If our third-party manufacturers use hazardous materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

If we decide to establish collaborations but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration depends, among other things, upon our assessment of the potential collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the collaborator's evaluation of a number of factors. Those factors may include the design or results of preclinical studies or clinical trials, the likelihood of approval by the FDA, EMA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our research programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We may enter into collaborations with third parties for the development and commercialization of product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

If we enter into any collaboration arrangements with any third parties for the development and commercialization of our product candidates, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates would pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a business combination or sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely;
- to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- we may grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us 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 attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all;
- collaborators may not provide us with timely and accurate information regarding development progress and activities under the collaboration or may limit our ability to share such information, which could adversely impact our ability to report progress to our investors and otherwise plan our own development of our product candidates;
- collaborators may own or co-own intellectual property covering our products or product candidates that result from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Risks Related to the Securities Markets and Ownership of Our Common Stock

The market price of our common stock is volatile, and investors could lose all or part of their investment.

The trading price of our common stock is highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, these factors include:

- the timing and results of INDs, preclinical studies and clinical trials of our product candidates or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or product candidates or our competitors' products or product candidates;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries, including changes in leadership at various federal departments and agencies as well as new legislation, executive, and administrative actions under the Biden administration;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements;
- the impact of any natural disasters or public health emergencies, such as COVID-19; and
- general economic, political, industry and market conditions and instability (such as those created by the ongoing conflicts in the Middle East and between Ukraine and Russia, including, without limitation, sanctions against Russia imposed by the United States, the European Union and others, and instability in the banking sector).

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us, our business or our market. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our programs, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- our ability to timely initiate sites for clinical trials;
- the cost of manufacturing our current product candidates and any future product candidates, which may vary depending on FDA, EMA or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies or other assets;
- the timing and outcomes of preclinical studies and clinical trials for product candidates including from our c-MET inhibitor KIN-8741 and CDK4 selective inhibitor KIN-7324 research programs, or competing product candidates;
- the need to conduct unanticipated clinical trials or clinical trials that are larger or more complex than anticipated;
- competition from existing and potential future products that compete with our programs including, our c-MET inhibitor KIN-8741 research program or our CDK4 selective inhibitor KIN-7324 research program, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of product candidates from our programs including, our c-MET inhibitor KIN-8741 research program or our CDK4 selective inhibitor KIN-7324 research program;
- the level of demand for any of our product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with our programs including, our c-MET inhibitor KIN-8741 research program or our CDK4 selective inhibitor KIN-7324 research program;
- our ability to commercialize product candidates from our programs including, our c-MET inhibitor KIN-8741 research program or our CDK4 selective inhibitor KIN-7324 research program, if approved, inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic and political environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of March 13, 2024, our executive officers, directors, and their affiliates, in the aggregate, beneficially owned approximately 46% of our outstanding voting stock. These stockholders, acting together, may be able to impact matters requiring stockholder approval. For example, they may be able to impact elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that investors may feel are in their best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with each investor's interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. For example, we filed a shelf registration statement with the SEC on Form S-3ASR (File No. 333-261970) that included a prospectus supplement for an at-the-market offering to sell up to an aggregate of $150.0 million of shares of our common stock (ATM Offering). To date, no shares have been issued and sold pursuant to the ATM Offering. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

Certain holders of shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act, would result in the shares becoming freely tradeable in the public market, subject to the restrictions of Rule 144 in the case of our affiliates. If these shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

We are an "emerging growth company" and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an EGC, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in our periodic reports;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (SOX);
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (iv) December 31, 2025.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of SOX and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We incur increased costs as a result of operating as a public company, and our management will devote substantial time to related compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an "emerging growth company." We are subject to the reporting requirements of the Exchange Act, SOX, the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly, which will increase our operating expenses. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage, particularly in light of recent cost increases related to coverage. We cannot accurately predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

In addition, as a public company we are required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of SOX. We are required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm, unless we continue to qualify as a "smaller reporting company" at such time. We engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting.

If we identify material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

In connection with the audit of our consolidated financial statements as of December 31, 2020 and 2019 and for the years ended December 31, 2020 and 2019, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

Although we were able to remediate these material weaknesses, we may in the future discover additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of SOX in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate consolidated financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock is volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock and we have no current plans to pay cash dividends on our common stock. We expect any return to stockholders therefore to be limited to any payments pursuant to the XOMA transaction and the sale of Exarafenib.

Anti-takeover provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause";
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan (also known as a "poison pill");
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting;
- authorize our board of directors to amend the bylaws;
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend or repeal specified provisions of our amended and restated certificate of incorporation and amended and restated bylaws.

In addition, Section 203 of the General Corporation Law of the State of Delaware (DGCL) prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner or certain other conditions are met.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for the following (except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction):

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Such amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. We also note that stockholders cannot waive compliance (or consent to noncompliance) with the federal securities laws and the rules and regulations thereunder. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

We conduct risk assessments to identify cybersecurity threats at least annually, as well as assessments in the event of a material change in our business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.
Following these risk assessments, we re-design, implement, and maintain reasonable safeguards to minimize identified risks, reasonably address any identified gaps in existing safeguards and regularly monitor the effectiveness of our safeguards. We devote internal and external resources and designate high-level personnel, including our Chief Operating Officer, who reports to our Chief Executive Officer, to manage the risk assessment and mitigation process.

As part of our overall risk management system, we monitor and test our safeguards and train our employees on these safeguards, in collaboration with human resources, IT and management. Personnel at all levels and departments are made aware of our cybersecurity policies through trainings.

We engage third parties in connection with our risk assessment processes. These service providers assist us in designing and implementing our cybersecurity policies and procedures, as well as monitoring and testing our safeguards.

We believe that our business strategy, results of operations and financial condition have not been materially affected as a result of any previously identified cybersecurity incidents at this time but we cannot provide assurance that they will not be materially affected in the future by any such incidents or any future material incidents. For additional information regarding risks related to cybersecurity threats, please refer to Item 1A, "Risk Factors," in this Annual Report on Form 10-K, including the risk factor entitled "*Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer actual or suspected security or data privacy breaches or incidents or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations, and potentially significant delays in our delivery to market*."

Governance

One of the key functions of our board of directors is informed oversight of our risk management process, including risks from cybersecurity threats. Our board of directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks we face. Our board of directors administers its cybersecurity risk oversight function directly as a whole, as well as through the nominating and corporate governance committee.

Our Chief Operating Officer, in conjunction with our information security team and third-party consultants, are primarily responsible for assessing and managing our material risks from cybersecurity threats.

Our Chief Operating Officer oversees our cybersecurity policies and processes, including those described in "Risk Management and Strategy" above. The processes by which our Chief Operating Officer is informed about and monitors the prevention, detection, mitigation and remediation of cybersecurity incidents includes vulnerability reports, security awareness training results and security tool threat detections.

Our Chief Operating Officer provides briefings to the nominating and corporate governance committee of the board of directors regarding our company's cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties and the like. In addition, our Chief Operating Officer provides the nominating and corporate governance committee annual updates of cybersecurity risks and activities and the board of directors briefings of any significant cybersecurity matters.

Item 2. Properties.

We formerly had offices located in San Diego, California and San Francisco, California. In January and February 2024, we assigned our lease agreements in San Diego and San Francisco, respectively, and became a remote-only company. We believe that suitable office space will be available as and when needed.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

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 Information for Common Stock

Our common stock is publicly traded on the Nasdaq Global Select Market under the symbol "KNTE."

Holders of Record

As of December 31, 2023, there were 10 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions and other factors that our board of directors may deem relevant.

Recent Sales of Unregistered Securities

None.

Use of Proceeds from Public Offering of Common Stock

On December 2, 2020, our registration statement on Form S-1 (File No. 333-250086) was declared effective by the SEC for our IPO of common stock. We began trading on the Nasdaq Global Select Market on December 3, 2020, and the transaction formally closed on December 7, 2020. In connection with our IPO, we issued and sold an aggregate of 13,800,000 shares of our common stock at a price of $20.00 per share, including 1,800,000 shares issued and sold in connection with the full exercise by the underwriters of their option to purchase additional shares of common stock. The aggregate offering price for shares sold in our IPO was $276.0 million. The joint book-running managers for the initial public offering were Goldman Sachs & Co. LLC, SVB Leerink LLC, and Piper Sandler & Co. and Wedbush Securities Inc. After deducting underwriting discounts and commissions and offering costs paid or payable by us of approximately $22.7 million, the net proceeds from the offering were approximately $253.3 million. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors pursuant to our director compensation policy.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

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

Investors should read the following discussion and analysis of our financial condition and results of operations together with the section entitled "Selected Consolidated Financial Data" and our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties, including those described in the section titled "Special Note Regarding Forward Looking Statements." Our actual results and the timing of selected events could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the section titled "Risk Factors" included elsewhere in this report. Unless the context requires otherwise, references in this section to "Kinnate," "the Company," "we," "us," "our" and any related terms are intended to mean Kinnate Biopharma, Inc.

Overview

We are a clinical-stage precision oncology company that has focused on the discovery, design and development of small molecule kinase inhibitors for difficult-to-treat, genomically defined cancers.

In September 2023, we announced pipeline updates, a reprioritization plan and workforce restructuring based on a strategic review of our business. As part of the September 2023 Strategic Plan, which was approved by our board of directors, we reduced our workforce by approximately 70%. We also took related measures to reduce operating expenses. This included separating from all employees of our wholly-owned subsidiary in China, Kinnjiu Biopharma.

In January 2024, we announced exploration of strategic alternatives for the company in an effort to maximize shareholder value and implemented a further RIF. As a result of the Strategic Plans and a subsequent RIF we completed in March 2024, we currently have 10 full-time employees.

On February 16, 2024, we entered into the Merger Agreement with XOMA and Merger Sub. The Merger Agreement provides for, among other things: (i) the acquisition of all of our Common Stock, by XOMA through a cash tender offer by Merger Sub, for the Base Price Per Share, *plus* (B) the Additional Price Per Share, *plus* (C) one CVR; and (ii) after the completion of the Offer, the satisfaction or waiver of certain conditions set forth in the Merger Agreement and in accordance with the DGCL, the merger of Merger Sub with and into us with us surviving the Merger as a wholly owned subsidiary of XOMA, without a meeting or vote of our stockholders. Subject to the terms of the Merger Agreement and the CVR Agreement, the Offer Price will be paid net of any applicable tax withholding and without interest.

We anticipate that the Offer and the Merger contemplated under the Merger Agreement will be consummated in the first half of 2024. However, there can be no assurance that the transactions contemplated by the Merger Agreement will be completed.

If the Merger is effected, our Common Stock will be delisted from The Nasdaq Stock Market LLC and our obligation to file periodic reports under the Exchange Act will terminate, and we will be privately held.

Asset Purchase Agreement

On February 27, 2024, we entered into the Purchase Agreement by and among us and Pierre Fabre, pursuant to which we sold the global rights to Exarafenib, and other pan-RAF program assets to Pierre Fabre, subject to the terms and conditions of the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, Pierre Fabre purchased Exarafenib and other pan-RAF assets and will assume 100% of the ongoing program and costs associated with these assets. We will receive a total consideration of up to $31.0 million, consisting of $500,000 at closing, and an additional $30.5 million contingent upon the earlier of (i) the dosing of the first patient in the first pivotal trial for Exarafenib or any other acquired asset, (ii) the application for accelerated approval pursuant to the U.S. Food and Drug Administration's Accelerated Approval Program for Exarafenib or any other acquired asset or (iii) the submission of a marketing application for regulatory approval for Exarafenib or any other acquired asset. In addition, Pierre Fabre will assume up to $5.0 million of trade payables for the transferred assets. The transaction is not subject to closing conditions and closed upon signing.

In connection with our transaction with XOMA, our stockholders will receive 100% of the Net Proceeds payable from the $30.5 million contingent payment, assuming the closing of the proposed transaction with XOMA occurs and such proceeds are received prior to the Expiration Date.

Business and Programs

In September 2023, our board of directors, based on a strategic review of our business, approved the September 2023 Strategic Plan. As part of the September 2023 Strategic Plan, we reduced our workforce by approximately 70%. We also took related measures to reduce operating expenses. This included separating from all employees of our wholly-owned subsidiary in China, Kinnjiu Biopharma.

In January 2024, we announced the January 2024 Strategic Plan. As a result of the Strategic Plans and a subsequent RIF we completed in March 2024, we currently have 10 full-time employees. Prior to the January 2024 Strategic Plan, our business focused on expanding on the promise of targeted therapies and developing medicines for known oncogenic drivers where there are no approved targeted drugs and to overcome the limitations of marketed cancer therapies, such as non-responsiveness or acquired and intrinsic resistance.

Exarafenib and other pan-RAF programs

On February 27, 2024, we entered into the Purchase Agreement, pursuant to which we sold the global rights to Exarafenib and our other pan-RAF program assets to Pierre Fabre, as previously described.

Prior to the Purchase Agreement, we conducted a Phase 1 study of Exarafenib for the treatment of patients with lung cancer, melanoma and other solid tumors with BRAF Class I, Class II and Class III alterations, as well as NRAS mutant melanoma. We explored Exarafenib as a monotherapy and in combination with a MEK inhibitor binimetinib. In September 2023, we announced results from the monotherapy dose expansion phase of KN-8701. The clinical data support Exarafenib's favorable safety and tolerability profile and favorable pharmacokinetic/pharmacodynamic properties. However, considering these results and our assessment of clinical development timelines for Class II fusion-driven solid tumors, as part of the September 2023 Strategic Plan, we decided not to proceed with further clinical development of Exarafenib as a monotherapy agent. We have ceased further development of the program in light of the January 2024 Strategic Plan and the Purchase Agreement with Pierre Fabre.

KIN-3248

KIN-3248, an FGFR inhibitor, was designed for the treatment of patients with intrahepatic cholangiocarcinoma (ICC), a cancer of the bile ducts in the liver, and urothelial carcinoma (UC), a cancer of the bladder lining, as well as other solid tumors. In the first quarter of 2022, we initiated KN-4802, a Phase 1 clinical trial evaluating KIN-3248. In September 2023, we announced results from the dose escalation phase of KN-4802 and, as part of the September 2023 Strategic Plan we decided not to proceed with further clinical development of KIN-3248 and to instead explore strategic alternatives for the KIN-3248 program.

Other Research Programs

We have developed three additional small molecule programs, a MEK inhibitor (KIN-7136), a c-MET inhibitor (KIN-8741) and a CDK4 inhibitor. In the third quarter of 2023, we announced that the FDA cleared the IND application for KIN-7136. In the fourth quarter of 2023, the FDA cleared the IND application for KIN-8741 and we declared a drug candidate for our CDK4 program (KIN-7324). We have suspended further development of these programs in light of the January 2024 Strategic Plan.

We currently own worldwide development and commercial rights for all our programs.

Kinnjiu Acquisition

In February 2023, we announced that we acquired the ownership stake of Kinnjiu, the China joint venture that we established in May 2021, previously held by the Series A investors for $24.0 million, using a combination of $9.1 million in cash and 2.2 million shares of common stock of Kinnate. We retain Kinnjiu's cash, intellectual property and other assets, including its legal entity structure. As part of the September 2023 Strategic Plan, we separated from all Kinnjiu employees.

Liquidity Overview

Since our inception in 2018 until the January 2024 Strategic Plan, we have devoted substantially all of our resources to research and development activities, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations.

We do not have any products approved for commercial sale, and we have not generated any revenue from product sales or other sources since inception. Our ability to generate product revenue sufficient to achieve profitability, if ever, will depend on the successful development and eventual commercialization of one or more of our product candidates which we expect, if it ever occurs, will take a number of years. We also do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacturing if any of our product candidates obtain marketing approval.

To date, we have financed our operations primarily through proceeds from the issuance of common stock (including our IPO) and private placements of our convertible preferred stock. As of December 31, 2023, we had cash and cash equivalents and short-term and long-term investments of $164.3 million. Based on our current operating plan, we believe that our current cash and cash equivalents and short-term and long-term investments will be sufficient to fund our planned operating expenses and capital expenditure requirements for at least the next twelve months from the date this Annual Report on Form 10-K is filed with the SEC.

We have incurred significant losses since the commencement of our operations. Our consolidated net loss for the year ended December 31, 2023 was $112.6 million, and we expect to continue to incur significant losses for the foreseeable future. As of December 31, 2023, we had an accumulated deficit of $372.0 million.

In September 2023, we began implementing the September 2023 Strategic Plan to focus the business on our Exarafenib combination with binimetinib, our c-MET inhibitor KIN-8741, and discovery efforts around our CDK4 selective inhibitor KIN-7324 program. As part of the September 2023 Strategic Plan, we reduced our workforce by approximately 70% and took related measures to reduce operating expenses. In January 2024, we implemented the January 2024 Strategic Plan, and in March 2024 we completed a further RIF, to a total of 10 full-time employees. In January 2024, we also announced the exploration of strategic alternatives for the Company in an effort to maximize shareholder value. In light of the Strategic Plans, we expect our expenses and capital requirements will decrease in connection with our ongoing activities as we pursue the Merger and explore strategic alternatives for our clinical stage and research programs.

However, our expenses and capital requirements could increase if and as we:

- resume our product discovery and development efforts and expand our pipeline of product candidates through our own product discovery and development efforts, in particular our c-MET inhibitor KIN-8741 and CDK4 selective inhibitor KIN-7324 research programs;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- implement operational, financial and management systems;
- attract, hire and retain additional clinical, scientific, management and administrative personnel;
- maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know how; and
- operate as a public company.

In the event we do not consummate the Offer and Merger, we will require substantial additional funding to develop our product candidates and support our continuing operations. Until such time that we can generate significant revenue from product sales or other sources, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, which could include income from collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide caused by public health concerns, the ongoing conflicts in the Middle East and between Russia and Ukraine, inflation rates, instability in the banking sector and other factors. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to have to delay, reduce or eliminate our product development or future commercialization efforts. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development efforts. We cannot provide assurance that we will ever be profitable or generate positive cash flow from operating activities.

We were incorporated in the State of Delaware in January 2018. We are a remote-only company and therefore do not have a principal executive office.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue and we do not expect to generate any revenue from the sale of products or from other sources in the foreseeable future.

Operating Expenses

Research and Development

Research and development expenses account for a significant portion of our operating expenses and consist primarily of external and internal expenses incurred in connection with the discovery and development of our product candidates.

External expenses include:

- expenses incurred in connection with the discovery, preclinical and clinical development of our product candidates, including under agreements with third parties, such as consultants and CROs;
- the cost of manufacturing compounds for use in our preclinical studies and clinical trials, including under agreements with third parties, such as consultants and CMOs; and
- costs associated with consultants for chemistry, manufacturing and controls (CMC) development, regulatory, statistics and other services, including expenses for technology and facilities

Internal expenses include employee-related expenses, including salaries and benefits, travel and stock-based compensation expense for employees engaged in research and development functions.

We expense research and development expenses in the periods in which they are incurred. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. We track external expenses on the basis of lead programs and other programs. However, we do not track internal costs on a program specific basis because these costs are deployed across multiple programs and, as such, are not separately classified. We utilize third party contractors for our research and development activities and CMOs for our manufacturing activities and we do not have our own laboratory or manufacturing facilities. Therefore, we have no material facilities expenses attributed to research and development.

We expect our research and development expenses to be lower in 2024 than in prior periods as a result of the implementation of the Strategic Plans, both of which included a reduction in workforce. Product candidates in later stages of development generally have higher development costs than those in earlier stages. As a result, our research and development expenses may increase in the future if we advance our programs such as our c-MET inhibitor KIN-8741 and CDK4 selective inhibitor KIN-7324 research programs through clinical development.

The successful development of our product candidates is highly uncertain, and we do not believe it is possible at this time to accurately project the nature, timing and estimated costs of the efforts necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. To the extent our product candidates continue to advance into clinical trials, as well as advance into larger and later-stage clinical trials, our expenses will increase substantially and may become more variable. We are also unable to predict when, if ever, we will generate revenue from our product candidates to offset these expenses. Our expenditures on current and future preclinical and clinical programs are subject to numerous uncertainties in timing and cost to completion. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to maintain our current research and development programs and to establish new ones;
- establishing an appropriate safety profile with IND-enabling toxicology studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;

- per-subject clinical trial costs;
- the number of clinical trials required for regulatory approval;
- the countries in which the clinical trials are conducted;
- the length of time required to enroll eligible subjects and initiate clinical trials;
- the number of subjects that participate in the clinical trials;
- the drop-out and discontinuation rate of subjects;
- potential additional safety monitoring requested by regulatory authorities;
- the duration of subject participation in the clinical trials and follow-up;
- the successful completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to applicable regulatory authorities;
- the receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals and post-marketing approval commitments from applicable regulatory authorities;
- the extent to which we establish collaborations, strategic partnerships or other strategic arrangements with third parties, if any, and the performance of any such third party;
- obtaining and retaining research and development personnel;
- establishing commercial manufacturing capabilities or making arrangements with CMOs;
- development and timely delivery of commercial-grade drug formulations that can be used in our planned clinical trials and for commercial launch; and
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights.

Any changes in the outcome of any of these factors could significantly impact the costs, timing and viability associated with the development of our product candidates.

General and Administrative

General and administrative expenses consist of salaries and benefits, travel and stock-based compensation expense for personnel in executive, human resources, finance and administrative functions; professional fees for legal, patent, consulting, accounting and audit services; and expenses for technology and facilities. We expense general and administrative expenses in the periods in which they are incurred.

We expect our general and administrative expenses to be lower in 2024 than in prior periods as a result of the implementation of the Strategic Plans, both of which included a reduction in workforce.

We expect this decrease in our general and administrative expenses to be partially offset by increased expenses we will continue to incur as a result of operating as a public company, including expenses related to accounting, audit, legal, regulatory, compliance with the rules and regulations of the SEC, SOX, and those of the Nasdaq Global Select Market or any other national securities exchange on which our securities are traded, director and officer insurance, investor and public relations, and other administrative and professional services. Our future general and administrative expenses will also be dependent on the advancement of our product candidates.

Restructuring Costs

Restructuring costs related to the September 2023 Strategic Plan primarily consist of severance and other employee-related costs. As part of the September 2023 Strategic Plan, we reduced our workforce by approximately 70%. In December 2023, the Company implemented additional measures whereby employees are required to render services beyond a minimum retention period to receive their one-time termination benefits.

Other Income, Net

Other income, net primarily consists of interest income generated from our cash equivalents in interest-bearing money market accounts and short-term and long-term investments.

Results of Operations

Comparison of the Years Ended December 31***, 2023 and 2022***

The following table summarizes our results of operations for the periods indicated (in thousands):

	Years Ended December 31,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 90,767	$ 88,150	$ 2,617
General and administrative	28,241	30,371	(2,130)
Restructuring costs	2,168	-	2,168
Total operating expenses	121,176	118,521	2,655
Loss from operations	(121,176)	(118,521)	(2,655)
Other income, net	8,527	2,250	6,277
Net loss	$ (112,649)	$ (116,271)	$ 3,622

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the periods indicated (in thousands):

	Years Ended December 31,		Increase
	2023	2022	(Decrease)
External expenses:			
RAF	$ 28,289	$ 23,713	$ 4,576
FGFR	14,620	13,588	1,032
Other programs and other unallocated costs	14,854	16,924	(2,070)
Total external expenses	57,763	54,225	3,538
Internal expenses	33,004	33,925	(921)
Total research and development expenses	$ 90,767	$ 88,150	$ 2,617

Research and development expenses were $90.8 million for the year ended December 31, 2023 compared to $88.2 million for the year ended December 31, 2022, an increase of $2.6 million. The increase was primarily driven by an increase of $5.6 million in external expenses for our RAF and FGFR programs given the increased activity and costs incurred in these programs, including increased patient enrollment and site activation, during 2023 prior to the implementation of the September 2023 Strategic Plan. This increase was partially offset by a decrease of $2.1 million in external expenses for our other programs reflecting decreased spend in pipeline research, as well as a decrease of $0.9 million in internal research and development expenses primarily as a result of a decrease in compensation costs for research and development personnel in connection with a reduction in headcount as a result of the September 2023 Strategic Plan.

General and Administrative Expenses

General and administrative expenses were $28.2 million for the year ended December 31, 2023 compared to $30.4 million for the year ended December 31, 2022, a decrease of $2.2 million. The decrease was primarily driven by a decrease in compensation costs for general and administrative personnel due to a reduction in headcount as a result of the September 2023 Strategic Plan, as well as decreased expenses for consulting fees and business insurance during the year ended December 31, 2023.

Restructuring Costs

Restructuring costs were $2.2 million for year ended December 31, 2023 compared to nil for the year ended December 31, 2022, since we did not have any restructuring costs during the prior year. The increase of $2.2 million was primarily due to severance and employee-related costs provided to separated employees related to the September 2023 Strategic Plan.

Other Income, Net

Other income, net was $8.5 million for the year ended December 31, 2023 compared to $2.3 million for the year ended December 31, 2022, an increase of $6.3 million. The increase was primarily driven by a significant increase in interest rates during 2023 compared to 2022 allowing us to invest maturing securities into higher yielding investments.

Liquidity and Capital Resources

Sources of Liquidity

On December 7, 2020, we completed our IPO. In connection with our IPO, we issued and sold 13,800,000 shares of our common stock at a price to the public of $20.00 per share resulting in gross proceeds of $276.0 million before deducting underwriting discounts and commissions and other offering expenses. Additionally, in January 2022, we filed a shelf registration statement with the SEC on Form S-3ASR (File No. 333-261970). The shelf registration statement included a prospectus supplement for an at-the-market offering to sell up to an aggregate of $150.0 million of shares of our common stock (ATM Offering) that may be issued and sold from time to time under a sales agreement with SVB Leerink LLC. In March 2022, we filed certain post-effective amendments to the Form S-3ASR for the purpose of, among other things, converting the registration statement to the current submission type for a non-automatic shelf registration statement and providing that the base prospectus included in the registration statement covers the offering, sale and issuance by us of up to $350.0 million in the aggregate of the securities identified in the registration statement in one or more offerings. The $150.0 million of common stock that may be offered, issued and sold in the ATM Offering is included in the $350.0 million of securities that may be offered, issued and sold by us under the base prospectus included in the shelf registration statement. To date, no shares have been issued and sold pursuant to the ATM Offering. Prior to our IPO, we funded our operations primarily through private placements of our convertible preferred stock with aggregate gross proceeds of $191.6 million.

Our primary uses of cash to date have been to fund our research and development activities, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations.

September 2023 Strategic Plan and Additional Measures

In September 2023, we began implementing our September 2023 Strategic Plan to (i) prioritize our Exarafenib combination with binimetinib, our c-MET inhibitor KIN-8741, and our discovery efforts around our CDK4 selective program; (ii) explore strategic alternatives for our Exarafenib monotherapy and KIN-3248 FGFR inhibitor programs; (iii) pause development of our MEK inhibitor KIN-7136; and (iv) implement a workforce restructuring.

As part of the September 2023 Strategic Plan, we reduced our workforce by approximately 70% and took related measures to reduce operating expenses.

The restructuring costs recorded during the year ended December 31, 2023 related to one-time employee termination benefits, including severance and employee-related costs provided to separated employees, were $2.2 million.

In December 2023, we implemented additional measures, including offering severance and retention bonuses, whereby employees are required to render services beyond a minimum retention period to receive their one-time termination benefits.

In January 2024, we announced exploration of strategic alternatives for the Company in an effort to maximize shareholder value and implemented a further RIF. As a result of the Strategic Plans and a subsequent RIF we completed in March 2024, we currently have 10 full-time employees.

Future Funding Requirements

To date, we have not generated any revenue. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates, and we do not know when, or if, that will occur. Until such time as we can generate significant revenue from product sales, if ever, we will continue to require substantial additional capital to develop our product candidates and fund operations for the foreseeable future. We expect our expenses in 2024 to be lower than in prior periods because of the implementation of the Strategic Plans, both of which included a reduction in workforce. However, we may not realize, in full or in part, the anticipated benefits and savings in operating expenses from the Strategic Plans due to unforeseen difficulties, delays or unexpected costs. As a result, our future expenses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on whether we decide to pursue any future development efforts. We are subject to all the risks incident in the development of new biopharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. Our expenses could increase significantly, if and as we:

- advance the development of our programs, including our c-MET inhibitor KIN-8741 and CDK4 selective inhibitor KIN-7324 research programs;
- expand our pipeline of product candidates through our own product discovery and development efforts;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- implement operational, financial and management systems;
- attract, hire and retain additional clinical, scientific, management and administrative personnel;
- maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know how; and
- operate as a public company.

In order to complete the development of our product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we will require substantial additional funding. Until we can generate a sufficient amount of revenue from the commercialization of our product candidates, we may seek to raise any necessary additional capital through the sale of equity, debt financings or other capital sources, which could include income from collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, including restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our common stock, make certain investments or engage in merger, consolidation, licensing or asset sale transactions. If we raise funds through collaborations, strategic partnerships and other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. If we are unable to raise additional funds when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts.

Based on our current operating plan, we believe that our current cash and cash equivalents and short-term and long-term investments will be sufficient to fund our planned operating expenses and capital expenditure requirements through at least the next twelve months from the date this Annual Report on Form 10-K is filed with the SEC. We have based our projections of operating capital requirements on our current operating plan, which includes several assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount and timing of our working capital requirements. Our future funding requirements will depend on, and could increase significantly as a result of many factors, including:

- the scope, timing, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the scope, timing, progress, results and costs of researching and developing other product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and sufficient inventory to support commercial launch;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the cost and timing of attracting, hiring and retaining skilled personnel to support our operations and continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties on favorable terms, if at all;
- the extent to which we acquire or in-license other product candidates and technologies, if any;
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any; and
- the costs associated with operating as a public company.

A change in the outcome of any of these or other factors with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

We formerly had offices located in San Francisco and San Diego, California. In January and February 2024, we assigned our lease agreements in San Diego and San Francisco respectively and became a remote-only company. We believe that suitable office space will be available as and when needed. As of December 31, 2023, we have $0.9 million and $2.3 million in current and long-term operating lease liabilities, respectively.

As part of our September 2023 Strategic Plan and additional measures, as of December 31, 2023, we recorded restructuring costs of $2.2 million related to one-time employee termination benefits as discussed in Note 15. In addition, in January 2024, we incurred one-time costs of approximately $1.1 million in connection with the additional RIF, relating to severance and related benefits, as discussed in Note 16.

In addition, we have entered into agreements in the normal course of business with certain vendors for the provision of goods and services, which includes manufacturing services with CMOs and development services with CROs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreement. These obligations and commitments are not separately presented.

Cash Flows

The following table summarizes our cash flow for the periods indicated (in thousands):

	Years Ended December 31,	
	2023	2022
Net cash used in operating activities	$ (100,043)	$ (89,034)
Net cash provided by (used in) investing activities	109,869	(6,830)
Net cash (used in) provided by financing activities	(7,808)	1,160
Effect of exchange rate changes on cash and cash equivalents	(6)	1
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 2,012	$ (94,703)

Operating Activities

Net cash used in operating activities during the year ended December 31, 2023 was $100.0 million. This consisted of our consolidated net loss of $112.6 million and a net decrease in operating assets and liabilities of $3.7 million, net of stock compensation expense of $19.9 million, depreciation expense of $0.8 million and amortization/accretion of investments of $(4.4) million.

Net cash used in operating activities during the year ended December 31, 2022 was $89.0 million. This consisted of our consolidated net loss of $116.3 million and a net increase in operating assets and liabilities of $6.4 million, net of stock-based compensation expense of $19.6 million, depreciation expense of $0.6 million and amortization/accretion of investments of $0.7 million.

Investing Activities

Net cash provided by investing activities during the year ended December 31, 2023 was $109.9 million and related primarily to the sales and maturities of short-term and long-term investments totaling $264.6 million partially offset by purchases of short-term and long-term investments totaling $154.7 million.

Net cash used in investing activities during the year ended December 31, 2022 was $6.8 million and related primarily to purchases of short-term and long-term investments totaling $176.5 million partially offset by the sales and maturities of short-term and long-term investments totaling $172.4 million. Additionally, purchases of property and equipment totaled $2.7 million during the year ended December 31, 2022.

Financing Activities

Net cash used in financing activities during the year ended December 31, 2023 was $7.8 million, which consisted of the cash portion of the acquisition of redeemable convertible noncontrolling interests in the amount of $9.1 million, partially offset by proceeds from the issuance of common stock under our equity incentive plans and purchases under our employee stock purchase plan of $1.0 million and $0.3 million, respectively.

Net cash provided by financing activities during the year ended December 31, 2022 was $1.2 million, which consisted of proceeds from the issuance of common stock upon stock option exercises and under our employee stock purchase plan of $0.9 million and $0.6 million, respectively, partially offset by the payment of deferred offering costs in the amount of $0.4 million.

Off-Balance Sheet Arrangements

We currently do not have, and did not have during the periods presented, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on a periodic basis. Our actual results may differ from these estimates.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are critical to understanding our historical and future performance, as the policies relate to the more significant areas involving management's judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, based on a pre-determined schedule or when contractual milestones are met, but some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. If timelines or contracts are modified based upon changes in the protocol or scope of work to be performed, we modify our estimates and accruals accordingly on a prospective basis.

We base our expenses related to external research and development services on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly.

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 reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of employee, officer, director and non-employee awards, estimated in accordance with the applicable accounting guidance, recognized on a straight-line basis over the vesting period. The vesting period generally approximates the expected service period of the awards. We recognize forfeitures as they occur.

The fair value of stock options and employee stock plan awards under the 2020 ESPP is estimated using a Black-Scholes valuation model on the date of grant. The Black-Scholes option-pricing model requires inputs based on certain subjective assumptions. Changes to these assumptions can materially affect the fair value of stock options and employee stock plan awards, and ultimately the amount of stock-based compensation expense recognized in our consolidated financial statements. These assumptions include:

- Fair Value of Common Stock: Since the completion of our initial public offering, the fair value of each share of common stock underlying stock option grants is based on the closing price of our common stock on the Nasdaq Global Select Market as reported on the date of grant.
- Expected Term: We have opted to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option, which is generally 10 years.
- Expected Volatility: Due to the limited trading history of our common stock, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.
- Risk-Free Interest Rate: The risk-free interest rates used are based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. treasury notes with maturities approximately equal to the expected term of the stock options.
- Expected Dividend: To date, we have not issued any dividends and do not expect to issue dividends over the life of the options and therefore have estimated the dividend yield to be zero.

The assumptions underlying these valuations represent our board's and management's best estimates, which involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

The fair value of RSUs is estimated based on the fair value of our common stock on the date of grant.

Variable Interest Entity

Our consolidated financial statements include the accounts of our variable interest entity (VIE), Kinnjiu. We evaluate our ownership, contractual and other interests in entities that are not wholly-owned to determine if these entities are VIEs, and, if so, whether we are the primary beneficiary of the VIE. In determining whether we are the primary beneficiary of a VIE and therefore required to consolidate the VIE, we apply a qualitative approach that determines whether we have both (1) the power to direct the activities of the VIE that most significantly impact the VIE's economic performance and (2) the obligation to absorb losses of, or the rights to receive benefits from, the VIE that could potentially be significant to that VIE. As of December 31, 2022, prior to the acquisition of the minority ownership stake discussed elsewhere in this Annual Report on Form 10-K, we held an approximately 58% equity interest in Kinnjiu. Based on our assessment, we concluded that Kinnjiu was a VIE and we were the primary beneficiary. As of December 31, 2023, Kinnjiu is a wholly-owned subsidiary of the Company.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (JOBS Act). We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have $1.235 billion or more in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (iv) December 31, 2025. As a result of this status, we have taken advantage of reduced reporting requirements in this Annual Report on Form 10-K and may elect to take advantage of other reduced reporting requirements in our future filings with the SEC. In particular, in this Annual Report on Form 10-K, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to use the extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date on which we (i) are no longer an emerging growth company and (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a "smaller reporting company" meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time, we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation and other matters.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

As of December 31, 2023, our cash equivalents consisted primarily of interest-bearing money market accounts. We also had investments in short-term, high-grade securities. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term maturities of our investments, a hypothetical 100 basis point increase or decrease in interest rates during any of the periods presented would not have had a material impact on our financial results.

As of December 31, 2023, we had no debt outstanding and are therefore not exposed to interest rate risk with respect to debt.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development contracts. We do not believe that inflation has had a material effect on our financial results during the periods presented.

Foreign Currency Risk

Our expenses are generally denominated in U.S. dollars. However, we have entered into a limited number of contracts with vendors for research and development services that are denominated in foreign currencies, including the Canadian dollar. Additionally, Kinnjiu has contracts that are denominated in the Chinese Renminbi. Accordingly, we are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material to our consolidated financial statements, and we have not had a formal hedging program with respect to foreign currency. A hypothetical 10% increase or decrease in exchange rates during any of the periods presented would not have had a material impact on our financial results.

Item 8. Financial Statements and Supplementary Data

KINNATE BIOPHARMA INC.
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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Kinnate Biopharma Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Kinnate Biopharma Inc. and subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these 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.

/s/ KPMG LLP

We have served as the Company's auditor since 2020.

San Diego, California
March 28, 2024

KINNATE BIOPHARMA INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and par value amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 56,998	$ 29,261
Cash at consolidated joint venture	-	25,725
Short-term investments	97,036	172,214
Prepaid expenses and other current assets	4,143	3,637
Total current assets	158,177	230,837
Property and equipment, net	2,272	3,071
Right-of-use lease assets	2,488	3,377
Long-term investments	10,259	39,139
Restricted cash	371	371
Other non-current assets	38	2,031
Total assets	$ 173,605	$ 278,826
Liabilities, Redeemable Convertible Noncontrolling Interests and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,031	$ 2,970
Accrued expenses	9,072	13,206
Current portion of operating lease liabilities	892	991
Total current liabilities	11,995	17,167
Operating lease liabilities, long-term	2,283	3,191
Total liabilities	14,278	20,358
Commitments and contingencies (See Note 13)		
Redeemable convertible noncontrolling interests	-	35,000
Stockholders' equity:		
Preferred stock, $0.0001 par value; 200,000,000 shares authorized at December 31, 2023 and 2022; 0 shares outstanding at December 31, 2023 and 2022	-	-
Common stock, $0.0001 par value; 1,000,000,000 shares authorized at December 31, 2023 and 2022; 47,124,349 and 44,342,292 shares issued and outstanding at December 31, 2023 and 2022, respectively	5	4
Additional paid-in capital	531,346	484,237
Accumulated other comprehensive loss	(12)	(1,410)
Accumulated deficit	(372,012)	(259,363)
Total stockholders' equity	159,327	223,468
Total liabilities, redeemable convertible noncontrolling interests and stockholders' equity	$ 173,605	$ 278,826

See accompanying notes to consolidated financial statements.

KINNATE BIOPHARMA INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)

	Years Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 90,767	$ 88,150
General and administrative	28,241	30,371
Restructuring costs	2,168	-
Total operating expenses	121,176	118,521
Loss from operations	(121,176)	(118,521)
Other income, net	8,527	2,250
Net loss	$ (112,649)	$ (116,271)
Weighted-average shares outstanding, basic and diluted	46,575,378	44,065,749
Net loss per share, basic and diluted	$ (2.42)	$ (2.64)
Comprehensive loss:		
Net loss	$ (112,649)	$ (116,271)
Other comprehensive loss:		
Currency translation adjustments	(6)	1
Unrealized gain (loss) on investments	1,404	(887)
Total comprehensive loss	$ (111,251)	$ (117,157)

See accompanying notes to consolidated financial statements.

KINNATE BIOPHARMA INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity	Redeemable Convertible Noncontrolling Interests
	Shares	Amount					
Balance at December 31, 2021	43,855,944	$ 4	$ 463,089	$ (524)	$ (143,092)	$ 319,477	$ 35,000
Stock-based compensation expense	-	-	19,582	-	-	19,582	-
Shares issued under equity incentive plans	414,051	-	945	-	-	945	-
Shares issued under employee stock purchase plan	72,297	-	621	-	-	621	-
Net loss	-	-	-	-	(116,271)	(116,271)	-
Other comprehensive loss	-	-	-	(886)	-	(886)	-
Balance at December 31, 2022	44,342,292	$ 4	$ 484,237	$ (1,410)	$ (259,363)	$ 223,468	$ 35,000
Stock-based compensation expense	-	-	19,918	-	-	19,918	-
Acquisition of redeemable convertible noncontrolling interests	2,200,000	1	25,866	-	-	25,867	(35,000)
Shares issued under equity incentive plans	503,856	-	1,041	-	-	1,041	-
Shares issued under employee stock purchase plan	78,201	-	284	-	-	284	-
Net loss	-	-	-	-	(112,649)	(112,649)	-
Other comprehensive gain	-	-	-	1,398	-	1,398	-
Balance at December 31, 2023	47,124,349	$ 5	$ 531,346	$ (12)	$ (372,012)	$ 159,327	$ -

See accompanying notes to consolidated financial statements.

KINNATE BIOPHARMA INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (112,649)	$ (116,271)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	19,918	19,582
Depreciation	799	604
Amortization/accretion of investments	(4,407)	682
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,487	1,369
Operating lease right-of-use assets and liabilities, net	(118)	805
Accounts payable and accrued expenses	(5,073)	4,195
Net cash used in operating activities	(100,043)	(89,034)
Cash flows from investing activities:		
Purchases of short-term and long-term investments	(154,719)	(176,528)
Sales and maturities of short-term and long-term investments	264,588	172,417
Purchases of property and equipment	-	(2,719)
Net cash provided by (used in) investing activities	109,869	(6,830)
Cash flows from financing activities:		
Acquisition of redeemable convertible noncontrolling interests	(9,133)	-
Proceeds from issuance of common stock under equity incentive plans	1,041	945
Proceeds from issuance of common stock under employee stock purchase plan	284	621
Payment of deferred offering costs	-	(406)
Net cash (used in) provided by financing activities	(7,808)	1,160
Effect of exchange rate changes on cash and cash equivalents	(6)	1
Net increase (decrease) in cash, cash equivalents and restricted cash	2,012	(94,703)
Cash, cash equivalents and restricted cash at the beginning of the period	55,357	150,060
Cash, cash equivalents and restricted cash at the end of the period	$ 57,369	$ 55,357
Supplemental non-cash investing and financing activity:		
Acquisition of redeemable convertible noncontrolling interests	$ 14,907	$ -
Capitalized value of tenant improvement allowance	$ -	$ 606
Operating lease liabilities arising from obtaining right-of-use assets	$ -	$ 4,569
Write-off of deferred offering costs	$ -	$ 641

See accompanying notes to consolidated financial statements.

KINNATE BIOPHARMA INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1) Organization and Basis of Presentation

a) Organization and Nature of Operations

Kinnate Biopharma Inc. (Kinnate or the Company) was incorporated in the State of Delaware in January 2018. The Company formerly had offices in San Francisco and San Diego, California. In January and February 2024, the Company assigned its lease agreements in San Diego and San Francisco. The Company is currently a remote-only company and therefore does not have principal executive offices. The Company is a precision oncology company focused on the discovery, design and development of small molecule kinase inhibitors for difficult-to-treat, genomically defined cancers.

Since its inception, the Company has devoted substantially all of its resources to research and development activities, business planning, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. It has incurred losses and negative cash flows from operations since commencement of its operations. The Company had an accumulated deficit of $372.0 million and had cash and cash equivalents and short-term and long-term investments totaling $164.3 million as of December 31, 2023. From its inception through December 31, 2023, the Company has financed its operations primarily through issuances of common stock, including in the Company's initial public offering (IPO), and private placements of convertible preferred stock.

In May 2021, the Company announced the closing of a Series A preferred stock financing of a China joint venture, Kinnjiu Biopharma Inc. (Kinnjiu), to enable the potential development and commercialization of certain targeted oncology product candidates across People's Republic of China, Hong Kong, Taiwan and Macau. Contributions from noncontrolling interest members totaled $35.0 million before issuance costs of $0.2 million. In February 2023, the Company acquired the ownership stake of Kinnjiu previously held by Series A investors (Kinnjiu Transaction) (see Note 11). Kinnjiu is a wholly-owned subsidiary of the Company.

In September 2023, the Company's board of directors, based on a strategic review of the Company's business, approved a reprioritization of the Company's research and development programs and a workforce restructuring. See Note 15 for more details.

In December 2023, the Company implemented additional measures, including offering severance and retention bonuses, whereby employees are required to render services beyond a minimum retention period to receive their one-time termination benefits.

In January 2024, the Company announced a further RIF and the exploration of strategic alternatives and suspended almost all of its research and development activities. As a result of the Strategic Plans and a subsequent RIF the Company completed in March 2024, it currently has 10 full-time employees.

In February 2024, the Company entered into the Merger Agreement which provides for, among other things, the acquisition of all of Company's outstanding shares of Common Stock through a cash tender offer. The Company also entered into the Purchase Agreement with Pierre Fabre pursuant to which it sold the global rights to Exarafenib and other pan-RAF program assets to Pierre Fabre, subject to the terms and conditions of the Purchase Agreement. See Note 16 for more details.

b) Basis of Presentation

The Company's consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP). The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Kinnjiu. All intercompany transactions and balances have been eliminated in consolidation.

The accompanying consolidated financial statements include all known adjustments necessary for a fair presentation of the results as required by GAAP. These adjustments consist primarily of normal recurring accruals and estimates that impact the carrying value of assets and liabilities. Operating results presented in these consolidated financial statements are not necessarily indicative of future results.

Prior to the completion of the Kinnjiu Transaction, the Company evaluated its ownership, contractual and other interests in entities that were not wholly-owned to determine if these entities were VIEs, and, if so, whether the Company was the primary beneficiary of the VIE. In determining whether the Company was the primary beneficiary of a VIE and therefore required to consolidate the VIE, the Company applied a qualitative approach that determined whether the Company had both (1) the power to direct the activities of the VIE that most significantly impacted the VIE's economic performance and (2) the obligation to absorb losses of, or the rights to receive benefits from, the VIE that could potentially be significant to that VIE. As of December 31, 2022, the Company held an approximately 58% equity interest in Kinnjiu. Based on the Company's assessment, the Company concluded that Kinnjiu was a VIE and the Company was the primary beneficiary. See Note 11 with respect to Kinnjiu Transaction.

2) Summary of Significant Accounting Policies

a) Use of Estimates

The preparation of consolidated 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 and the reported amounts of expenses during the reporting period. Accounting estimates and management judgments reflected in the consolidated financial statements include: normal recurring accruals, including the accrual of research and development expenses; accrued restructuring costs; fair value of investments; valuation of deferred tax assets; and stock-based compensation. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions. The Company uses the best information available to update its critical accounting estimates.

b) Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash and cash equivalents and short-term and long-term investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company has not experienced any losses on deposits since inception. The Company's short-term and long-term investments are invested in high grade securities with limited concentration in any one issuer, and as a result, the Company believes represent minimal credit risk.

c) Fair Value of Financials Instruments

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value, and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

The carrying amounts of cash, cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses are reasonable estimates of their fair value because of the short maturity of these items.

d) Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash equivalents primarily represent funds invested in readily available money market accounts. As of December 31, 2023 and 2022, the Company had cash and cash equivalents balances deposited at major financial institutions.

e) Investments

All investments have been classified as "available-for-sale" and are carried at fair value as determined based upon quoted market prices or pricing models for similar securities at period end. Investments with contractual maturities less than 12 months at the balance sheet date are considered short-term investments. Those investments with contractual maturities 12 months or greater at the balance sheet date are considered long-term investments. Dividend and interest income are recognized in the Company's consolidated statements of operations and comprehensive loss when earned. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of securities sold. Unrealized gains and losses are reported as a component of accumulated other comprehensive loss. The cost of the Company's available-for-sale debt securities is adjusted for amortization of premium and accretion of discounts to maturity. The Company reviews its portfolio of available-for-sale debt securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost have resulted from a credit-related loss or other factors. If the decline in fair value is due to credit-related factors, a loss is recognized in statements of operations, whereas if the decline in fair value is not due to credit-related factors, the loss is recorded in other comprehensive loss.

f) Property and Equipment, Net

Property and equipment, net are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which ranges between three to five years. Leasehold improvements are stated at cost and depreciated over the shorter of the estimated useful life or the remaining lease term at the time the asset is placed into service.

g) Impairment of Property and Equipment

The Company accounts for the impairment of long-lived assets by reviewing these assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group to be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying value. If the carrying value of the long-lived asset or asset group is not recoverable on an undiscounted-cash-flow basis, an impairment is recognized to the extent that the carrying value exceeds its fair value. The Company did not recognize impairment losses for the periods ended December 31, 2023 and 2022.

h) Leases

The Company determines if an arrangement is or contains a lease at inception. For leases with a term greater than one year, right-of-use assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, the Company uses its incremental borrowing rate which represents an estimated rate of interest that the Company would have to pay to borrow equivalent funds on a collateralized basis at the lease commencement date. Leases are classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the consolidated statement of operations and comprehensive loss. The Company's leases often include options to extend or terminate the lease. These options are included in the lease term when it is reasonably certain that the Company will exercise that option. As of December 31, 2023, it is reasonably certain that these options will not be exercised, and they are not included within the lease term. As disclosed in Note 16 below, in January and February of 2024, the Company entered into agreements to assign its leases.

i) Research and Development

Research and development expenses are expensed in the periods in which they are incurred. External expenses consist primarily of payments to outside consultants and contract research organizations in connection with the Company's clinical trials, discovery and preclinical activities, process development, manufacturing activities, regulatory and other services. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to the Company by its service providers or the estimate of the level of service that has been performed at each reporting date.

The Company makes estimates of accrued expenses as of each balance sheet date based on facts and circumstances known at that time. The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments if necessary. The significant estimates in its accrued research and development expenses include the costs incurred for services performed by vendors in connection with research and development activities for which the Company has not yet been invoiced. Research and development expenses amounted to $90.8 million and $88.2 million for the years ended December 31, 2023 and 2022, respectively.

j) Redeemable Convertible Noncontrolling Interests

Prior to the Kinnjiu Transaction, the shares third parties owned in Kinnjiu represented an interest in the equity the Company did not control. The redeemable convertible noncontrolling interests attributable to other owners was classified in temporary equity on the consolidated balance sheets as the preferred stock was redeemable by the noncontrolling interests.

Since the preferred stock held at Kinnjiu did not represent a residual equity interest, net losses of Kinnjiu were not allocated to the preferred shares. As a result, the balance of the preferred stock classified as a redeemable convertible noncontrolling interest equaled the carrying value. Additionally, net losses of Kinnjiu were not allocated to the noncontrolling interest related to ordinary shares held by a third party as the amounts to be allocated were immaterial.

k) Commitments and Contingencies

The Company recognizes a liability with regard to loss contingencies when it believes it is probable a liability has been incurred, and the amount can be reasonably estimated. If some amount within a range of loss appears at the time to be a better estimate than any other amount within the range, the Company accrues that amount. When no amount within the range is a better estimate than any other amount the Company accrues the minimum amount in the range. The Company has not recorded any such liabilities as of December 31, 2023 and 2022.

l) Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

As of December 31, 2023 and 2022, the Company maintained valuation allowances against its deferred tax assets as the Company concluded it had not met the "more likely than not" to be realized threshold. Changes in the valuation allowance when they are recognized in the provision for income taxes would result in a change in the estimated annual effective tax rate.

m) Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of employee, officer, director and non-employee stock option grants, estimated in accordance with the applicable accounting guidance, recognized on a straight-line basis over the vesting period. The vesting period generally approximates the expected service period of the awards. The Company recognizes forfeitures as they occur.

The fair value of restricted stock units is based on the Company's closing stock price on the grant date. The fair value of stock options is estimated using a Black-Scholes valuation model on the date of grant. This method requires certain assumptions be used as inputs, such as the fair value of the underlying common stock, expected term of the option before exercise, expected volatility of the Company's common stock, risk-free interest rate and expected dividend. Options granted have a maximum contractual term of ten years. The Company has limited historical stock option activity and therefore estimates the expected term of stock options granted using the simplified method, which represents the arithmetic average of the original contractual term of the stock option and its weighted-average vesting term. The expected volatility of stock options is based upon the historical volatility of a number of publicly traded companies in similar stages of clinical development. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available. The risk-free interest rates used are based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. treasury notes with maturities approximately equal to the expected term of the stock options. The Company has historically not declared or paid any dividends and does not currently expect to do so in the foreseeable future, and therefore has estimated the dividend yield to be zero.

n) Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on investments and foreign currency gains and losses. The unrealized losses on available-for-sale investments and foreign currency translation adjustments are included as a component of other comprehensive loss that is excluded from the reported net loss.

o) Net Loss Per Share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the Company's common stock options are considered to be potentially dilutive securities. As the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

The following table sets forth the computation of the basic and diluted net loss per share (in thousands, except share and per share amounts).

	Years Ended December 31,	
	2023	2022
Numerator		
Net loss	$ (112,649)	$ (116,271)
Denominator		
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	46,575,378	44,065,749
Net loss per share, basic and diluted	$ (2.42)	$ (2.64)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable for the periods presented because including them would have been anti-dilutive:

	Years Ended December 31,	
	2023	2022
Options to purchase common stock	9,692,516	9,107,467
Non-vested restricted stock units	200,900	287,916
Total	9,893,416	9,395,383

p) Recently Issued and Adopted Accounting Standards

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326) (ASC 326): Measurement of Credit Losses on Financial Instruments, which introduced the expected credit losses methodology for the measurement of credit losses on financial assets measured at amortized cost basis, replacing the previous incurred loss methodology. The amendments in Update 2016-13 added Topic 326, Financial Instruments—Credit Losses, made several consequential amendments to the Codification. Update 2016-13 also modified the accounting for available-for-sale debt securities, which must be individually assessed for credit losses when fair value is less than the amortized cost basis, in accordance with Subtopic 326-30, Financial Instruments— Credit Losses—Available-for-Sale Debt Securities. The guidance is effective for public business entities for annual periods beginning after December 15, 2019, including interim periods within those years. For all other entities, the standard is effective for annual periods beginning after December 15, 2022 and interim periods, therein. Early adoption is permitted. Since the Company has elected to use the extended transition period under the JOBS Act available to emerging growth companies (EGCs), the ASU is effective for the Company for fiscal years beginning after December 15, 2022. The Company adopted this standard on the required effective date of January 1, 2023. The ASU did not have a material impact on its consolidated financial statements and related disclosures.

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2023-07, Segment Reporting - Improvements to Reportable Segment Disclosures. The amendments require disclosure of incremental segment information on an annual and interim basis. The amendments also require companies with a single reportable segment to provide all disclosures required by this amendment and all existing segment disclosures in Accounting Standards Codification 280, Segment Reporting. The amendments are effective for fiscal years beginning after December 15, 2023, and interim periods beginning after December 15, 2024. The Company does not expect the adoption of the amendments to have a significant impact on its financial statements.

3) Cash, Cash Equivalents and Restricted Cash

The following table provides a reconciliation of the components of cash, cash equivalents and restricted cash reported in the consolidated statements of cash flows (in thousands):

	As of December 31,	
	2023	**2022**
Cash and cash equivalents	$ 56,998	$ 29,261
Cash at consolidated joint venture	-	25,725
Restricted cash, non-current	371	371
Total cash, cash equivalents and restricted cash reported in the Consolidated Statements of Cash Flows	$ 57,369	$ 55,357

The cash at the consolidated joint venture represents cash held at Kinnjiu prior to the Kinnjiu Transaction and the use of such cash was limited to the operations of Kinnjiu (see Note 11). As a result of the Kinnjiu Transaction, such cash is no longer limited in its use and accordingly is no longer presented separately on the consolidated balance sheet. The restricted cash balance relates to the Company's office lease in San Diego, California (see Note 13).

4) Property and Equipment, Net

Property and equipment, net, consisted of the following (in thousands):

	As of December 31,	
	2023	**2022**
Furniture and fixtures	$ 760	$ 760
Computers and equipment	433	442
Computer software	99	99
Leasehold improvements	2,520	2,511
Property and equipment	3,812	3,812
Less accumulated depreciation	(1,540)	(741)
Property and equipment, net	$ 2,272	$ 3,071

Depreciation expense for the years ended December 31, 2023 and 2022 was $0.8 million and $0.6 million, respectively.

5) Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	As of December 31,	
	2023	**2022**
Accrued research and development	$ 5,784	$ 7,884
Accrued compensation	2,452	4,832
Accrued restructuring costs	255	-
Accrued legal fees	454	243
Other accruals	127	247
Total	$ 9,072	$ 13,206

6) Investments

The Company's investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of its investments to preserve principal and maintain liquidity. In accordance with the Company's investment policy, it has invested funds in marketable securities as of December 31, 2023 and 2022.

The cost, gross unrealized holding gains, gross unrealized holding losses and fair value of available-for-sale investments by types and classes of security at December 31, 2023 and 2022 consisted of the following (in thousands):

	December 31, 2023				
	Maturity in Years	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Corporate debt securities	less than 1	$ 5,970	$ 1	$ -	$ 5,971
Commercial paper	less than 1	37,019	10	(1)	37,028
U.S. Agency bonds	less than 1	51,485	-	(46)	51,439
Asset-backed securities		2,599	-	(1)	2,598
Short-term investments		$ 97,073	$ 11	$ (48)	$ 97,036
Corporate debt securities	1 - 2	$ 1,524	$ 25	$ -	$ 1,549
Asset-backed securities	1 - 2	8,705	12	(7)	8,710
Long-term investments		$ 10,229	$ 37	$ (7)	$ 10,259

	December 31, 2022				
	Maturity in Years	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Corporate debt securities	less than 1	$ 9,604	$ 2	$ (72)	$ 9,534
Commercial paper	less than 1	41,243	-	-	41,243
U.S. Treasury securities	less than 1	119,810	-	(1,254)	118,556
U.S. Agency bonds	less than 1	2,877	4	-	2,881
Short-term investments		$ 173,534	$ 6	$ (1,326)	$ 172,214
Corporate debt securities	1 - 2	$ 15,426	$ -	$ (60)	$ 15,366
U.S. Agency bonds	1 - 2	5,907	-	(9)	5,898
Asset-backed securities	1 - 2	17,897	20	(42)	17,875
Long-term investments		$ 39,230	$ 20	$ (111)	$ 39,139

The available-for-sale investments' gross unrealized losses and fair value aggregated by classes of security and length of time that individual securities have been in a continuous loss position at December 31, 2023 and 2022 consisted of the following (in thousands):

	December 31, 2023								
	Less than 12 months			More than 12 months			Total		
	Count	Fair Value	Unrealized Losses	Count	Fair Value	Unrealized Losses	Count	Fair Value	Unrealized Losses
Commercial paper	1	$ 4,978	$ (1)	-	$ -	$ -	1	$ 4,978	$ (1)
U.S. Agency bonds	13	45,547	(36)	2	5,892	(10)	15	51,439	(46)
Asset-backed securities	5	5,507	(5)	3	1,816	(3)	8	7,323	(8)
	19	$ 56,032	$ (42)	5	$ 7,708	$ (13)	24	$ 63,740	$ (55)

	December 31, 2022								
	Less than 12 months			More than 12 months			Total		
	Count	Fair Value	Unrealized Losses	Count	Fair Value	Unrealized Losses	Count	Fair Value	Unrealized Losses
Corporate debt securities	7	$ 22,806	$ (132)	-	$ -	$ -	7	$ 22,806	$ (132)
U.S. Treasury securities	3	14,625	(57)	7	103,931	(1,197)	10	118,556	(1,254)
U.S. Agency bonds	2	5,898	(9)	-	-	-	2	5,898	(9)
Asset-backed securities	6	7,843	(42)	-	-	-	6	7,843	(42)
	18	$ 51,172	$ (240)	7	$ 103,931	$ (1,197)	25	$ 155,103	$ (1,437)

The Company reviews its investments to identify and evaluate investments that have an indication of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. At December 31, 2023 and 2022, the Company held securities in a total unrealized loss position of $0.1 million and $1.4 million, respectively. The Company generally does not intend to sell any investments prior to recovery of their amortized cost basis for any investment in an unrealized loss position. Further, such investments are invested in high grade securities. As such, the Company has classified these losses as temporary in nature.

The Company has determined that there were no material declines in fair value of its investments due to credit-related factors as of December 31, 2023 and 2022.

7) Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The carrying amounts of the Company's cash, prepaid expenses and other current assets, accounts payable and accrued expenses are generally considered to be representative of their fair value because of the short-term nature of these instruments. The Company's investments, which may include money market funds and available-for-sale investment securities consisting of high-quality, marketable debt instruments of corporations and the U.S. government are measured at fair value in accordance with the fair value hierarchy.

Following are the major categories of assets measured at fair value on a recurring basis as of December 31, 2023 and 2022 (in thousands):

	Fair Value Measurements at December 31, 2023			
	Level 1	**Level 2**	**Level 3**	**Total**
Money market funds	$ 49,676	$ -	$ -	$ 49,676
Corporate debt securities	-	7,520	-	7,520
Commercial paper	-	41,009	-	41,009
U.S. Agency bonds	-	51,439	-	51,439
Asset-backed securities	-	11,308	-	11,308
Total cash equivalents and investments	$ 49,676	$ 111,276	$ -	$ 160,952

	Fair Value Measurements at December 31, 2022			
	Level 1	**Level 2**	**Level 3**	**Total**
Money market funds	$ 28,261	$ -	$ -	$ 28,261
Corporate debt securities	-	24,900	-	24,900
Commercial paper	-	41,243	-	41,243
U.S. Treasury securities	-	118,556	-	118,556
U.S. Agency bonds	-	8,779	-	8,779
Asset-backed securities	-	17,875	-	17,875
Total cash equivalents and investments	$ 28,261	$ 211,353	$ -	$ 239,614

Money market funds are classified as cash and cash equivalents in the Company's consolidated balance sheets at December 31, 2023 and 2022.

8) Stockholders' Equity

Under its Amended and Restated Articles of Incorporation dated December 7, 2020, the Company had a total of 1,200,000,000 shares of capital stock authorized for issuance, consisting of 1,000,000,000 shares of common stock, par value of $0.0001 per share, and 200,000,000 shares of preferred stock, par value of $0.0001 per share.

Common stock reserved for future issuance consisted of the following:

	As of December 31,	
	2023	2022
Common stock options outstanding	9,692,516	9,107,467
RSUs outstanding	200,900	287,916
Common stock reserved for future equity grants	2,651,449	1,700,947
Total common stock reserved for future issuance	12,544,865	11,096,330

At the Market Offering Program

In January 2022, the Company filed a shelf registration with the SEC on Form S-3ASR (File No. 333-261970). The shelf registration statement included a prospectus supplement for an at-the-market offering (ATM Offering) to sell up to an aggregate of $150.0 million of shares of the Company's common stock that may be issued and sold from time to time under a sales agreement with SVB Leerink LLC. As of December 31, 2023 and 2022, no shares had issued and sold pursuant to the ATM Offering. Accordingly, deferred offering costs in the amount of $0.6 million were expensed in the fourth quarter of 2022.

9) Equity Incentive Plans and Stock-Based Compensation

a) Company Equity Incentive Plans

In December 2020, the Company adopted the 2020 Equity Incentive Plan (the 2020 Plan), which replaced the 2018 Equity Incentive Plan (the 2018 Plan). The 2020 Plan allows for the issuance of incentive stock options (ISOs), nonstatutory stock options (NSOs), stock appreciation rights (SARs), restricted stock and restricted stock units (RSUs). The 2020 Plan was established to enable the Company to attract and retain the best available personnel, to provide additional incentive to its employees, directors, and consultants of the Company and to promote the financial success and progress of the Company. Under the 2020 Plan, the Company can offer ISOs to employees and NSOs to employees, non-employee directors, and consultants. The 2020 Plan allows the Company to issue options for shares of its common stock, restricted stock units (RSUs) and other award types, up to a total of 5,218,000 shares (the Equity Pool), subject to annual evergreen adjustments and appropriate adjustments for stock splits, combinations and other similar events for issuance pursuant to awards made under the 2020 Plan. The 588,039 shares of the Company's common stock that remained available for issuance under the 2018 Plan immediately prior to the effectiveness of the 2020 Plan are also reserved under the 2020 Plan.

Under the 2020 and 2018 Plans, the exercise price of each share shall be established at the sole discretion of the Company's board of directors (or any of the committees of the Company's board of directors); provided, however, that the exercise price per share shall not be less than the fair market value for shares of the Company's common stock on the date of grant. The exercise price per share of an ISO granted to an optionee who on the date of the grant owns stock possessing more than 10% of the total combined voting power of all classes of the Company's stock shall not be less than 110% of the fair market value of a share of its common stock on the date of grant.

The options that are granted under the 2020 and 2018 Plans are exercisable at various dates as determined upon grant and terminate within 10 years of the date of grant, unless the optionee owns 10% or more of the common shares at which point the expiration period is 5 years, or upon the employee's termination (whereupon the terminated employee has thirty days after termination to exercise vested options from the date of termination). The vesting period generally occurs over two to four years unless there is a specific performance vesting trigger at which time those shares will vest when the performance trigger is probable to occur. RSUs granted under the 2020 Plan vest over four years from the grant date and represent share awards that, upon vesting, will deliver to the holder shares of the Company's common stock.

Stock Options

Stock option activity is as follows for the year ended December 31, 2023:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	9,107,467	$ 10.81	7.8	$ 11,521
Granted	3,284,310	6.26		
Exercised	(438,269)	2.38		
Forfeited	(2,260,992)	9.85		
Outstanding at December 31, 2023	9,692,516	$ 9.87	5.9	$ 272
Exercisable at December 31, 2023	6,424,943	$ 9.82	5.5	$ 272

All exercisable options are vested. Total intrinsic value of options exercised was $0.4 million and $2.8 million for the years ended December 31, 2023 and 2022, respectively.

Restricted Stock Units

Restricted stock unit activity is as follows for the year ended December 31, 2023:

	Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	287,916	$ 14.71	$ 1,756
Granted	243,295	6.07	
Vested	(102,634)	12.07	
Forfeited	(227,677)	8.56	
Outstanding at December 31, 2023	200,900	$ 12.57	$ 476

b) Kinnjiu Equity Incentive Plan

In May 2021, Kinnjiu adopted the 2021 Equity Incentive Plan (2021 Plan) to attract and retain the best available personnel, to provide additional incentive to its employees, directors, and consultants of Kinnjiu and to promote the financial success and progress of Kinnjiu. The 2021 Plan allows for the issuance of ISOs, NSOs, SARs, restricted stock and RSUs with respect to the ordinary shares of Kinnjiu. The 2021 Plan allows Kinnjiu to issue awards with respect to up to a total of 9,000,000 of its ordinary shares. As of December 31, 2023, 6,662,500 shares of Kinnjiu ordinary shares remained available for future grants under the 2021 Plan. In connection with the Kinnjiu Transaction in February 2023, all SARs outstanding under the 2021 Plan were cancelled.

Under the 2021 Plan, the exercise price of each share shall be established at the sole discretion of Kinnjiu's board of directors (or any of the committees of Kinnjiu's board of directors); provided, however, that, for awards to U.S. taxpayers, the exercise price per share shall not be less than the fair market value for shares of Kinnjiu's common stock on the date of grant. During the year ended December 31, 2023, no awards were granted pursuant to the 2021 Plan.

Pursuant to the 2021 Plan, both SARs and NSOs were granted to employees and consultants to Kinnjiu. The NSOs generally vest over 4 years. The vesting provisions for SAR awards, which have been granted to Kinnjiu employees, included both a service-based vesting requirement and liquidity event requirement. The service-based vesting was as follows: (i) 30% of the SAR would vest on the two-year anniversary of the vesting commencement date, (ii) 30% of the SAR would vest on the three-year anniversary of the vesting commencement date, and (iii) 40% of the SAR would vest on the four-year anniversary of the vesting commencement date. The liquidity event requirement would be satisfied upon the earlier of the expiration of a lock-up period following an IPO event or a change in control, subject to the holder of the SAR continuing to be a service provider through the date such earlier event occurs, with the applicable event referred to here as a Vesting Event. The SARs were to be automatically exercised, to the extent vested, upon the occurrence of a Vesting Event. Unless otherwise determined by the administrator of the plan, the portion of the SAR that had not satisfied the service-based vesting requirement as of immediately prior to the liquidity event would terminate on the liquidity event without consideration. As the settlement of the SARs granted to Kinnjiu employees was contingent upon both a service condition and performance condition (liquidity event such as an IPO) that is not deemed probable, compensation cost for such awards were not recognized. In connection with the Kinnjiu Transaction in February 2023, all SARs outstanding under the 2021 Plan were cancelled.

Equity award activity for Kinnjiu is as follows for the year ended December 31, 2023:

Stock Options	**Shares**	**Weighted-Average Exercise Price**
Outstanding at December 31, 2022	2,337,500	$ 0.34
Granted	-	-
Exercised	-	-
Forfeited	-	-
Outstanding at December 31, 2023	2,337,500	$ 0.34
Exercisable at December 31, 2023	1,311,200	$ 0.34

SARs	**Shares**	**Weighted-Average Exercise Price**
Outstanding at December 31, 2022	4,230,000	$ 0.34
Granted	-	-
Exercised	-	-
Forfeited	(4,230,000)	0.34
Outstanding at December 31, 2023	-	$ -
Exercisable at December 31, 2023	-	-

c) Employee Stock Purchase Plan

In December 2020, the Company's board of directors approved and adopted the 2020 Employee Stock Purchase Plan (the ESPP). The ESPP became effective on the business day immediately prior to the effective date of the Company's first registration statement. The ESPP permits eligible employees who elect to participate in an offering under the ESPP to have up to 15% of their eligible earnings withheld, subject to certain limitations, to purchase shares of common stock pursuant to the ESPP. The price of common stock purchased under the ESPP is equal to 85% of the lower of the fair market value of the common stock at the commencement date of each offering period or the relevant date of purchase. Each offering period is six months, with new offering periods commencing every six months on or about the dates of May 15 and November 15 of each year. A total of 435,000 shares of common stock were initially reserved for issuance under the ESPP. In connection with the September 2023 Strategic Plan (see Note 15), the Company's board of directors approved the suspension of the ESPP and all outstanding contributions from ESPP participants were refunded in September 2023.

d) Stock-Based Compensation Expense

The Company measures and recognizes stock-based compensation expense based on the fair value of the award as measured on the grant date. The fair value of RSUs granted is based on the Company's closing stock price on the grant date. The fair value of Company stock options and employee stock purchase plan awards is estimated using the Black-Scholes valuation model. The Company accounts for any forfeitures of share-based awards when they occur. Previously recognized compensation expense for an award is reversed in the period that the award is forfeited. The fair value of Company stock options was estimated using the following assumptions:

	Years Ended December 31,	
	2023	**2022**
Expected term (in years)	5 - 6	5 - 6
Expected volatility	73% - 80%	79% - 86%
Risk-free interest rate	3.50% - 4.29%	1.62% - 4.35%
Expected dividend	0%	0%

The weighted-average grant-date fair value of options granted was $4.43 and $7.13 for the years ended December 31, 2023, and 2022, respectively.

The assumptions used for the years ended December 31, 2023 and 2022 under the ESPP were as follows:

	Years Ended December 31,	
	2023	2022
Expected term (in years)	0.50	0.50
Expected volatility	76% - 86%	50% - 86%
Risk-free interest rate	4.54% - 5.24%	0.07% - 4.54%
Expected dividend	0%	0%

Stock-based compensation expense related to the Company's stock options, RSUs and ESPP totaled the following (in thousands):

	Years Ended December 31,	
	2023	2022
Research and development	$ 8,450	$ 8,604
General and administrative	11,468	10,978
Total stock-based compensation	$ 19,918	$ 19,582

As of December 31, 2023 and 2022, there was $22.5 million and $39.2 million of total unrecognized stock-based compensation expense related to nonvested stock-based compensation arrangements, which is expected to be recognized over a weighted-average period of approximately 2.13 years and 2.33 years, respectively.

As of December 31, 2023 and 2022, there was $2.5 million and $4.4 million of total unrecognized stock-based compensation expense related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 2.74 years and 3.67 years, respectively.

As of December 31, 2023 and 2022, there was none and $0.2 million of total unrecognized stock-based compensation expense related to the ESPP. In connection with the September 2023 Strategic Plan (see Note 15), the Company's board of directors approved the suspension of the ESPP and all outstanding contributions from ESPP participants were refunded in September 2023. As a result of the suspension, unrecognized compensation in the amount of $0.1 million was recognized in the period the ESPP was suspended.

10) Related Party Transactions

Series A Preferred Stock Financing of Kinnjiu

In connection with the Series A preferred stock financing of Kinnjiu, contributions from noncontrolling interest members totaled $35.0 million before issuance costs of $0.2 million. Such noncontrolling interest members are also investors or affiliates of investors in the Company and have representatives that serve on both the Company's board of directors and the board of directors of Kinnjiu. In February 2023, the Company acquired the ownership stake of Kinnjiu previously held by Series A investors (see Note 11).

11) Kinnjiu Transaction

As disclosed above, in May 2021, the Company announced the closing of a Series A preferred stock financing of Kinnjiu to enable the potential development and commercialization of certain targeted oncology product candidates across People's Republic of China, Hong Kong, Taiwan and Macau. Contributions from noncontrolling interest members totaled $35.0 million before issuance costs of $0.2 million. As of December 31, 2022, the Company held an approximately 58% equity interest in Kinnjiu. As the Company determined it was the primary beneficiary of this VIE, the VIE was consolidated in the Company's consolidated financial statements as of December 31, 2022.

The following table summarizes the carrying amount of assets and liabilities of Kinnjiu as of December 31, 2022, excluding intercompany balances (in thousands):

	December 31, 2022
Cash at consolidated joint venture	$ 25,725
Prepaid expenses and other current assets	20
Right-of-use lease assets	223
Other non-current assets	48
Accounts payable and accrued expenses	491
Operating lease liabilities	206

In February 2023, the Company entered in a Stock Purchase Agreement, which was approved by the independent directors of the Company, to acquire the ownership stake of Kinnjiu previously held by Series A investors for total consideration of $24.0 million, consisting of $9.1 million in cash and $14.9 million in Company stock, which resulted in the issuance of 2,200,000 shares of Company stock to the Series A investors. The number of shares issued was determined by dividing the $14.9 million Company stock consideration by the volume-weighted average price for one share of common stock for the three trading days prior to the effective date of the transaction. As the Company had a controlling financial interest in Kinnjiu prior to the Kinnjiu Transaction, the acquisition of the remaining interest in Kinnjiu was accounted for as an equity transaction with no gain or loss recognized in the consolidated statements of operations and comprehensive loss. Accordingly, the difference between the consideration and the carrying value of the redeemable convertible noncontrolling interests has been recorded within equity and is reflected as acquisition of redeemable convertible noncontrolling interests on the consolidated statements of stockholders' equity. The Kinnjiu Transaction gives the Company greater control over its clinical development programs in the People's Republic of China, Hong Kong, Macau and Taiwan. Kinnjiu is a wholly-owned subsidiary of the Company.

12) Income Taxes

Significant components of the Company's provision for income taxes and income taxes computed using the U.S. federal statutory corporate tax rate were as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Income taxes computed at the statutory rate	$ (23,656)	$ (24,417)
State income taxes, net of federal benefit	(19)	(21)
Permanent items	721	1,419
Stock-based compensation	1,809	331
Research credits	(4,002)	(4,233)
Other	558	2,140
Change in valuation allowance	24,589	24,781
Provision for income taxes	$ -	$ -

Significant components of the Company's deferred taxes were as follows (in thousands):

	As of December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforward	$ 40,392	$ 34,119
Research and development credit carryforwards	9,525	5,524
Stock-based compensation	4,509	3,213
Accrued compensation	508	858
Capitalized research and development expenditures	26,590	13,311
Other, net	685	1,151
Gross deferred tax assets:	82,209	58,176
Less valuation allowance	(81,222)	(56,928)
Total deferred tax assets	987	1,248
Deferred tax liabilities:		
Right-of-use lease assets	(523)	(663)
Property and equipment	(464)	(585)
Other	-	-
Total deferred tax liabilities	(987)	(1,248)
Net deferred tax assets	$ -	$ -

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company has established a valuation allowance against net deferred tax assets due to the uncertainty that such assets will be realized. The Company periodically evaluates the recoverability of its deferred tax assets. Due to the Company's history of losses, management cannot conclude that the deferred tax assets will be realized. The change in the valuation allowance for the year ended December 31, 2023 was an increase of $24.3 million.

As of December 31, 2023, the Company has federal and California net operating loss carryforwards of approximately $185.7 million and $25.1 million, respectively.

As a result of the Tax Cuts and Jobs Act of 2017, as amended by the Coronavirus Aid, Relief, and Economic Security Act, for U.S. income tax purposes, net operating losses generated in taxable years beginning after December 31, 2017 can be carried forward indefinitely, but for taxable years beginning after December 31, 2020 the deductibility of such NOLs is limited to 80% of current year taxable income. The California net operating losses will begin to expire in 2038 and the foreign losses carry forward indefinitely.

Pursuant to the Internal Revenue Code, as amended (IRC) Sections 382 and 383, annual use of the Company's NOL and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes have occurred or occur in the future, the amount of remaining tax attribute carryforwards available to offset taxable income and income tax expense in future years may be restricted or eliminated. If eliminated, the related asset would be removed from deferred tax assets with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company's effective tax rate.

As of December 31, 2023, the Company has federal and California research and development tax credit carryforwards of $9.8 million and $3.9 million, respectively. The federal research and development tax credits begin to expire in 2040 unless previously utilized, and the California credit carryforwards are available indefinitely.

Uncertain tax positions are evaluated based upon the facts and circumstances that exist at each reporting period. Subsequent changes in judgment based upon new information may lead to changes in recognition, derecognition, and measurement. Adjustment may result, for example, upon resolution of an issue with the taxing authorities or expiration of a statute of limitations barring an assessment for an issue.

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination by tax authorities. As of December 31, 2023 and 2022, the Company did not have gross unrecognized tax benefits.

The Company is subject to taxation in the United States, certain states, Hong Kong and People's Republic of China. All of the Company's tax years from inception are subject to examination by the tax authorities. The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense. The Company had no accrued interest or penalties related to income tax matters in the Company's balance sheets at December 31, 2023 and 2022 and has not recognized interest or penalties in the Company's statements of operations and comprehensive loss for the years ended December 31, 2023 and 2022. Further, the Company is not currently under examination by any federal, state or local tax authority.

13) Commitments and Contingencies

Litigation

The Company, from time to time, is involved in legal proceedings, regulatory actions, claims and litigation arising in the ordinary course of business. The Company was not a defendant in any lawsuit for the years ending December 31, 2023 and 2022, that, in the opinion of Company's management, is likely to have a material adverse effect on the Company's business.

Operating Leases

In June 2021, the Company entered into an agreement to lease 8,088 rentable square feet of office space located in San Diego, California (SD Lease) for a period of five years and four months expiring on July 31, 2027. Additionally, the Company had an option to extend the SD Lease for an additional five years at the end of the initial term. The SD Lease commenced in March 2022. In January 2024, the Company entered into an agreement to assign the SD Lease (see Note 16).

In connection with the execution of the SD Lease, the Company provided a standby letter of credit for $0.4 million in lieu of a security deposit, which is classified as restricted cash on the consolidated balance sheets. So long as the Company was not in default under the SD Lease, this amount was to decrease after each of years three and four of the SD Lease term to $0.3 million. As part of the SD Lease assignment, the standby letter of credit was terminated and, accordingly, this cash is no longer restricted.

In August 2021, the Company entered into an agreement to lease 5,698 rentable square feet of office space located in San Francisco, California (SF Lease). The SF Lease commenced in January 2022 and would have expired on June 30, 2026. The Company had an option to extend the SF Lease for an additional three years at the end of the initial term. In February 2024, the Company entered into an agreement to assign its SF Lease (see Note 16).

The operating lease right-of-use assets and liabilities on the Company's consolidated balance sheets related to these facility leases. The right-of-use lease assets were $2.5 million and $3.4 million as of December 31, 2023 and 2022, respectively. Operating lease liabilities were $3.2 million and $4.2 million as of December 31, 2023 and 2022, respectively, including $0.9 million and $1.0 million classified as a current liability.

The Company's facility leases required the Company to pay property taxes, insurance and common area maintenance. While these payments are not included as part of its lease liabilities, they are recognized as variable lease cost in the period they are incurred.

Operating lease costs under operating leases for the years ended December 31, 2023 and 2022 were approximately $1.2 million and $1.0 million, respectively. The weighted-average discount rate used was 7.0%. The weighted-average remaining lease term for operating leases was 3.3 years. Cash paid for leases included in operating cash flows for the years ended December 31, 2023 and 2022 was $1.2 million and $0.6 million, respectively.

Prior to the assignments of the SD Lease and SF Lease, future lease payments of operating lease liabilities as of December 31, 2023 were as follows (in thousands):

	Operating Leases
2024	$ 1,080
2025	1,112
2026	927
Thereafter	428
Total minimum lease payments	3,547
Less: imputed interest	(372)
Total operating lease liabilities	3,175
Less: current portion	(892)
Lease liability, net of current portion	$ 2,283

Transaction Bonuses and Severance

The Company has entered into letter agreements with five members of its senior leadership team. In the event of a change in control or other sale of material assets of the Company (as reasonably determined by the Company's board of directors), subject to the terms of these letter agreements, transaction bonuses will be payable in an aggregate amount up to 5% of the deal value. In the event of a stock deal, payment under these agreements may be provided in the form of equity, which may be satisfied by awards of RSUs under the 2020 Plan. In addition, such members of the senior leadership team will receive certain severance and other related benefits in the event of a change in control subject to the terms of change in control and severance agreements. As the events triggering the transaction bonuses and severance and related payments are outside the control of the Company and given the level of uncertainty surrounding such a transaction, the expense related to these payments would not be recognized until the event occurs.

14) Employee Benefit Plan

The Company has a defined-contribution 401(k) plan for employees. Employees are eligible to participate in the plan beginning immediately following date of hire. Under the terms of the plan, employees may make voluntary contributions as a percentage of compensation and the Company may make a discretionary match or another contribution. The Company contributed $0.6 million and $0.5 million to the plan during the years ended December 31, 2023 and 2022, respectively.

15) Restructuring Costs

In September 2023, the Company began implementing its September 2023 Strategic Plan to (i) prioritize its Exarafenib combination with binimetinib, its c-MET inhibitor KIN-8741, and its discovery efforts around its CDK4 selective program; (ii) explore strategic alternatives for its Exarafenib monotherapy and KIN-3248 FGFR inhibitor programs; (iii) pause development of its MEK inhibitor KIN-7136; and (iv) implement a workforce restructuring.

As part of the September 2023 Strategic Plan, the Company reduced its workforce by approximately 70% in September 2023. Employees affected by the September 2023 Strategic Plan obtained involuntary termination benefits that were provided pursuant to a one-time benefit arrangement. All impacted employees were notified of their termination in September 2023 and were not required to provide services beyond a minimum retention period or 60 days to receive benefits. Accordingly, the Company measured and recognized the liability at its fair value at the communication date in the amount of $2.0 million. In December 2023, the Company implemented additional measures as part of the September 2023 Strategic Plan and exploration of strategic alternatives for the Company, whereby certain employees are required to render services beyond a minimum retention period to receive their one-time termination benefits. These termination benefits are recognized ratably over the estimated future service period, which began in December 2023 and is expected to end at the beginning of the second quarter of 2024. The Company incurred costs of $0.2 million during the year ended December 31, 2023 related to these employees with the remaining costs of $0.7 million to be recognized over the estimated remaining service period. All such costs are presented in the restructuring costs line item on the consolidated statements of operations and comprehensive loss.

Restructuring costs are presented under the accrued expenses line item on the consolidated balance sheets. The following shows the liability related to the September 2023 Strategic Plan (in thousands):

	Year Ended December 31, 2023
Accrued restructuring costs beginning balance	$ -
One-time employee termination benefits	2,168
Amounts paid during the period	(1,913)
Accrued restructuring costs as of December 31, 2023	$ 255

The Company's estimates are subject to a number of assumptions, and actual results may materially differ. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the September 2023 Strategic Plan.

16) Subsequent Events

In January 2024, the Company reduced its workforce by approximately 56% to a total of 12 full-time employees as part of the January 2024 Strategic Plan. The Company incurred one-time costs of approximately $1.1 million in the first quarter of 2024 in connection with this RIF, relating to severance and related benefits. Cash payments related to these expenses were paid during the first quarter of 2024.

In January and February 2024, the Company entered into lease assignment agreements for its SD Lease and SF Lease (the Lease Assignment Transactions). In accordance with the Lease Assignment Transactions, the Company sold corresponding furniture and fixtures and leasehold improvements within the San Diego and San Francisco offices.

On February 16, 2024, the Company entered into a Merger Agreement with XOMA and Merger Sub, which provides for, among other things: (i) the acquisition of all of outstanding shares of common stock through a through a cash tender offer by Merger Sub, for a price per share of the Common Stock of (A) $2.3352, plus (B) an additional amount of cash between $0.00 and $0.2527 per share of Common Stock (such amount as finally determined in accordance with the Merger Agreement, plus (C) one CVR; and (ii) after the completion of the Offer, the satisfaction or waiver of certain conditions set forth in the Merger Agreement and in accordance with the DGCL, the merger of Merger Sub with and into the Company, with the Company surviving the Merger as a wholly owned subsidiary of XOMA, without a meeting or vote of our stockholders. Closing of the Merger is subject to certain conditions, including the tender of the Company's common stock representing one share more than 50% of the number of outstanding shares, the availability of at least $120 million of cash (net of transaction costs, wind-down costs and other liabilities) at closing, and other customary closing conditions. The Merger is expected to close in the first half of 2024. On February 27, 2024, the Company entered into the Purchase Agreement by and among the Company and Pierre Fabre, pursuant to which it sold the global rights to its investigational pan-RAF inhibitor, Exarafenib, and other pan-RAF program assets to Pierre Fabre, subject to the terms and conditions of the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, Pierre Fabre purchased Exarafenib and other pan-RAF assets and will assume 100% of the ongoing program and costs associated with these assets. The Company will receive a total consideration of up to $31.0 million, consisting of $500,000 at closing, and an additional $30.5 million contingent upon the earlier of (i) the dosing of the first patient in the first pivotal trial for Exarafenib or any other acquired asset, (ii) the application for accelerated approval pursuant to the U.S. Food and Drug Administration's Accelerated Approval Program for Exarafenib or any other acquired asset or (iii) the submission of a marketing application for regulatory approval for Exarafenib or any other acquired asset. In addition, Pierre Fabre will assume up to $5.0 million of trade payables for the transferred assets. The transaction is not subject to closing conditions and closed upon signing.

In connection with the Company's transaction with XOMA, the Company's stockholders are expected to receive 100% of the Net Proceeds payable from the $30.5 million contingent payment, assuming the closing of the proposed transaction with XOMA occurs and such proceeds are received prior to the Expiration Date.

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 maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time period specified in the SEC's rules and forms, and that such information is accumulated and communicated to management including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. As of December 31, 2023, we carried out an evaluation under the supervision and with the participation of our 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 defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2023, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level and we believe the consolidated financial statements included in this Annual Report on Form 10-K fairly represent in all material respects our financial condition, results of operations and cash flows at and for the periods presented in accordance with U.S. GAAP.

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) under the Exchange Act). Under the supervision of and with the participation of our principal executive officer and principal financial officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in "Internal Control—Integrated Framework" (2013). Based on this assessment, management 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 independent registered public accounting firm on our internal control over financial reporting due to the exemptions established by the JOBS Act for "emerging growth companies" and in Section 404(c) of SOX for non-accelerated filers.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and Rule 15d-15(d) of the Securities Exchange Act of 1934 that occurred during the quarter ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

A control system, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information.

During our last fiscal quarter, no director or officer, as defined in Rule 16a-1(f), adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," each as defined in Regulation S-K Item 408.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Identification of Directors

Our business affairs are managed under the direction of our board of directors, which currently consists of ten (10) members. Our board of directors has affirmatively determined that nine (9) of our ten (10) directors qualify as "independent" within the meaning of the listing standards of the Nasdaq Stock Market LLC (Nasdaq). Our board of directors is divided into three classes with staggered three-year terms. At each annual meeting of stockholders, a class of directors will be elected for a three-year term to succeed the same class whose term is then expiring.

The following table sets for the names, ages, and certain other information for each of our directors as of March 1, 2024:

Name	Class	Age	Position	Director Since	Current Term Expires
Carl L. Gordon, Ph.D., CFA(1)	I	59	Director	2019	2024
Helen Sabzevari, Ph.D.	I	62	Director	2021	2024
Jim Tananbaum, M.D.(1)	I	60	Director	2018(4)	2024
Jill DeSimone(1)(2)	II	68	Director	2023	2025
Melissa Epperly(2)	II	46	Director	2020	2025
Michael Rome, Ph.D.(3)	II	39	Director	2019	2025
Laurie Smaldone Alsup, M.D.(3)	II	70	Director	2020	2025
Nima Farzan	III	48	President, Chief Executive Officer and Director	2020	2026
Keith Flaherty, M.D.(3)	III	53	Director	2019	2026
Dean Mitchell (1)(2)(3)	III	68	Chair and Director	2020	2026

(1) Member of our compensation committee
(2) Member of our audit committee
(3) Member of our nominating and corporate governance committee
(4) Dr. Tananbaum served on our board of directors from March 2018 to December 2019 and rejoined our board of directors in June 2020

Carl L. Gordon, Ph.D., CFA has served on our board of directors since December 2019. Dr. Gordon is a founding member, Managing Partner, and Co-Head of Global Private Equity at OrbiMed Advisors LLC, an investment firm. Dr. Gordon currently serves on the boards of directors of Adicet Bio, Inc. (Nasdaq: ACET), ArriVent Biopharma, Inc. (Nasdaq: AVBP), Compass Therapeutics Inc. (Nasdaq: CMPX), Keros Therapeutics, Inc. (Nasdaq: KROS), and Terns Pharmaceuticals, Inc. (Nasdaq: TERNS), as well as several private companies. Dr. Gordon previously served on the boards of directors of several companies, including Alector Inc. (Nasdaq: ALEC), Arsanis, Inc. (which merged with X4 Pharmaceuticals, Inc.), Gemini Therapeutics Inc. (Nasdaq: GMTX), ORIC Pharmaceuticals, Inc. (Nasdaq: ORIC), Passage Bio Inc. (Nasdaq: PASG), Prevail Therapeutics, Inc. (Nasdaq: PRVL), SpringWorks Therapeutics, Inc. (Nasdaq: SWTX), Theseus Pharmaceuticals, Inc. (Nasdaq: THRX), and Turning Point Therapeutics, Inc. (Nasdaq: TPTX). Dr. Gordon holds a B.A. in Chemistry from Harvard College, a Ph.D. in Molecular Biology from the Massachusetts Institute of Technology and was a Fellow at The Rockefeller University.

We believe Dr. Gordon is qualified to serve on our board of directors due to his scientific expertise, extensive business experience, and experience in venture capital and the life science industry.

Helen Sabzevari, Ph.D. has served as a member of our board of directors since June 2021. Dr. Sabzevari currently serves as President, Chief Executive Officer, and a member of the board of directors of Precigen, Inc. (Nasdaq: PGEN), a dedicated discovery and clinical stage biopharmaceutical company, and since July 2017 has served in various other senior executive positions at Precigen and its wholly owned subsidiary, PGEN Therapeutics, Inc. Prior to Precigen, Dr. Sabzevari was co-founder and Chief Scientific Officer of Compass Therapeutics, a fully integrated drug discovery and development company focused on manipulating the immune system to treat human disease, from 2015 to 2017. Prior to Compass Therapeutics, Dr. Sabzevari was Senior Vice President of Immuno-Oncology as well as Global Head of Immunotherapy, Oncology, Global Research and Early Development at EMD Serono (a subsidiary of Merck KGaA, Darmstadt, Germany) from 2008 to 2014. Dr. Sabzevari received her Ph.D. in cell and molecular immunology and completed her postdoctoral work at the department of immunology at the Scripps Research Institute working on various immunotherapeutic modalities in the treatment of cancer and autoimmune diseases.

We believe Dr. Sabzevari is qualified to serve on our board of directors because of her expertise in the research and development of immunotherapy-based therapeutics and her leadership experience in and knowledge of the biotherapeutics industry.

Jim Tananbaum, M.D. is a founding board member of Kinnate, first appointed to our board of directors in March 2018, and has served on our board of directors from March 2018 to December 2019 and since June 2020. He has also served as Founder and Chief Executive Officer of Foresite Capital Management, an investment firm, since 2010. Prior to that, he co-founded, and served as Managing Director of, Prospect Venture Partners, an investment firm. Dr. Tananbaum also co-founded Theravance, Inc., now Innoviva, Inc., in 1997. Dr. Tananbaum formerly served on the board of directors of Pardes Biosciences Inc. (Nasdaq: PRDS) and Quantum-SI Inc. (Nasdaq: QSI). Dr. Tananbaum also served on the boards of directors of FS Development Corp. (Nasdaq: FSDC) from July 2020 to February 2021 and FS Development Corp. II (Nasdaq: FSII) from August 2020 to December 2021. He holds a B.S. and BSEE in Applied Math, Electrical Engineering/Computer Science from Yale University, an M.D. from Harvard Medical School, an M.B.A. from Harvard Business School and an M.S. from the Harvard-MIT Health Sciences and Technology Program.

We believe Dr. Tananbaum is qualified to serve on our board of directors because of his educational background and extensive experience in investing in biotechnology companies.

Jill DeSimone has served on our board of directors since March 2023. Ms. DeSimone served as President of U.S. Oncology at multinational pharmaceutical company Merck & Co., Inc. from 2014 to 2022. Prior to that, Ms. DeSimone served as Senior Vice President of Women's Global Health at multinational pharmaceutical company Teva Pharmaceuticals Industries Ltd. from 2012 to 2014. From 1980 to 2012, Ms. DeSimone served in various commercial leadership roles, including Senior Vice President of U.S. Oncology, at multinational pharmaceutical company Bristol-Myers Squibb Company. Ms. DeSimone serves on the boards of directors of Praxis Precision Medicines, Inc. (Nasdaq: PRAX) and Oncternal Therapeutics, Inc. (Nasdaq: ONCT). Ms. DeSimone holds a B.S. in Pharmacy from Northeastern University and completed a fellowship with the Wharton School of the University of Pennsylvania.

We believe Ms. DeSimone is qualified to serve on our board of directors because of her extensive experience as an executive in the pharmaceutical and biotechnology industry.

Melissa Epperly has served on our board of directors since October 2020. Ms. Epperly has served as Chief Financial Officer at Zentalis Pharmaceuticals, Inc. (Nasdaq: ZNTL), a clinical-stage biopharmaceutical company, since September 2019. Prior to her current position, she served as Chief Financial Officer of PsiOxus Therapeutics Ltd., a clinical-stage gene therapy cancer company, from June 2018 to August 2019. Prior to that, Ms. Epperly also served as Chief Financial Officer and Head of Business Development at R-Pharm US, a commercial-stage oncology company, from October 2015 to June 2018. Ms. Epperly also served as a Director at Anchorage Capital Group, a credit-focused hedge fund from August 2012 to September 2015. Ms. Epperly serves on the boards of directors of Nautilus Biotechnology (Nasdaq: NAUT) and Roivant Sciences (Nasdaq: ROIV). Ms. Epperly holds a B.A. in Biochemistry and Economics from the University of Virginia and an M.B.A. from Harvard Business School.

We believe Ms. Epperly is qualified to serve on our board of directors because she brings extensive experience as a senior financial executive in the life sciences industry.

Michael Rome, Ph.D. has served on our board of directors since December 2019. He has served in various roles with Foresite Capital Management, an investment firm, since August 2016, including serving as Managing Director since May 2020. Prior to that, he served as an Analyst at DAFNA Capital Management LLC, a healthcare hedge fund, from September 2015 to July 2016. Dr. Rome also worked in early-stage drug development as a Senior Scientist for Vault Pharma, an academic start-up out of the California NanoSystems Institute at UCLA, from April 2014 to September 2015. Dr. Rome served on the boards of directors of FS Development Corp. (Nasdaq: FSDC) from July 2020 to February 2021 and FS Development Corp. II (Nasdaq: FSII) from August 2020 to December 2021. Dr. Rome holds a B.S. in Molecular, Cellular and Developmental Biology from University of California, Los Angeles and a Ph.D. in Biochemistry, Biophysics and Molecular Biology from California Institute of Technology.

We believe Dr. Rome is qualified to serve on our board of directors because of his extensive experience in investing in diverse biotechnology companies and his depth of knowledge and substantial experience as a research scientist.

Laurie Smaldone Alsup, M.D. has served on our board of directors since August 2020. Since August 2023, Dr. Smaldone Alsup has served as the Senior Vice President of Regulatory Science at SSI Strategy. From March 2016 to August 2023, Dr. Smaldone Alsup served as the Chief Scientific Officer and Chief Medical Officer of NDA Group AB, a drug regulatory and drug consulting company. Prior to her current position, she served as the President and Chief Scientific Officer of PharmApprove LLC, a drug development consulting company, from August 2011 until its acquisition by NDA Group AB in March 2016. Prior to that, from 2008 to 2011, Dr. Smaldone Alsup served as the President and Chief Executive Officer of Phytomedics, Inc., a biopharmaceutical company, and from 1998 to 2007 in senior positions at Bristol-Myers Squibb Company, a pharmaceutical company, including as Vice President, Corporate Strategy and Business Risk Management and as Senior Vice President, Global Regulatory Science. Dr. Smaldone Alsup serves on the boards of directors of Blackberry, Ltd. (NYSE: BB), Arvinas, Inc. (Nasdaq: ARVN), and Theravance Biopharma, Inc. (Nasdaq: TBPH). Dr. Smaldone Alsup previously served on the board of directors of Pardes Biosciences Inc. (Nasdaq: PRDS) from September 2022 to August 2023. Dr. Smaldone Alsup holds a B.A. in Biology and Philosophy from Fordham College and a M.D. from Yale School of Medicine.

We believe Dr. Smaldone Alsup is qualified to serve on our board of directors due to her medical expertise, her expertise as an executive in the biotechnology industry and her experience as a public company board member, including within the biotechnology industry.

Nima Farzan has served as our President and Chief Executive Officer and as a member of our board of directors since March 2020. Mr. Farzan has also served as an Executive in Residence at Foresite Capital, a venture capital fund, from February 2020 to March 2020. From October 2018 to March 2020, Mr. Farzan worked as an advisor to various life sciences companies, including Emergent BioSolutions Inc. and MODA Pharmaceuticals. Prior to joining us, Mr. Farzan was with PaxVax, Inc., a biopharmaceutical company (acquired by Emergent BioSolutions Inc. in 2018), where he served initially as Chief Operating Officer and then Chief Executive Officer and President from September 2011 to October 2018. From August 2004 to September 2011, he served in a number of roles at Novartis AG, a pharmaceutical company, including VP, Global Program Head for Metabolic Disease and VP, US Marketing at Novartis Vaccines and Diagnostics, a division of Novartis. Mr. Farzan currently serves on the board of directors of Keros Therapeutics, Inc. (Nasdaq: KROS). Mr. Farzan holds a B.A. in Human Biology from Stanford University and an M.B.A. from Harvard Business School.

We believe Mr. Farzan is qualified to serve on our board of directors because of the perspective and experience he brings as our Chief Executive Officer, his experience in leadership positions in the biotechnology industry, his educational background and his strong scientific knowledge.

Keith Flaherty, M.D. has served as a member of our board of directors since December 2019. Dr. Flaherty is the Director of Clinical Research at Massachusetts General Hospital Cancer Center, where he has worked since July 2009. From July 2009 to October 2015, Dr. Flaherty served as an Associate Professor of Medicine at Harvard Medical School and since October 2015 as Professor of Medicine. He has also served as the Chair of the Developmental Therapeutics Committee at the Eastern Cooperative Oncology Group and American College of Radiology Imaging Network (ECOG-ACRIN) Cancer Research Group, and in April 2013 he was appointed as the ECOG Deputy Chair for Biomarker Science. In September 2018, Dr. Flaherty joined the National Cancer Institute (NCI) Board of Scientific Advisors. Dr. Flaherty trained in internal medicine at Brigham and Women's Hospital, and in medical oncology at the University of Pennsylvania, earning board certifications in these specialties. Dr. Flaherty formerly served on the boards of directors of Clovis Oncology (Nasdaq: CLVS), Checkmate Pharmaceuticals, Inc. (Nasdaq: CMPI) and Loxo Oncology, Inc. (Nasdaq: LOXO) (acquired by Eli Lilly and Company). Dr. Flaherty holds an M.D. from The Johns Hopkins School of Medicine and a B.S. in Neurobiology from Yale University.

We believe Dr. Flaherty is qualified to serve on our board of directors because of his scientific and educational background and his extensive expertise in the oncology field.

Dean Mitchell has served as a member of our board of directors since August 2020 and has served as the Chair of our board of directors since August 2020. Mr. Mitchell also served as Executive Chair of the board of directors of Covis Pharma Holdings, a specialty pharmaceutical company, from July 2013 until its sale in March 2020. He previously served as Chair of PaxVax, a biopharmaceutical company, from October 2016 to October 2018. Prior to that, he served as President and Chief Executive Officer of Lux Biosciences, Inc., a biotechnology company focusing on the treatment of ophthalmic diseases, from July 2010 to July 2013. Prior to Lux Biosciences, he served as President and Chief Executive Officer of both Alpharma, Inc., a publicly traded specialty pharmaceutical company, from 2006 until its acquisition by King Pharmaceuticals, Inc. in 2008, and Guilford Pharmaceuticals, Inc., a publicly traded pharmaceutical company focused in oncology and acute care, from 2004 until its acquisition by MGI Pharma Inc. in 2005. From 2001 to 2004, he served in various senior executive capacities in the worldwide medicines group of Bristol-Myers Squibb Company, a pharmaceutical company. Prior to the Bristol-Myers Squibb Company, he spent 14 years at GlaxoSmithKline plc, in assignments of increasing responsibility spanning sales, marketing, general management, commercial strategy and clinical development and product strategy. Mr. Mitchell also serves on the boards of directors of Precigen, Inc. (Nasdaq: PGEN), Theravance BioPharma, Inc. (Nasdaq: TBPH), and Praxis Precision Medicines, Inc. (Nasdaq: PRAX). Additionally, Mr. Mitchell served on the board of directors of ImmunoGen, Inc. from 2012 until its acquisition by Abbvie Inc. in February 2024. Mr. Mitchell holds a B.S. in Applied Biology from Coventry University and an M.B.A. from Cass Business School, London.

We believe Mr. Mitchell's qualifications to serve on our board of directors include his management experience in the pharmaceutical and biotherapeutics industries and his experience as an executive officer and board member of several biotechnology companies.

Identification of Executive Officers

The following table sets forth the names, ages, and certain other information about our executive officers as of March 1, 2024. Officers are elected by our board of directors to hold office until their successors are elected and qualified.

Name	Age	Position
Nima Farzan	48	President, Chief Executive Officer and Director
Neha Krishnamohan	37	Chief Financial Officer and Executive Vice President, Corporate Development
Mark Meltz	50	Chief Operating Officer, General Counsel and Corporate Secretary
Richard Williams, MBBS, Ph.D.	55	Chief Medical Officer*

*Dr. Williams' employment as our Chief Medical Officer was terminated effective March 15, 2024.

For the biography of Mr. Farzan, please see "Identification of Directors."

Neha Krishnamohan has served as our Chief Financial Officer and Executive Vice President, Corporate Development since June 2021. Prior to joining us, she was with Goldman Sachs from July 2008 to May 2021, where she served most recently as Vice President, Healthcare Investment Banking from January 2015 to May 2021 and was an Associate in the Healthcare Investment Banking Group from August 2011 to December 2014. Ms. Krishnamohan serves on the board of directors of Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT). Ms. Krishnamohan holds a B.S.E. with a double major in Biomedical Engineering and Economics from Duke University.

Mark Meltz has served as our Chief Operating Officer and General Counsel since April 2020 and our Corporate Secretary since May 2020. Prior to joining us, from March 2019 to February 2020 he served as Senior Vice President and General Counsel at Audentes Therapeutics, Inc. (now part of Astellas Gene Therapies), a biotechnology company. From June 2014 to March 2019, Mr. Meltz served as Executive Vice President and Chief Business Development and Legal Officer at PaxVax, Inc., a biotechnology company (acquired by Emergent BioSolutions in 2018). He holds a B.A. in Psychology from Yale University and a J.D. from Boston College Law School.

Richard Williams, MBBS, Ph.D. served as our Chief Medical Officer from June 2020 to March 2024. Prior to joining us, he was with WuXi NextCODE Genomics USA, Inc. (now known as Genuity Science, Inc.) from March 2018 to June 2020, where he served most recently as Chief Medical Officer from June 2019 to June 2020. From January 2017 to February 2018, Dr. Williams served as the Medical Director and Group Medical Director at GRAIL, Inc. a biotechnology company. From September 2015 to January 2017, Dr. Williams was with Amgen, where he most recently served as Head, Early Development Oncology Group from June 2016 to January 2017. From November 2012 to September 2015, Dr. Williams was with Puma Biotechnology, Inc. where he most recently served as the Senior Medical Director, Clinical Research & Development from November 2013 to September 2015. From September 2010 to November 2012, Dr. Williams was with Amgen as Clinical Research Medical Director in its Global Development (late phase) group. Dr. Williams holds an MBBS in Medicine and Surgery and a Ph.D. in Cancer Biology from the University of Queensland.

Legal Proceedings

There are no material legal proceedings to which any of our directors is a party adverse to us or in which any such person has a material interest adverse to us.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires that our executive officers and directors, and persons who own more than 10% of our common stock, file reports of ownership and changes of ownership with the SEC. Such directors, executive officers and 10% stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

SEC regulations require us to identify in this Annual Report on Form 10-K anyone who filed a required report late during the most recent fiscal year. Based solely on our review of forms we received, or written representations from reporting persons stating that they were not required to file these forms, we believe that during our fiscal year ended December 31, 2023, all executive officers, directors and greater than 10% stockholders complied with all applicable SEC filing requirements, except that during our fiscal year ended December 31, 2023, entities affiliated with OrbiMed filed one late Form 4 with respect to two transactions.

Corporate Governance Guidelines and Code of Business Conduct and Ethics

Our board of directors has adopted Corporate Governance Guidelines that address items such as the qualifications and responsibilities of our directors and director candidates and corporate governance policies and standards applicable to us in general. In addition, our board of directors has adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer and other executive officers and senior financial officers. The full text of our Corporate Governance Guidelines and our Code of Business Conduct and Ethics is posted on our investor relations website at investors.kinnate.com. We will post any amendments to our Code of Business Conduct and Ethics and any waivers of our Code of Business Conduct and Ethics for directors and executive officers on the same website or in filings under the Exchange Act.

Audit Committee

Our audit committee consists of Ms. DeSimone, Ms. Epperly, and Mr. Mitchell, with Ms. Epperly serving as chair. Our board of directors has determined that Ms. Epperly is an audit committee financial expert, as that term is defined under the SEC rules implementing Section 407 of the Sarbanes-Oxley Act of 2002, and possesses financial sophistication and is independent, as each of those terms are defined under the rules of Nasdaq. Our audit committee oversees our corporate accounting and financial reporting process and assists our board of directors in monitoring our financial systems. Our audit committee is responsible for, among other things:

- selecting and hiring the independent registered public accounting firm to audit our financial statements;
- helping to ensure the independence and performance of the independent registered public accounting firm;
- approving audit and non-audit service and fees;
- reviewing financial statements and discussing with management and the independent registered public accounting firm our annual audited and quarterly financial statements, the results of the independent audit and the quarterly reviews and the reports and certifications regarding internal controls over financial reporting and disclosure controls;
- preparing the audit committee report that the SEC requires to be included in our annual proxy statement;
- reviewing reports and communications from the independent registered public accounting firm;
- reviewing the adequacy and effectiveness of our internal controls and disclosure controls and procedure;
- reviewing our policies on risk assessment and risk management;
- reviewing related party transactions; and
- establishing and overseeing procedures for the receipt, retention and treatment of accounting related complaints and the confidential submission by our employees of concerns regarding questionable accounting or auditing matters.

Our audit committee operates under a written charter that satisfies the applicable rules and regulations of the SEC and the listing standards of Nasdaq. A copy of the charter for our audit committee is available on our investor relations website at investors.kinnate.com. During 2023, our audit committee held five meetings.

Employee, Officer and Director Hedging and Pledging Policy

Under our Insider Trading Policy, our directors, officers, employees, consultants, contractors and advisors (Covered Persons) may not, directly or indirectly, (a) trade in publicly-traded options, such as puts and calls, and other derivative securities with respect to our securities (other than stock options, restricted stock units and other compensatory awards issued to them by us) or (b) purchase financial instruments (including prepaid variable forward contracts, equity swaps, collars and exchange funds), or otherwise engage in transactions, that hedge or offset, or are designed to hedge or offset, any decrease in the market value our equity securities either (i) granted to them by us as part of their compensation or (ii) held, directly or indirectly, by them. Also, Covered Persons may not pledge our securities as collateral for any loan or as part of any other pledging transaction.

Item 11. Executive Compensation.

Processes and Procedures for Compensation Decisions

Our compensation committee is responsible for evaluating the executive compensation programs for our executive officers and reports to our board of directors on its discussions, and makes recommendations to our board of directors for decisions and other actions with respect to this program. Typically, our Chief Executive Officer makes recommendations to our compensation committee, often attends committee meetings and is involved in the determination of compensation for the respective executive officers who report to him, except that the Chief Executive Officer does not make recommendations as to his own compensation. Our Chief Executive Officer makes recommendations to our compensation committee regarding short- and long-term compensation for all executive officers (other than himself) based on our results, an individual executive officer's contribution toward these results and performance toward individual goal achievement. Our compensation committee then reviews the recommendations and other data. Our compensation committee makes recommendations to our board of directors as to total compensation for each executive officer.

Our compensation committee is authorized to retain the services of one or more executive compensation advisors, as it sees fit, in connection with the establishment of our compensation programs and related policies. In 2023, our compensation committee retained Aon/Radford, a national compensation consultant, to provide it with information, recommendations and other advice relating to executive compensation on an ongoing basis. Radford serves at the discretion of our compensation committee. As part of its engagement, Aon/Radford assists our compensation committee in developing an appropriate group of peer companies to help us determine the appropriate level of overall compensation for our executive officers and to assess each separate element of compensation, with a goal of ensuring that the compensation we offer to our executive officers is competitive and fair.

Our compensation committee periodically considers and assesses Aon/Radford's independence, including whether Aon/Radford has any potential conflicts of interest with the Company or members of our compensation committee. In connection with Aon/Radford's engagement, our compensation committee conducted such a review and concluded that it was not aware of any conflict of interest that had been raised by work performed by Aon/Radford or the individual consultants employed by Radford that perform services for our compensation committee.

Our named executive officers for the fiscal year ended December 31, 2023, which consist of our principal executive officer and the next two most highly compensated executive officers who were serving as executive officers as of December 31, 2023, are:

- Nima Farzan, our President, Chief Executive Officer and Director;
- Mark Meltz, our Chief Operating Officer, General Counsel and Corporate Secretary; and
- Richard Williams, MBBS, Ph.D., our Chief Medical Officer.

Dr. Williams' employment as our Chief Medical Officer was terminated effective March 15, 2024.

Summary Compensation Table

The following table provides information regarding the compensation of our named executive officers during the years ended December 31, 2022 and 2023.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Nima Farzan *President, Chief Executive Officer and Director*	2023 2022	607,703 583,206	320,763 307,038	— —	3,609,600 2,886,280	— —	1,710 1,710	4,539,776 3,778,234
Mark Meltz *Chief Operating Officer, General Counsel and Corporate Secretary*	2023 2022	480,725 461,354	184,542 206,045	— 367,750	1,034,752 974,120	— —	2,622 4,465	1,702,641 2,013,734
Richard Williams, MBBS, Ph.D.(2) *Chief Medical Officer*	2023	503,437	192,358	—	1,034,752	—	4,902	1,735,449

(1) This column reflects the aggregate grant date fair value of stock and option awards granted to the officer in the applicable fiscal year, computed in accordance with FASB ASC Topic 718. See Note 2(m) to our financial statements for the year ended December 31, 2023 included in this Annual Report on Form 10-K for a discussion of the assumptions made by us in determining the grant date fair value of our equity awards. For option awards, our named executive officers will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such option awards.

(2) Dr. Williams was not a named executive officer in our 2023 proxy statement. Therefore, this table does not provide 2022 data for him.

Employment Arrangements with Our Named Executive Officers

Each of our current named executive officers has executed our standard form of confidential information, invention assignment and arbitration agreement.

Nima Farzan
In November 2020, we entered into a confirmatory employment letter with Mr. Farzan, our President and Chief Executive Officer. The confirmatory employment letter has no specific term and provides that Mr. Farzan is an at-will employee and supersedes all prior employment agreements between Mr. Farzan and us. Mr. Farzan's current annual base salary is $612,612 and he is eligible for an annual target cash incentive payment equal to 55% of his annual base salary. Mr. Farzan is eligible for severance and change in control benefits, as more fully described in "-Potential Payments upon Termination or Change in Control." In November 2023, we entered into a transaction bonus agreement with Mr. Farzan, as more fully described in Note 13 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Mark Meltz
In November 2020, we entered into a confirmatory employment letter with Mr. Meltz, our Chief Operating Officer and General Counsel. The confirmatory employment letter has no specific term and provides that Mr. Meltz is an at-will employee and supersedes all prior employment agreements between Mr. Meltz and us. Mr. Meltz's current annual base salary is $484,600 and he is eligible for an annual target cash incentive payment equal to 40% of his annual base salary. Mr. Meltz is eligible for severance and change in control benefits, as more fully described in "-Potential Payments upon Termination or Change in Control." In November 2023, we entered into a transaction bonus agreement with Mr. Meltz, as more fully described in Note 13 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Richard Williams, MBBS, Ph.D.
In November 2020, we entered into a confirmatory employment letter with Dr. Williams, our former Chief Medical Officer. The confirmatory employment letter has no specific term and provides that Dr. Williams is an at-will employee and supersedes all prior employment agreements between Dr. Williams and us. Dr. Williams' current annual base salary is $507,500 and he is eligible for an annual target cash incentive payment equal to 40% of his annual base salary. Dr. Williams is eligible for severance and change in control benefits, as more fully described in "-Potential payments upon termination or change in control." In November 2023, we entered into a transaction bonus agreement with Dr. Williams, as more fully described in Note 13 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Potential Payments upon Termination or Change in Control

In November 2020, we entered into change in control and severance agreements (amended in part by the November 2023 transaction bonus agreements) with each of Mr. Farzan, Mr. Meltz and Dr. Williams. Each agreement provides for certain severance and change in control benefits as described below.

If the employment of an executive officer with whom we have entered into a change in control and severance agreement is terminated outside the period beginning six months prior to the date of a change in control and ending 12 months following that change in control (the Change in Control Period) either (1) by the company without "cause" (excluding by reason of death or disability) or (2) by the executive officer for "good reason" (as such terms are defined in the executive officer's change in control and severance agreement), the executive officer will receive the following benefits if he or she timely signs and does not revoke a release of claims in our favor:

- a lump-sum payment equal to 9 months (or 12 months in the case of Mr. Farzan) of the executive officer's annual base salary as in effect immediately prior to such termination (or if such termination is due to a resignation for good reason based on a material reduction in base salary, then as in effect immediately prior to the reduction);
- payment of premiums for coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (COBRA), for the executive officer and their eligible dependents, if any, for up to 9 months (or 12 months in the case of Mr. Farzan); and
- vesting acceleration of any outstanding equity award that would have otherwise vested had the executive officer remained employed for another 12 months (in the case of Mr. Farzan) or 9 months (in the case of Mr. Meltz and, previously, Dr. Williams).

If, during the Change in Control Period, the employment of an executive officer with whom we have entered into a change in control and severance agreement is terminated either (1) by the company without cause (excluding by reason of death or disability) or (2) by the executive officer for good reason, the executive officer will receive the following benefits if the executive officer timely signs and does not revoke a separation agreement and release of claims in our favor:

- a lump-sum payment equal to 12 months (or 18 months in the case of Mr. Farzan) of the executive officer's annual base salary as in effect immediately prior to such termination (or if such termination is due to a resignation for good reason based on a material reduction in base salary, then as in effect immediately prior to the reduction) or if greater, at the level in effect immediately prior to the change in control, based on the number of days in such year for which the executive officer is employed by, or provided service to, us;
- a lump-sum payment equal to the sum of (x) 100% (or 150% in the case of Mr. Farzan) of the executive officer's target annual bonus as in effect for the fiscal year in which such termination occurs or if greater, at the level in effect, immediately prior to the change in control, plus (y) a pro-rated portion of the executive officer's target bonus for the year in which the change of control occurs;
- payment of premiums for coverage under COBRA for the executive officer and the executive officer's eligible dependents, if any, for up to 12 months (or 24 months in the case of Mr. Farzan); and
- 100% accelerated vesting and exercisability of all company equity awards with service-based vesting (but that are not subject to performance-based vesting) that are outstanding and unvested as of the date of the qualifying termination.

If any of the amounts provided for under these change in control and severance agreements or otherwise payable to the named executive officer would constitute "parachute payments" within the meaning of Section 280G of the Internal Revenue Code (the Code) and could be subject to the related excise tax, the executive officer would be entitled to receive either full payment of benefits or such lesser amount which would result in no portion of the benefits being subject to the excise tax, whichever results in the greater amount of after-tax benefits to the executive officer. The change in control and severance agreements do not require us to provide any tax gross-up payments.

Under the change in control and severance agreement, "cause" generally means the executive officer's (i) conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony, (ii) engagement in material dishonesty, willful misconduct or gross negligence in each case in connection with the executive officer's position at the company, (iii) material breach of any confidentiality, invention assignment, non-disclosure, or non-solicitation agreement entered into between us and the executive officer, (iv) material violation of a written company policy or procedure that has been provided to the executive officer causing substantial injury to us, and/or (v) gross negligence or willful misconduct by the executive officer with respect to his performance of his assigned duties for us, following written notice of such refusal by us and a period of fifteen (15) days to cure the same and the executive officer's failure to cure during such time period.

Under the change in control and severance agreement, "good reason" generally means that the executive officer resigns from the company within 30 days following the end of our cure period (discussed below) as a result of any (i) a material diminution in executive officer's base salary, (ii) the assignment to executive officer of duties that are materially inconsistent with the executive officer's duties that results in a material diminution of the executive officer's duties, (iii) a material diminution in the executive officer's authority, duties, or responsibilities; (iv) a material change in the location of the executive officer's primary place of work to a location more than thirty (30) miles from his primary place of work immediately prior to such change and further from his residence, or (v) following a change in control, if the executive officer served as a Section 16 officer prior to the change in control, the executive officer is not a Section 16 officer of the company or its ultimate parent, or if the ultimate parent is not a public company with the executive officer not reporting to the chief executive officer of the ultimate parent company. For a resignation to qualify as "good reason," the executive officer also must provide written notice within 90 days following the initial existence of the good reason condition, and we must have failed to materially remedy such event within 30 days after receipt of such notice.

Executive Incentive Compensation Plan

In November 2020, our board of directors adopted an Executive Incentive Compensation Plan (the Incentive Compensation Plan). The Incentive Compensation Plan became effective in connection with our initial public offering. The Incentive Compensation Plan allows our compensation committee to grant incentive awards, generally payable in cash, to employees selected by our compensation committee, including our executive officers, based upon performance goals established by our compensation committee.

Under the Incentive Compensation Plan, our compensation committee determines the performance goals applicable to any award, which goals may include, without limitation, goals related to research and development, regulatory milestones or regulatory-related goals, gross margin, financial milestones, new product or business development, operating margin, product release timelines or other product release milestones, publications, cash flow, procurement, savings, internal structure, leadership development, project, function or portfolio-specific milestones, license or research collaboration agreements, capital raising, initial public offering preparations, patentability and individual objectives such as peer reviews or other subjective or objective criteria. The performance goals may differ from participant to participant and from award to award.

The compensation committee administers the Incentive Compensation Plan and may, in its sole discretion and at any time, increase, reduce or eliminate a participant's actual award, and/or increase, reduce or eliminate the amount allocated to the bonus pool for a particular performance period. The actual award may be below, at or above a participant's target award, in the discretion of the administrator. The administrator may determine the amount of any increase, reduction or elimination on the basis of such factors as it deems relevant, and it is not required to establish any allocation or weighting with respect to the factors it considers.

Actual awards generally are paid in cash (or its equivalent) only after they are earned, and, unless otherwise determined by the administrator, to earn an actual award a participant must be employed by us through the date the actual award is paid. The administrator of the Incentive Compensation Plan may reserve the right to settle an actual award with a grant of an equity award under our then-current equity compensation plan, which equity award may have such terms and conditions, including vesting, as the administrator determines. Payment of awards occurs as soon as practicable after they are earned, but no later than the dates set forth in the Incentive Compensation Plan.

Awards under the Incentive Compensation Plan are subject to any clawback policy of ours, which we may be required to adopt from time to time to comply with applicable laws, including our Compensation Recovery Policy. The administrator also may impose such other clawback, recovery or recoupment provisions with respect an award under the Incentive Compensation Plan as the administrator determines necessary or appropriate, including for example, reduction, cancellation, forfeiture or recoupment upon a termination of a participant's employment for cause. Certain participants may be required to reimburse us for certain amounts paid under an award under the Incentive Compensation Plan in connection with certain accounting restatements we may be required to prepare due to our material noncompliance with any financial reporting requirements under applicable securities laws, as a result of misconduct.

Our board of directors and our compensation committee has the authority to amend, suspend or terminate the Incentive Compensation Plan, provided such action does not impair the existing rights of any participant with respect to any earned awards.

401(k) Plan

We maintain a 401(k) retirement savings plan (the 401(k) plan) for the benefit of our employees, including our executive officers who remain employed with us and who satisfy certain eligibility requirements. Under the 401(k) plan, eligible employees may elect to defer a portion of their compensation, within the limits prescribed by the Code and the applicable limits of the 401(k) plan, on a pre-tax or after-tax (Roth) basis, through contributions to the 401(k) plan. The 401(k) plan permits us to make matching and other contributions to eligible participants. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Code. As a tax-qualified retirement plan, pre-tax contributions to the 401(k) plan and earnings on those pre-tax contributions are not taxable to the employees until distributed from the 401(k) plan, and earnings on Roth contributions are not taxable when distributed from the 401(k) plan. Our 401(K) plan is to be terminated upon consummation of the Merger.

Outstanding Equity Awards at 2023 Year-End

The following table provides information regarding outstanding equity awards held by our named executive officers as of December 31, 2023.

		Option Awards				Stock Awards	
Name	Date of Grant	Number of Securities Underlying Exercisable Options (#) Exercisable	Number of Securities Underlying Unexercisable Options (#) Unexercisable[1]	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)[1]	Market Value of Shares or Units of Stock That Have not Vested ($)
Nima Farzan[2]	3/23/2020	1,281,642	0	2.57	3/23/2030	—	—
Nima Farzan[3]	8/18/2020	364,510	72,903	5.63	8/18/2030	—	—
Nima Farzan[4]	2/12/2021	194,791	80,209	35.38	2/12/2031	—	—
Nima Farzan[5]	2/11/2022	183,333	216,667	10.03	2/11/2032	—	—
Nima Farzan[6]	2/10/2023	156,229	593,771	6.78	2/10/2033	—	—
Mark Meltz[7]	4/2/2020	384,508	0	2.57	4/2/2030	—	—
Mark Meltz[8]	8/18/2020	101,252	20,251	5.63	8/18/2030	—	—
Mark Meltz[9]	2/12/2021	70,833	29,167	35.38	2/12/2031	—	—
Mark Meltz[10]	2/11/2022	61,875	73,125	10.03	2/11/2032	—	—
Mark Meltz[11]	2/10/2023	44,785	170,215	6.78	2/10/2033	—	—
Mark Meltz[12]	9/1/2022	—	—	—	—	17,188	40,736
Richard Williams, MBBS, Ph.D.[13]	6/22/2020	276,757	47,252	2.57	6/22/2030	—	—
Richard Williams, MBBS, Ph.D.[14]	8/18/2020	94,502	18,901	5.63	8/18/2030	—	—
Richard Williams, MBBS, Ph.D.[15]	2/12/2021	70,833	29,167	35.38	2/12/2031	—	—
Richard Williams, MBBS, Ph.D.[16]	2/11/2022	61,875	73,125	10.03	2/11/2032	—	—
Richard Williams, MBBS, Ph.D.[17]	2/10/2023	44,785	170,215	6.78	2/10/2033	—	—
Richard Williams, MBBS, Ph.D.[18]	9/1/2022	—	—	—	—	17,188	40,736

(1) The unvested portion of these awards are also subject to vesting acceleration under certain circumstances, as will be more fully described below under "-Potential Payments upon Termination or Change in Control-Change in Control and Severance Policy."

(2) 1/4th of the shares subject to the option shall vest on March 3, 2021 and 1/48th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date. All of the shares subject to the option may be early exercised.

(3) 1/4th of the shares subject to the option shall vest on August 1, 2021 and 1/48th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.

(4) 1/48th of the shares subject to the option shall vest on March 1, 2021 and 1/48th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.

(5) 1/48th of the shares subject to the option shall vest on March 1, 2022 and 1/48th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.

(6) 1/48th of the shares granted under the option shall vest on March 1, 2023, and 1/48th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.

(7) 1/4th of the shares subject to the option shall vest on April 1, 2021 and 1/48th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date. All of the shares subject to the option may be early exercised.

(8) 1/4th of the shares subject to the option shall vest on August 1, 2021 and 1/48th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.

(9) 1/48th of the shares subject to the option shall vest on March 1, 2021 and 1/48th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.

(10) 1/48th of the shares subject to the option shall vest on March 1, 2022 and 1/48th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.

(11) 1/48th of the shares granted under the option shall vest on March 1, 2023, and 1/48th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.

(12) 1/16th of the shares subject to the RSU award shall vest on each of March 1, June 1, September 1 and December 1 of each calendar year, beginning December 1, 2022 subject to continued service through each such vesting date.

(13) 1/4th of the shares subject to the option shall vest on the one year anniversary of July 1, 2020, the Vesting Commencement Date, and thereafter 1/48th of the shares subject to the option shall vest each month in equal installments on the same day of the month as the Vesting Commencement Date.

(14) 1/4th of the shares subject to the option shall vest on August 1, 2021 and 1/48th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.

(15) 1/48th of the shares subject to the option shall vest on March 1, 2021 and 1/48th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.

(16) 1/48th of the shares subject to the option shall vest on March 1, 2022 and 1/48th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.

(17) 1/48th of the shares granted under the option shall vest on March 1, 2023, and 1/48th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.

(18) 1/16th of the shares subject to the RSU award shall vest on each of March 1, June 1, September 1 and December 1 of each calendar year, beginning December 1, 2022 subject to continued service through each such vesting date.

Director Compensation

Our board of directors adopted, and our stockholders approved, an amended and restated compensation policy for our non-employee directors (the Outside Director Compensation Policy), in consultation with our compensation committee's independent compensation consultant, Aon/Radford, in February 2023. This policy was developed with input from Aon/Radford regarding practices and compensation levels at comparable companies. It is designed to attract, retain and reward non-employee directors. Our nominating and corporate governance committee reviews the form and amount of compensation paid for service on our board of directors and its committees at least annually.

Under the Outside Director Compensation Policy, each non-employee director receives the cash and equity compensation for his or her service as a member of our board of directors, as described below. We also reimburse our non-employee directors for reasonable, customary and documented travel expenses to meetings of our board of directors or its committees.

The Outside Director Compensation Policy includes a maximum annual limit of $750,000 of cash compensation and equity awards that may be paid, issued or granted to a non-employee director in any fiscal year (increased to $1,000,000 in the fiscal year in which the non-employee director joins our board of directors). For purposes of these limitations, the value of an equity award is based on its grant date fair value. Any cash compensation paid or equity awards granted to a person for his or her service as an employee, or for his or her service as a consultant (other than as a non-employee director), will not count for purposes of the limitation. The maximum limit does not reflect the intended size of any potential compensation or equity awards to our non-employee directors.

Cash Compensation

Under our Outside Director Compensation Policy, each non-employee director is paid an annual cash retainer of $40,000. In addition, each non-employee director was and is entitled to receive the following cash compensation under the Outside Director Compensation Policy for his or her service:

- $30,000 per year for service as chair of our board of directors;
- $15,000 per year for service as chair of our audit committee;
- $7,500 per year for service as a member of our audit committee;
- $10,000 per year for service as chair of our compensation committee;
- $5,000 per year for service as a member of our compensation committee;
- $8,000 per year for service as chair of our nominating and corporate governance committee; and
- $4,000 per year for service as a member of our nominating and corporate governance committee.

Each non-employee director who serves as a committee chair receives only the additional annual cash fee as the chair of the committee, and not the additional annual fee as a member of the committee. All cash payments to non-employee directors are paid quarterly in arrears on a prorated basis. The above-listed fees for service as chair or members of committees are payable in addition to the non-employee director retainer.

Equity Compensation

Initial Options. Each person who first became a non-employee director after the effective date of our Outside Director Compensation Policy was entitled to receive, on the first trading day on or after the date that the person first became a non-employee director, an initial award (an Initial Award) of stock options to purchase 50,000 shares of our common stock. Each Initial Award will be scheduled to vest in equal installments as to 1/36th of the shares of our common stock subject to the Initial Award on a monthly basis following the Initial Award's grant date, on the same day of the month as the grant date, subject to continued services to us through the applicable vesting dates. Our board of directors or a committee thereof may change or revise the terms of an Initial Award, including the number of shares subject to the award. If the person was a member of our board of directors and also an employee, then becoming a non-employee director due to termination of employment will not entitle the person to an Initial Award.

Annual Options. Each non-employee director who had completed at least six months of continuous service as a non-employee director automatically was entitled to receive, on the first trading day immediately after the date of each annual meeting of our stockholders after the effective date of our Outsider Director Compensation Policy, an annual award (an Annual Award) of stock options to purchase 25,000 shares of our common stock. Each Annual Award will be scheduled to vest as to 1/12th shares subject to the Annual Award on a monthly basis following the Annual Award's grant date on the same day of the month as such grant date (or the last day of the month, if there is no corresponding day in such month), or if earlier, the day immediately before the date of the next annual meeting that occurs after the Annual Award's grant date, subject to continued service to us through the applicable vesting date. Our board of directors or a committee thereof may change or revise the terms of an Annual Award, including the number of shares subject to the award.

Change in Control. In the event of a change in control, as defined in our 2020 Equity Incentive Plan (the 2020 Plan), each non-employee director's then outstanding equity awards covering shares of our common stock will accelerate vesting in full, provided that he or she remains a non-employee director through the date of the change in control.

Other Award Terms. Each Initial Award and Annual Award is granted under the 2020 Plan (or its successor plan, as applicable) and form of award agreement under such plan. These awards have a maximum term to expiration of 10 years from their grant and a per share exercise price equal to 100% of the fair market value of a share of our common stock on the award's grant date.

2023 Compensation

Directors who are also our employees receive no additional compensation for their service as directors. In 2023, Mr. Farzan was our only employee director. Please see the section titled, "Executive Compensation" for additional information about Mr. Farzan's compensation for his service as our President and Chief Executive Officer.

The following table presents the total compensation each of our non-employee directors received during the year ended December 31, 2023. Other than as set forth in the table, we did not pay any compensation, make any equity awards or non-equity awards, or pay any other compensation, to any of our non-employee directors in 2023.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Jill DeSimone(2)	43,750	180,240	—	223,990
Melissa Epperly	55,000	55,280	—	110,280
Keith Flaherty, M.D.	48,000	55,280	—	103,280
Carl L. Gordon, Ph.D., CFA	52,500	55,280	—	107,780
Dean Mitchell	84,000	55,280	—	139,280
Michael Rome, Ph.D.(3)	—	—	—	—
Helen Sabzevari, Ph.D.	40,000	55,280	—	95,280
Laurie Smaldone Alsup, M.D.	44,000	55,280	—	99,280
Jim Tananbaum, M.D.(3)	—	—	—	—

(1) This column reflects the aggregate grant date fair value of option awards granted to the director in the applicable fiscal year, computed in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 718, *Compensation-Stock Compensation* (Topic 718). See Note 2(m) to our financial statements for the year ended December 31, 2022 included in this Annual Report on Form 10-K for a discussion of the assumptions made by us in determining the grant date fair value of our equity awards. Our named executive officers will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options.

(2) Ms. DeSimone began serving as a member of our board of directors effective March 1, 2023.

(3) Drs. Rome and Tananbaum previously waived their right to receive cash compensation and the annual equity award for their service as a member of our board of directors or its committees.

The following table lists all outstanding equity awards held by non-employee directors as of December 31, 2023:

		Option Awards			
Name	Date of Grant	Number of Securities Underlying Exercisable Options	Number of Securities Underlying Unexercisable Options	Option Exercise Price ($)	Option Expiration Date
Jill DeSimone[1]	3/1/2023	12,500	37,500	5.21	3/1/2033
Melissa Epperly[2]	10/23/2020	60,751	0	8.39	10/23/2030
Melissa Epperly[3]	6/11/2021	20,250	0	24.46	6/11/2031
Melissa Epperly[4]	6/13/2022	20,250	0	8.38	6/13/2032
Melissa Epperly[5]	6/12/2023	12,500	12,500	3.48	6/12/2023
Keith Flaherty, M.D.[6]	9/17/2018	32,064	0	0.18	9/17/2028
Keith Flaherty, M.D.[7]	2/5/2020	56,112	0	2.57	2/5/2030
Keith Flaherty, M.D.[8]	8/18/2020	9,366	2,025	5.63	8/18/2030
Keith Flaherty, M.D.[9]	6/11/2021	20,250	0	24.46	6/11/2031
Keith Flaherty, M.D.[10]	6/13/2022	20,250	0	8.38	6/13/2032
Keith Flaherty, M.D.[11]	6/12/2023	12,500	12,500	3.48	6/12/2033
Carl L. Gordon, Ph.D., CFA[12]	12/2/2020	40,501		20.00	12/2/2030
Carl L. Gordon, Ph.D., CFA[13]	6/13/2022	20,250	0	8.38	6/13/2032
Carl L. Gordon Ph.D., CFA[14]	6/12/2023	12,500	12,500	3.48	6/12/2033
Dean Mitchell[15]	8/18/2020	121,503	0	5.63	8/18/2030
Dean Mitchell[16]	6/11/2021	20,250	0	24.46	6/11/2031
Dean Mitchell[17]	6/13/2022	20,250	0	8.38	6/13/2032
Dean Mitchell[18]	6/12/2023	12,500	12,500	3.48	6/12/2023
Michael Rome, Ph.D.[19]	12/2/2020	40,501	0	20.00	12/2/2030
Michael Rome, Ph.D.[20]	6/13/2022	20,250	0	8.38	6/13/2032
Helen Sabzevari, Ph.D.[21]	6/24/2021	33,750	6,751	24.38	6/24/2031
Helen Sabzevari, Ph.D.[22]	6/13/2022	20,250	0	8.38	6/13/2032
Helen Sabzevari Ph.D.[23]	6/12/2023	12,500	12,500	3.48	6/12/2033
Laurie Smaldone Alsup, M.D.[24]	8/22/2020	60,751	0	5.63	8/22/2030
Laurie Smaldone Alsup, M.D.[25]	6/11/2021	20,250	0	24.46	6/11/2031
Laurie Smaldone Alsup, M.D.[26]	6/13/2022	20,250	0	8.38	6/13/2032
Laurie Smaldone Alsup, M.D.[27]	6/12/2023	12,500	12,500	3.48	6/12/2033
Jim Tananbaum, M.D.[28]	12/2/2020	40,501	0	20.00	12/2/2030
Jim Tananbaum, M.D.[29]	6/13/2022	20,250	0	8.38	6/13/2032

(1) 1/36th of the shares subject to the option vest on each monthly anniversary of the date of grant subject to continued service through each such vesting date.
(2) 1/24th of the shares subject to the option vested on December 1, 2020 and 1/24th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(3) 1/12th of the shares subject to the option vested on July 11, 2021 and 1/12th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(4) 1/12th of the shares subject to the option vested on July 13, 2022 and 1/12th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(5) 1/12th of the shares subject to the option vested on July 12, 2023 and 1/12th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.
(6) 1/48th of the shares subject to the option vested on July 1, 2018 and 1/48th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(7) 1/48th of the shares subject to the option vested on January 19, 2020 and 1/48th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(8) 1/48th of the shares subject to the option vested on September 1, 2020 and 1/48th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.
(9) 1/12th of the shares subject to the option vested on July 11, 2021 and 1/12th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(10) 1/12th of the shares subject to the option vested on July 13, 2022 and 1/12th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(11) 1/12th of the shares subject to the option vested on July 12, 2023 and 1/12th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.
(12) 1/36th of the shares subject to the option vested on January 2, 2021 and 1/36th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(13) 1/12th of the shares subject to the option vested on July 13, 2022 and 1/12th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(14) 1/12th of the shares subject to the option vested on July 12, 2023 and 1/12th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.
(15) 1/24th of the shares subject to the option vested on September 1, 2020 and 1/24th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(16) 1/12th of the shares subject to the option vested on July 11, 2021 and 1/12th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(17) 1/12th of the shares subject to the option vested on July 13, 2022 and 1/12th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(18) 1/12th of the shares subject to the option vested on July 12, 2023 and 1/12th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.
(19) 1/36th of the shares subject to the option vested on January 2, 2021 and 1/36th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(20) 1/12th of the shares subject to the option vested on July 13, 2022 and 1/12th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(21) 1/36th of the shares subject to the option vested on July 24, 2021 and 1/36th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.

(22) 1/12th of the shares subject to the option vested on July 13, 2022 and 1/12th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(23) 1/12th of the shares subject to the option vested on July 12, 2023 and 1/12th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.
(24) 1/24th of the shares subject to the option vested on September 1, 2020 and 1/24th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(25) 1/12th of the shares subject to the option vested on July 11, 2021 and 1/12th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(26) 1/12th of the shares subject to the option vested on July 13, 2022 and 1/12th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(27) 1/12th of the shares subject to the option vested on July 12, 2023 and 1/12th of the shares subject to the option vest monthly thereafter subject to continued service through each such vesting date.
(28) 1/36th of the shares subject to the option vested on January 2, 2021 and 1/36th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.
(29) 1/12th of the shares subject to the option vested on July 13, 2022 and 1/12th of the shares subject to the option vested monthly thereafter subject to continued service through each such vesting date.

Role of the Board of Directors in Risk Oversight

Our board of directors has an active role, as a whole and also at the committee level, in overseeing the management of our risks. Our board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including credit risks, liquidity risks and operational risks. Our compensation committee is responsible for overseeing the management of risks relating to our compensation policies and practices. Our audit committee is responsible for overseeing the management of risks relating to accounting matters and financial reporting. Our nominating and corporate governance committee is responsible for overseeing the management of risks associated with the independence of our board of directors and potential conflicts of interest. Although each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed through discussions from committee members about such risks.

Compensation Committee Interlocks and Insider Participation

During our fiscal year ended December 31, 2023, our compensation committee consisted of Ms. DeSimone, Mr. Mitchell, Dr. Gordon and Dr. Tananbaum. None of the members of our board of directors who serve on our compensation committee is or has been an officer or employee of our company. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee (or other committee of the board of directors performing equivalent functions or, in the absence of any such committee, the entire board of directors) of any entity that has one or more executive officers serving on our board of directors or compensation committee.

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

Equity Compensation Plan Information

The following table provides information as of December 31, 2023 with respect to shares of our common stock that may be issued under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Restricted Stock Units and Rights (#)		Weighted Average Exercise Price of Outstanding Options and Rights ($)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in the first Column) (#)
Equity compensation plans approved by security holders				
2018 Equity Incentive Plan, as Amended and Restated[1]	3,906,113	$	3.82	0
2020 Equity Incentive Plan[2]	5,987,303	$	13.49	2,651,449
2020 Employee Stock Purchase Plan[3]	0	$	0	1,116,217
Equity compensation plans not approved by security holders	0	$	0	0
TOTAL	9,893,416	$	9.67	3,767,666

(1) Our board of directors adopted, and our stockholders approved, the 2018 Equity Incentive Plan, as amended and restated (the 2018 Plan). In connection with our initial public offering and the adoption of the 2020 Plan, we no longer grant awards under the 2018 Plan; however, all outstanding options issued pursuant to the 2018 Plan continue to be governed by their existing terms. To the extent that any such awards are forfeited or lapse unexercised or are repurchased, the shares of common stock subject to such awards will become available for issuance under the 2020 Plan.

(2) Our board of directors adopted, and our stockholders approved, the 2020 Plan. The 2020 Plan provides that the number of shares available for issuance under the 2020 Plan will be increased on the first day of each fiscal year beginning with the 2022 fiscal year, in an amount equal to the least of (i) 4,348,000 shares, (ii) five percent (5%) of the outstanding shares of common stock on the last day of the immediately preceding fiscal year or (iii) such other amount as our board of directors may determine.

(3) Our board of directors adopted, and our shareholders approved, the 2020 Employee Stock Purchase Plan (the ESPP). The ESPP provides that the number of shares available for issuance under the ESPP will be increased on the first day of each fiscal year beginning with the 2022 fiscal year, in an amount equal to the least of (i) 870,000 shares, (ii) one percent (1%) of the outstanding shares of common stock on the last day of the immediately preceding fiscal year or (iii) such other amount as the administrator may determine.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 13, 2024 for:

- each of our directors and nominees for director;
- each of our named executive officers;
- all of our current directors and executive officers as a group; and
- each person or group known to us to be the beneficial owner of more than 5% of our common stock.

We have determined beneficial ownership in accordance with the rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable.

We have based our calculation of the percentage of beneficial ownership on 47,225,312 shares of our common stock outstanding as of March 13, 2024. We have deemed shares of our common stock subject to stock options that are currently exercisable or exercisable within 60 days of March 13, 2024, as well as shares of our common stock subject to stock awards that vest within 60 days of March 13, 2024, to be outstanding and to be beneficially owned by the person holding the stock option or stock award for the purpose of computing the percentage ownership of that person. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Kinnate Biopharma Inc., 800 West El Camino Real, Suite 180, Mountain View, CA 94040.

Name of Beneficial Owner	Number of Shares of Common Stock Beneficially Owned	Percentage of Shares Beneficially Owned
Greater than 5% Stockholders:		
Entities affiliated with Foresite Capital[1]	13,718,311	29.0%
Entities affiliated with OrbiMed[2]	8,009,729	17.0%
Tang Capital Partners, LP[3]	2,601,647	5.5%
Named Executive Officers and Directors:		
Nima Farzan[4]	2,376,696	4.8%
Mark Meltz[5]	734,738	1.5%
Richard Williams, MBBS, Ph.D.[6]	693,154	1.4%
Jill DeSimone[7]	19,444	*
Melissa Epperly[8]	124,167	*
Keith Flaherty, M.D.[9]	228,600	*
Carl L. Gordon, Ph.D., CFA[10]	8,093,396	17.1%
Dean Mitchell[11]	184,919	*
Michael Rome, Ph.D.[12]	60,751	*
Helen Sabzevari, Ph.D.[13]	81,416	*
Laurie Smaldone Alsup, M.D.[14]	124,167	*
Jim Tananbaum, M.D.[15]	13,779,062	29.1%
All current directors and executive officers as a group (thirteen persons)[16]	26,890,528	51.5%

* Represents beneficial ownership of less than 1%.

(1) Based on a Schedule 13D/A, reporting beneficial ownership as of February 16, 2024, and filed with the SEC on February 22, 2024, the shares consist of (i) 9,671,643 shares of capital stock held by Foresite Capital Fund IV, LP (FCF IV), (ii) 3,525,957 shares of capital stock held by Foresite Capital Fund V, LP (FCF V) and (iii) 520,711 shares of capital stock held by Foresite Capital Opportunity Fund V, L.P. (FCOF V). Jim Tananbaum, M.D., is a member of our board of directors and Chief Executive Officer and Managing Director of Foresite Capital. Foresite Capital Management IV, LLC (FCM IV), the general partner of FCF IV, may be deemed to have sole power to vote and sole power to dispose of shares directly owned by FCF IV. Foresite Capital Management V, LLC (FCM V), the general partner of FCF V, may be deemed to have sole power to vote and sole power to dispose of shares directly owned by FCF V. Foresite Capital Opportunity Management V, LLC (FCOM V), the general partner of FCOF V, may be deemed to have sole power to vote and sole power to dispose of shares directly owned by FCOF V. Dr. Tananbaum, the managing member of each of FCM IV, FCM V and FCOM V, may be deemed to have sole power to vote and sole power to dispose of shares directly owned by FCF IV, FCF V and FCOF V. FCF IV and FCM IV each have sole voting power over 9,671,643 shares and sole dispositive power over 9,671,643 shares. FVC V and FCM V each have sole voting power over 3,525,957 shares and sole dispositive power over 3,525,957 shares. FCOF V and FCOM V each have sole voting power over 520,711 shares and sole dispositive power over 520,711 shares. Dr. Tananbaum has sole voting power over 13,718,311 shares and sole dispositive power over 13,718,311 shares. The address of Dr. Tananbaum and each of the entities listed above is 900 Larkspur Landing Circle, Suite 150, Larkspur, California, 94939.

(2) Based on a Schedule 13D/A, reporting beneficial ownership as of February 16, 2024, and filed with the SEC on February 21, 2024, the shares consists of (i) 4,738,453 shares of capital stock held by OrbiMed Private Investments VII, LP (OPI VII), (ii) 1,368,338 shares of capital stock held by OrbiMed Private Investments VIII, LP (OPI VIII), (iii) 1,368,339 shares of capital stock held by OrbiMed Asia Partners IV, L.P. (OAP IV), (iv) 84,599 shares of capital stock held by OrbiMed Genesis Master Fund, L.P. (Genesis) and (v) 450,000 shares of capital stock held by OrbiMed Partners Master Fund Limited (OPM). OrbiMed Capital GP VII LLC (GP VII) is the general partner of OPI VII and OrbiMed Advisors LLC (OrbiMed Advisors) is the managing member of GP VII. By virtue of such relationships, GP VII and OrbiMed Advisors share power to direct the vote and disposition of the shares held by OPI VII and may be deemed directly or indirectly to be the beneficial owners of the shares held by OPI VII. OrbiMed Capital GP VIII LLC (GP VIII) is the general partner of OPI VIII and OrbiMed Advisors is the managing member of GP VIII. By virtue of such relationships, GP VIII and OrbiMed Advisors share power to direct the vote and disposition of the shares held by OPI VIII and may be deemed directly or indirectly to be the beneficial owners of the shares held by OPI VIII. OrbiMed Asia GP IV, L.P. (OAP GP IV) is the general partner of OAP IV, OrbiMed Advisors IV Limited (Advisors IV) is the general partner of OAP GP IV, and OrbiMed Advisors is the advisory company of OAP IV. By virtue of such relationships, OAP GP IV, Advisors IV, and OrbiMed Advisors share power to direct the vote and disposition of the shares held by OAP IV and may be deemed directly or indirectly to be the beneficial owners of the shares held by OAP IV. OrbiMed Genesis GP LLC (OrbiMed Genesis) is the general partner of Genesis and OrbiMed Advisors is the managing member of OrbiMed Genesis. By virtue of such relationships, OrbiMed Genesis and OrbiMed Advisors share power to direct the vote and disposition of the shares held by Genesis and may be deemed directly or indirectly to be the beneficial owners of the shares held by Genesis. OrbiMed Capital LLC (OrbiMed Capital) is the investment advisor of OPM. By virtue of such relationship, OrbiMed Capital has the power to direct the vote and disposition of the shares held by OPM and may be deemed directly or indirectly to be the beneficial owner of the shares held by OPM. Carl Gordon, a member of OrbiMed Advisors and OrbiMed Capital, serves on our board of directors. OrbiMed Advisors and OrbiMed Capital exercise voting and investment power through management committees comprised of Carl Gordon, Sven Borho and W. Carter Neild, each of whom disclaims beneficial ownership of the shares held by OPI VII, OPI VIII, OAP IV, Genesis, and OPM. OrbiMed Advisors has shared voting power over 7,559,729 shares and shared dispositive power over 7,559,729 shares. GP VII has shared voting power over 4,738,453 shares and shared dispositive power over 4,738,453 shares. GP VIII has shared voting power over 1,368,338 shares and shared dispositive power over 1,368,338 shares. Advisors IV has shared voting power over 1,368,338 shares and shared dispositive power over 1,368,338 shares. OAP GP IV has shared voting power over 1,368,339 shares and shared dispositive power over 1,368,339 shares. OrbiMed Genesis has shared voting power over 84,559 shares and shared dispositive power over 84,559 shares. OrbiMed Capital has shared voting power over 450,000 shares and shared dispositive power over 450,000 shares. The address of each of the individuals and entities listed above is 601 Lexington Avenue, 54th Floor, New York, NY 10022.

(3) Based on a Schedule 13G/A, reporting beneficial ownership as of December 31, 2023, and filed with the SEC on February 14, 2024, the shares consist of 2,601,647 shares of capital stock held by Tang Capital Partners, LP (Tang Capital Partners). Tang Capital Management, LLC (Tang Capital Management) serves as the general partner of Tang Capital Partners and may be deemed to beneficially own the shares held by Tang Capital Partners. Tang Capital Management owns no securities of the Company directly. Mr. Kevin Tang is the manager of Tang Capital Management and may be deemed to beneficially own the shares held by Tang Capital Partners. Mr. Tang owns no securities of the Company directly. Tang Capital Partners has shared voting power over 2,601,647 shares and shared dispositive power over 2,601,647 shares. Tang Capital Management has shared voting power over 2,601,647 shares and shared dispositive power over 2,601,647 shares. Mr. Tang has shared voting power over 2,601,647 shares and shared dispositive power over 2,601,647 shares. The address of each of the individuals and entities listed above is 4747 Executive Drive, Suite 210, San Diego, CA 92121.

(4) Consists of (i) 2,186 shares of common stock directly held by Mr. Farzan and (ii) 2,374,510] shares of common stock subject to options held by Mr. Farzan that are exercisable within 60 days of March 13, 2024.

(5) Consists of (i) 11,953 shares of common stock directly held by Mr. Meltz and (ii) 722,785 shares of common stock subject to options held by Mr. Meltz that are exercisable within 60 days of March 13, 2024.

(6) Consists of (i) 51,963 shares of common stock directly held by Dr. Williams and (ii) 641,191 shares of common stock subject to options held by Dr. Williams that are exercisable within 60 days of March 13, 2024.

(7) Consists of 19,444 shares of common stock subject to options held by Ms. DeSimone that are exercisable within 60 days of March 13, 2024.

(8) Consists of 124,167 shares of common stock subject to options held by Ms. Epperly that are exercisable within 60 days of March 13, 2024.

(9) Consists of (i) 66,377 shares of common stock directly held by Dr. Flaherty and (ii) 162,223 shares of common stock subject to options held by Dr. Flaherty that are exercisable within 60 days of March 13, 2024.

(10) Consists of (i) the 8,009,729 shares of common stock described in footnote (2) above and (ii) 83,667 shares of common stock subject to options held by Dr. Gordon that are exercisable within 60 days of March 13, 2024. Dr. Gordon disclaims beneficial ownership of the shares of common stock described in footnote (2).

(11) Consists of 184,919 shares of common stock subject to options held by Mr. Mitchell that are exercisable within 60 days of March 13, 2024.

(12) Consists of 60,751 shares subject to an option that is exercisable within 60 days of March 13, 2024. Dr. Rome has no voting or investment control over the shares held by entities affiliated with Foresite Capital that are included in footnote (1) above.

(13) Consists of 81,416 shares of common stock subject to options held by Dr. Sabzevari that are exercisable within 60 days of March 13, 2024.

(14) Consists of 124,167 shares of common stock subject to options held by Dr. Smaldone Alsup that are exercisable within 60 days of March 13, 2024.

(15) Consists of (i) the 13,718,311 shares of common stock described in footnote (1) above and (ii) 60,751 shares of common stock subject to options held by Dr. Tanenbaum that are exercisable within 60 days of March 13, 2024.

(16) Consists of (i) 21,882,418 shares of common stock directly or indirectly held by our current executive officers and directors and (ii) 5,008,110 shares of common stock subject to options held by our current executive officers and directors that are exercisable within 60 days of March 13, 2024.

Change in Control

The information disclosed in Part I. Business of this Annual Report on Form 10-K under the captions "—Proposed Agreement and Plan of Merger" and "—Asset Purchase Agreement" are incorporated herein by reference.

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

We describe below certain relationships with related persons and transactions and series of similar transactions, since the beginning of our 2023 fiscal year, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed the lesser of (i) $120,000 or (ii) 1% of the average of our total assets at year end of the last two completed fiscal years; and
- any of our directors, nominees for director, executive officers or beneficial holders of more than 5% of our outstanding capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities (each, a related person), had or will have a direct or indirect material interest.

Joint Venture

In May 2021, we closed a $35 million financing to establish a joint venture in Greater China, Kinnjiu Biopharma Inc. (Kinnjiu). In connection with the establishment of the joint venture, we entered into a collaboration and license agreement (License Agreement).

Pursuant to the License Agreement, we granted Kinnjiu an exclusive license under certain intellectual property controlled by us to develop, manufacture and commercialize compounds from our RAF, FGFR and CDK12 programs (Identified Products) in Greater China, subject to certain rights retained by us, and a non-exclusive license to manufacture the Identified Products outside Greater China solely for use and sale of the Identified Products within Greater China.

OrbiMed Asia Partners and another fund affiliated with OrbiMed Advisors LLC (OrbiMed) and a fund affiliated with Foresite Capital Management (Foresite) made investments in Kinnjiu on customary terms (together, the Series A Investors). Members of our management, and certain of our directors affiliated with OrbiMed and Foresite, served as members of the board of directors of Kinnjiu.

In February 2023, we announced that we acquired the ownership stake of Kinnjiu previously held by the Series A Investors for $24.0 million, using a combination of $9.1 million in cash and 2.2 million shares of our common stock. Kinnjiu is now our wholly-owned subsidiary.

Investors' Rights Agreement

We are party to an investors' rights agreement, as amended, with certain holders of our capital stock, including entities affiliated with Foresite Capital, Nextech V Oncology S.C.S., SICAV-SIF, entities affiliated with OrbiMed Advisors, entities affiliated with RA Capital Management, L.P. and Vida Ventures, LLC. Under our amended investors' rights agreement, certain holders of our capital stock have the right to demand that we file a registration statement or request that their shares of our capital stock be covered by a registration statement that we are otherwise filing.

Indemnification Agreements

We have entered into separate indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our Certificate of Incorporation and Bylaws. The indemnification agreements and our Certificate of Incorporation and Bylaws require us to indemnify our directors, executive officers and certain controlling persons to the fullest extent permitted by Delaware law.

Related Party Transaction Policy

Our audit committee has the primary responsibility for reviewing and approving or disapproving "related party transactions," which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed $120,000 and in which a related person has or will have a direct or indirect material interest. The charter of our audit committee provides that our audit committee shall review and approve in advance any related party transaction.

Our board of directors has adopted a formal written policy providing that we are generally not permitted to enter into transactions that exceed $120,000 and in which any related person has a direct or indirect material interest without the consent of our audit committee. In approving or rejecting any such transaction, our audit committee is to consider, among other factors, the following, to the extent relevant to the related party transaction: whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances; the extent of the related person's interest in the transaction; whether there are business reasons for the Company to enter into the related party transaction; whether the related party transaction would impair the independence of an outside director, including the ability of any director to serve on the compensation committee; and whether the related party transaction would present an improper conflict of interest for any director or executive officer of the Company, taking into account the size of the transaction, the overall financial position of the director, executive officer or related person, the direct or indirect nature of the director's, executive officer's or related person's interest in the transaction and the ongoing nature of any proposed relationship, and any other factors the audit committee deems relevant.

Director Independence

Our common stock is listed on the Nasdaq Global Select Market. Under the listing standards of Nasdaq, independent directors must comprise a majority of a listed company's board of directors within one year of the completion of its initial public offering. In addition, the listing standards of Nasdaq require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent. Audit committee members and compensation committee members must also satisfy the independence criteria set forth in Rule 10A-3 and Rule 10C-1, respectively, under the Exchange Act. Under the listing standards of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered to be independent for purposes of Rule 10A-3 and under the listing standards of Nasdaq, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

To be considered independent for purposes of Rule 10C-1 and under the listing standards of Nasdaq, the board of directors must affirmatively determine that each member of the compensation committee is independent, including a consideration of all factors specifically relevant to determining whether the director has a relationship to the company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including: (1) the source of compensation of such director, including any consulting, advisory or other compensatory fee paid by the company to such director and (2) whether such director is affiliated with the company, a subsidiary of the company or an affiliate of a subsidiary of the company.

Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of each director and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that Ms. DeSimone, Ms. Epperly, Dr. Flaherty, Dr. Gordon, Mr. Mitchell, Dr. Rome, Dr. Sabzevari, Dr. Smaldone Alsup and Dr. Tananbaum, representing nine of our ten directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the listing standards of Nasdaq.

In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled "Certain Relationships and Related Party and Other Transactions."

Item 14. Principal Accounting Fees and Services.

Our independent registered public accounting firm is KPMG LLP.

Fees Paid to the Independent Registered Public Accounting Firm

The following table presents fees for professional audit services and other services rendered to us by KPMG LLP for our fiscal years ended December 31, 2023 and 2022.

	2023	2022
Audit Fees(1)	$ 839,338	$ 832,995
Audit-Related Fees	$ 0	$ 0
Tax Fees(2)	$ 47,833	$ 208,673
All Other Fees	$ 0	$ 0
Total Fees	$ 887,171	$ 1,041,667

(1) "Audit Fees" consist of fees billed for professional services rendered in connection with the audit of our annual financial statements, reviews of our quarterly financial statements for those fiscal years, and related services that are normally provided by the independent registered public accounting firm in connection with statutory and regulatory filings, registration statements, including comfort letters and consents, or engagements for those fiscal years. Audit Fees include fees for services incurred in connection with our registration statement on Form S-3 filed with the SEC on January 3, 2022.

(2) "Tax Fees" consist of fees billed for professional services rendered by KPMG LLP for tax compliance, tax advice and tax planning.

Audit Committee Policy on Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm

Our audit committee has established a policy governing our use of the services of our independent registered public accounting firm. Under the policy, our audit committee is required to pre-approve all audit and permissible non-audit services performed by our independent registered public accounting firm in order to ensure that the provision of such services does not impair such accounting firm's independence. All fees paid to KPMG LLP for our fiscal years ended December 31, 2023 and 2022 were pre-approved by our audit committee.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this report:

(1) Financial Statements

The consolidated financial statements of Kinnate Biopharma Inc. are filed as part of this report on Form 10-K under Item 8. Financial Statements and Supplementary Data.

(2) Financial Statement Schedules

All other schedules have been omitted because they are not required, not applicable, or the required information is included in the consolidated financial statements or notes thereto.

(3) Exhibits

The documents listed in the Exhibit Index are incorporated by reference or are filed with this report, in each case as indicated herein (numbered in accordance with Item 601 of Regulation S-K).

Item 16. Form 10-K Summary.

None.

Exhibit Index

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
2.1	Agreement and Plan of Merger, dated February 16, 2024, by and among XOMA Corporation, XRA 1 Corp. and Kinnate Biopharma Inc.	8-K	001-39743	2.1	February 16, 2024
2.2	Asset Purchase Agreement, dated February 27, 2024, by and among Kinnate Biopharma Inc. and Pierre Fabre Médicament, SAS.	8-K	001-39743	2.1	March 1, 2024
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-39743	3.1	December 8, 2020
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-39743	3.1	July 28, 2023
4.1	Amended and Restated Investors' Rights Agreement by and among the Registrant and certain of its stockholders, dated August 24, 2020.	S-1	333-250086	4.1	November 13, 2020
4.2	Specimen common stock certificate of the Registrant.	S-1/A	333-250086	4.2	November 30, 2020
4.3	Description of Securities.	10-K	001-39743	4.3	March 28, 2022
10.1+	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1	333-250086	10.1	November 13, 2020
10.2+	2018 Equity Incentive Plan, as amended, and forms of agreement thereunder.	S-1	333-250086	10.2	November 13, 2020
10.3+	2020 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	333-250086	10.3	November 30, 2020
10.4+	2020 Employee Stock Purchase Plan and forms of agreements thereunder.	S-1/A	333-250086	10.4	November 30, 2020
10.5+	Employment Letter between the Registrant and Nima Farzan.	S-1	333-250086	10.5	November 13, 2020
10.6+	Employment Letter between the Registrant and Mark Meltz.	S-1	333-250086	10.6	November 13, 2020
10.7+	Employment Letter between the Registrant and Richard Williams, MBBS, Ph.D.	S-1	333-250086	10.8	November 13, 2020
10.8+	Employment Letter between the Registrant and Neha Krishnamohan.	8-K	001-39743	10.1	June 7, 2021
10.9+	Executive Incentive Compensation Plan.	S-1	333-250086	10.9	November 13, 2020
10.10+	Change in Control and Severance Agreement between the Registrant and Nima Farzan.	S-1	333-250086	10.10	November 13, 2020
10.11+	Change in Control and Severance Agreement between the Registrant and Mark Meltz.	S-1	333-250086	10.11	November 13, 2020
10.12+	Change in Control and Severance Agreement between the Registrant and Richard Williams, MBBS, Ph.D.	S-1	333-250086	10.13	November 13, 2020
10.13+	Change in Control and Severance Agreement between the Registrant and Neha Krishnamohan.	8-K	001-39743	10.2	June 7, 2021
10.14	Amended and Restated Outside Director Compensation Policy.	10-K	001-39743	10.14	March 15, 2023
10.15	Sales agreement, between the Company and SVB Leerink LLC, dated as of January 3, 2022.	S-3ASR	333-261970	1.2	January 3, 2022
10.16+	Letter Agreement, dated as of November 22, 2023, by and between the Registrant and Nima Farzan.	SC 14D-9	005-91893	99.E(16)	March 4, 2024
10.17+	Letter Agreement, dated as of November 22, 2023, by and between the Registrant and Mark Meltz.	SC 14D-9	005-91893	99.E(17)	March 4, 2024
10.18+	Letter Agreement, dated as of November 22, 2023, by and between the Registrant and Richard Williams, MBBS, Ph.D.	SC 14D-9	005-91893	99.E(18)	March 4, 2024

10.19+	Letter Agreement, dated as of November 22, 2023, by and between the Registrant and Neha Krishnamohan.	SC 14D-9	005-91893	99.E(19)	March 4, 2024
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm.				
24.1*	Power of Attorney (reference is made to the signature page hereto).				
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1†	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2†	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
97.1*	Kinnate Biopharma Inc. Compensation Recovery Policy.				
101.INS*	Inline XBRL Instance Document.				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				
104*	Cover Page Interactive Data File (formatted in inline XBRL and contained in Exhibit 101).				

* Filed herewith.
+ Indicates management contract or compensatory plan.
† The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Annual Report on Form 10-K are not deemed filed with the SEC and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Kinnate Biopharma Inc.

Date: March 28, 2024

By: /s/ Nima Farzan
Nima Farzan
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Nima Farzan and Neha Krishnamohan as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and substitution, for him or her and in his or her name, place, and stead, in any and all capacities (including his or her capacity as a director and/or officer of Kinnate Biopharma Inc.) to sign any or all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as they, he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agents or any of them, or their, his, or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Nima Farzan **Nima Farzan**	President, Chief Executive Officer and Director (*Principal Executive Officer)*	March 28, 2024
/s/ Neha Krishnamohan **Neha Krishnamohan**	Chief Financial Officer and Executive Vice President, Corporate Development *(Principal Financial Officer and Principal Accounting Officer)*	March 28, 2024
/s/ Dean Mitchell **Dean Mitchell**	Chair of the Board of Directors	March 28, 2024
/s/ Jill DeSimone **Jill DeSimone**	Director	March 28, 2024
/s/ Melissa Epperly **Melissa Epperly**	Director	March 28, 2024
/s/ Keith Flaherty **Keith Flaherty, M.D.**	Director	March 28, 2024
/s/ Carl L. Gordon **Carl L. Gordon, Ph.D., CFA**	Director	March 28, 2024
/s/ Michael Rome **Michael Rome, Ph.D.**	Director	March 28, 2024
/s/ Helen Sabzevari **Helen Sabzevari, Ph.D.**	Director	March 28, 2024
/s/ Laurie Smaldone Alsup **Laurie Smaldone Alsup, M.D.**	Director	March 28, 2024
/s/ Jim Tananbaum **Jim Tananbaum, M.D.**	Director	March 28, 2024

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (No. 333-251105, No. 333-263913 and No. 333-270655) on Form S-8 and in the registration statement (No. 333-261970) on Form S-3 of our report dated March 28, 2024, with respect to the consolidated financial statements of Kinnate Biopharma Inc.

/s/ KPMG LLP

San Diego, California
March 28, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Nima Farzan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Kinnate Biopharma Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2024

By: /s/ Nima Farzan
Nima Farzan
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Neha Krishnamohan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Kinnate Biopharma Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2024

By: /s/ Neha Krishnamohan

Neha Krishnamohan
Chief Financial Officer and Executive Vice President, Corporate Development

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Kinnate Biopharma Inc. (the Company) on Form 10-K for the period ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the Report), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, as amended, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2024

By: /s/ Nima Farzan

Nima Farzan
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Kinnate Biopharma Inc. (the Company) on Form 10-K for the period ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the Report), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, as amended, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2024

By: /s/ Neha Krishnamohan

Neha Krishnamohan
Chief Financial Officer and Executive Vice President, Corporate Development
(Principal Financial Officer)

Exhibit 97.1

KINNATE BIOPHARMA INC.

COMPENSATION RECOVERY POLICY

As adopted on July 25, 2023

Kinnate Biopharma Inc. (the "**Company**") is committed to strong corporate governance. As part of this commitment, the Company's Board of Directors (the "**Board**") has adopted this Compensation Recovery Policy (this "**Policy**"). This Policy is intended to further the Company's pay-for-performance philosophy and to comply with applicable law by providing for the reasonably prompt recovery of certain executive compensation in the event of an Accounting Restatement. Capitalized terms used in this Policy are defined below, and the definitions have substantive impact on its application so reviewing them carefully is important to an understanding of this Policy.

This Policy, which was approved as set forth above, is intended to comply with Section 10D of the Securities Exchange Act of 1934 (the "**Exchange Act**"), with Exchange Act Rule 10D-1 and with the listing standards of the national securities exchange (the "**Exchange**") on which the securities of the Company are listed. This Policy will be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act, Exchange Act Rule 10D-1 and with the listing standards of the Exchange, including any interpretive guidance provided by the Exchange.

In summary, this Policy provides rules related to the reasonably prompt recovery of certain incentive-based compensation received by Executive Officers. The application of this Policy to Executive Officers is not discretionary, except to the limited extent provided below, and applies without regard to whether an Executive Officer was at fault.

Persons Covered by this Policy

This Policy is binding and enforceable against all Executive Officers. "**Executive Officer**" means each individual who is or was ever designated as an "officer" by the Board in accordance with Exchange Act Rule 16a-1(f). Each Executive Officer will be required to sign and return to the Company an acknowledgement that such Executive Officer will be bound by the terms and comply with this Policy. The failure to obtain such acknowledgement will have no impact on the applicability or enforceability of this Policy.

Administration of this Policy

The Compensation Committee (the "**Committee**") of the Board has full delegated authority to administer this Policy. The Committee is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. In addition, if determined in the discretion of the Board, this Policy may be administered by the independent members of the Board or another committee of the Board made up of independent members of the Board, in which case all references to the Committee will be deemed to refer to the independent members of the Board or the other Board committee. All determinations of the Committee will be final and binding and will be given the maximum deference permitted by law.

Events Requiring Application of this Policy

If the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (an "**Accounting Restatement**"), then the Committee must determine what compensation, if any, must be recovered.

Compensation Covered by this Policy

This Policy applies to certain **Incentive-Based Compensation** (certain terms used in this Section are defined below) that is **Received** on or after October 2, 2023 (the "**Effective Date**"), during the **Covered Period** while the Company has a class of securities listed on a national securities exchange. Such Incentive-Based Compensation is considered "**Clawback Eligible Incentive-Based Compensation**" if the Incentive-Based Compensation is Received by a person after such person became an Executive Officer and the person served as an Executive Officer at any time during the performance period for the Incentive-Based Compensation. The Incentive-Based Compensation that must be recovered is the amount of Clawback Eligible Incentive-Based Compensation that exceeds the amount of Clawback Eligible Incentive-Based Compensation that otherwise would have been Received had such Clawback Eligible Incentive-Based Compensation been determined based on the restated amounts (such compensation, as computed without regard to any taxes paid, the "**Excess Compensation**," is referred to in the listings standards as "erroneously awarded incentive-based compensation").

To determine the amount of Excess Compensation for Incentive-Based Compensation based on stock price or total shareholder return, where it is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the amount must be based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was Received and the Company must maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange.

"**Incentive-Based Compensation**" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure. For the avoidance of doubt, (i) no compensation that is potentially subject to recovery under this Policy will be earned until the Company's right to recover under this Policy has lapsed, and (ii) the following items of compensation are not Incentive-Based Compensation under this Policy: (a) salaries, bonuses paid solely at the discretion of the Committee or Board that are not paid from a bonus pool that is determined by satisfying a Financial Reporting Measure, (b) bonuses paid solely upon satisfying one or more subjective standards and/or completion of a specified employment period, non-equity incentive plan awards earned solely upon satisfying one or more strategic measures or operational measures, and (c) equity awards for which the grant is not contingent upon achieving any Financial Reporting Measure performance goal and vesting is contingent solely upon completion of a specified employment period (e.g., time-based vesting equity awards) and/or attaining one or more non-Financial Reporting Measures."

"**Financial Reporting Measures**" are measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and total shareholder return are also Financial Reporting Measures. A Financial Reporting Measure need not be presented within the financial statements or included in a filing with the Securities and Exchange Commission.

Incentive-Based Compensation is "**Received**" under this Policy in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment, vesting, settlement or grant of the Incentive-Based Compensation occurs after the end of that period. For the avoidance of doubt, this Policy does not apply to Incentive-Based Compensation for which the Financial Reporting Measure is attained prior to the Effective Date.

"**Covered Period**" means the three completed fiscal years immediately preceding the Accounting Restatement Determination Date. In addition, Covered Period can include certain transition periods resulting from a change in the Company's fiscal year. The Company's obligation to recover Excess Compensation is not dependent on if or when the restated financial statements are filed.

"**Accounting Restatement Determination Date**" means the earliest to occur of: (a) the date the Board, a committee of the Board, or one or more of the officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement; and (b) the date a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement.

Repayment of Excess Compensation

The Company must recover such Excess Compensation reasonably promptly and Executive Officers are required to repay Excess Compensation to the Company. Subject to applicable law, the Company may recover such Excess Compensation by requiring the Executive Officer to repay such amount to the Company by direct payment to the Company or such other means or combination of means as the Committee determines to be appropriate (these determinations do not need to be identical as to each Executive Officer). These means may include:

(a) requiring reimbursement of cash Incentive-Based Compensation previously paid;

(b) seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;

(c) offsetting the amount to be recovered from any unpaid or future compensation to be paid by the Company or any affiliate of the Company to the Executive Officer;

(d) cancelling outstanding vested or unvested equity awards; and/or

(e) taking any other remedial and recovery action permitted by law, as determined by the Committee.

The repayment of Excess Compensation must be made by an Executive Officer notwithstanding any Executive Officer's belief (whether legitimate or non-legitimate) that the Excess Compensation had been previously earned under applicable law and therefore is not subject to clawback.

In addition to its rights to recovery under this Policy, the Company or any affiliate of the Company may take any legal actions it determines appropriate to enforce an Executive Officer's obligations to the Company or to discipline an Executive Officer, including (without limitation) termination of employment, institution of civil proceedings, reporting of misconduct to appropriate governmental authorities, reduction of future compensation opportunities or change in role. The decision to take any actions described in the preceding sentence will not be subject to the approval of the Committee and can be made by the Board, any committee of the Board, or any duly authorized officer of the Company or of any applicable affiliate of the Company.

Limited Exceptions to this Policy

The Company must recover the Excess Compensation in accordance with this Policy except to the limited extent that the conditions of Exchange Act Rule 10D-1(b)(1)(iv) and the Exchange listing standards are met, and the Committee determines that recovery of the Excess Compensation would be impracticable.

Other Important Information in this Policy

This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 that are applicable to the Company's Chief Executive Officer and Chief Financial Officer, as well as any other applicable laws, regulatory requirements, rules, or pursuant to the terms of any existing Company policy or agreement providing for the recovery of compensation.

Notwithstanding the terms of any of the Company's organizational documents (including, but not limited to, the Company's bylaws), any corporate policy or any contract (including, but not limited to, any indemnification agreement), neither the Company nor any affiliate of the Company will indemnify or provide advancement for any Executive Officer against any loss of Excess Compensation. Neither the Company nor any affiliate of the Company will pay for or reimburse insurance premiums for an insurance policy that covers potential recovery obligations. In the event the Company is required to recover Excess Compensation from an Executive Officer who is no longer an employee pursuant to this Policy, the Company will be entitled to seek such recovery in order to comply with applicable law, regardless of the terms of any release of claims or separation agreement such individual may have signed.

The Committee or Board may review and modify this Policy from time to time.

If any provision of this Policy or the application of any such provision to any Executive Officer is adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provisions of this Policy or the application of such provision to another Executive Officer, and the invalid, illegal or unenforceable provisions will be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

This Policy will terminate and no longer be enforceable when the Company ceases to be listed issuer within the meaning of Section 10D of the Exchange Act.

ACKNOWLEDGEMENT

- I acknowledge that I have received and read the Compensation Recovery Policy (the "**Policy**") of Kinnate Biopharma Inc. (the "**Company**").
- I understand and acknowledge that this Policy applies to me, and all of my beneficiaries, heirs, executors, administrators or other legal representatives and that the Company's right to recovery in order to comply with applicable law will apply, regardless of the terms of any release of claims or separation agreement I have signed or will sign in the future.
- I agree to be bound by and to comply with this Policy and understand that determinations of the Committee (as such term is used in this Policy) will be final and binding and will be given the maximum deference permitted by law.
- I understand and agree that my current indemnification rights, whether in an individual agreement or the Company's organizational documents, exclude the right to be indemnified for amounts required to be recovered under this Policy.
- I understand that my failure to comply in all respects with this Policy is a basis for termination of my employment with the Company and any affiliate of the Company as well as any other appropriate discipline.
- I understand that neither this Policy, nor the application of this Policy to me, gives rise to a resignation for good reason (or similar concept) by me under any applicable employment agreement or arrangement.
- I acknowledge that if I have questions concerning the meaning or application of this Policy, it is my responsibility to seek guidance from the Compliance Officer or my own personal advisers.
- I acknowledge that neither this Acknowledgement nor this Policy is meant to constitute an employment contract.

Please review, sign and return this form to the Compliance Officer or any delegate thereof.

Executive

_____

(*print name*)

_____

(*signature*)

_____

(date)