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

FORM 10-K

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

For the fiscal year ended December 31, 2022

OR

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

Commission file number: 001-39580

IMMUNOME, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0694340**
(State of Other Jurisdiction of incorporation or Organization)	(I.R.S. Employer Identification No.)
665 Stockton Drive, Suite 300, Exton, PA	**19341**
(Address of principal executive offices)	(Zip code)

Registrant's telephone number, including area code: (610) 321-3700

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	**IMNM**	**Nasdaq Global Select Market**

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

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

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

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

Indicate by check mark whether the Registrant has submitted electronically; every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.0405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☐ No ☒

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 common stock held by non-affiliates of the registrant was approximately $34.1 million based on the closing price reported by NASDAQ on June 30, 2022 (the last business day of the registrant's most recently completed second fiscal quarter). For purposes of making this calculation only, the registrant has defined affiliates as including all executive officers, directors and beneficial owners of more than 10% of the common stock of the registrant.

The number of outstanding shares of the Registrant's Common Stock as of March 13, 2023 was 12,215,018.

Documents Incorporated by Reference

Specified portions of the Registrant's definitive proxy statement to be filed in connection with the solicitation of proxies for its 2023 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. The exhibit index is located on pages 109 to 112 of this filing.

TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements made in this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 (this "Annual Report") may include forward-looking statements that reflect our current views with respect to our development programs, business strategy, business plan, financial performance and other future events. These statements include forward-looking statements both with respect to us, specifically, and our industry, in general. Such forward-looking statements include the words "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "positioned," "potential," "seek," "should," "suggest," "target," "will," "would" and similar statements of a future or forward-looking nature and identify forward-looking statements.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Forward-looking statements are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. There are or will be important factors that could cause actual results to differ materially from those indicated in these statements. These factors include, but are not limited to, those factors set forth in the sections captioned "Business - General," "Risk Factors," "Legal Proceedings," and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in this annual report on Form 10-K, which you should review carefully. We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as required by law.

Risk Factor Summary

The risks described in the section titled "Risk Factors" immediately following this summary could impact our ability to realize the full benefits of our strengths or execute all or part of our strategy. Some of the more significant risks described in "Risk Factors" include the following:

Risks Related to Our Business

- We are a biopharmaceutical company with history of losses. We expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- We will need to raise substantial additional funds to advance development of our pipeline and our discovery platform, and we cannot guarantee that we will have sufficient funds available in the future to develop and commercialize the pipeline.
- We may be unable to advance any programs or development candidates through clinical development, obtain regulatory approval to initiate clinical studies or maintain these approvals to continue the studies or commercialize them, and we could experience significant delays in doing so.
- Our approach to developing and identifying our pipeline using our discovery engine is novel and may not result in marketable or partnerable products.
- We may expend our limited resources and access to capital to pursue a particular program or development candidate; these decisions may prove to be wrong and may adversely impact other aspects of our business or our business overall.
- Our oncology program is at an early stage. We may be unable to identify or produce a product that successfully blocks IL-38 function in cancer patients and our efforts to define specific subsets of cancers to target may also be unsuccessful. Even if we are successful at developing an antibody that blocks IL-38 function, inhibiting IL-38 activity in patients may not lead to clinical benefit.
- Our further pursuit of our antibody cocktail development candidate for the treatment of COVID-19 is dependent on finding a partner. We may be unable to find a partner in a timely manner, if at all, and in any event preliminary data may not be indicative of future success, particularly given the continued emergence of variants.
- Clinical trials are expensive, time-consuming and difficult to design and implement.

- Clinical development has an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.
- If any program or development candidate begins clinical trials or receives marketing approval and we or others later identify undesirable side effects, our ability to market and derive revenue from it, and our business and reputation generally, could be compromised.
- Our business entails a significant risk of product liability, which may not be sufficiently covered by our insurance.
- If any of our programs or development candidates are approved for marketing and commercialization in the future and we are unable to develop sales, marketing and distribution capabilities on our own or enter into agreements with third parties to perform these functions on acceptable terms, we will be unable to successfully commercialize them.
- Additional regulatory burdens and other risks and uncertainties in foreign markets, if we decide to participate in those markets, may limit our growth.
- If we choose to pursue partnering or other strategic transactions, we may not be able to enter into such transactions on acceptable terms, if at all, which could adversely affect our ability to develop and commercialize programs or development candidates, impact our cash position, increase our expense, and present significant distractions to our management.
- Our third-party vendors may not perform under their obligations to us as anticipated if at all, in particular, our manufacturers may be unable to successfully scale manufacturing of our programs and development candidates in sufficient quality and quantity.
- If we choose to pursue strategic transactions, we may not be able to enter into such transactions on acceptable terms, if at all, which could adversely affect our development and commercialization activities, impact our cash position, increase our expense, and present significant distractions to our management.
- There is no guarantee that our collaboration with AbbVie will result in the successful discovery and validation of targets for further development and commercialization by AbbVie.
- Any inability to retain qualified key management, technical personnel and employees would impair our ability to implement our business plan.

Risks Related to Our Intellectual Property

- If we are unable to obtain or protect intellectual property rights related to our technology or programs and development candidates, or if our intellectual property rights are inadequate, we may not be able to compete effectively.
- If we fail to comply with our obligations under any license, collaboration or other intellectual property-related agreements, we may be required to pay damages and could lose intellectual property rights that may be necessary for developing, commercializing and protecting our current or future technologies or programs and development candidates or we could lose certain rights to grant sublicenses.
- Third parties may challenge our or our licensors' patent rights or may assert patent rights that prevent us from developing and commercializing any programs or development candidates.
- We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Risks Related to Government Regulation

- Health care legislative reform measures in the United States may have a material adverse effect on our business and results of operations.
- If we or our partners, manufacturers or service providers fail to comply with healthcare or other laws and regulations, we or they could be subject to enforcement actions.
- Even if we receive regulatory approval of our programs and development candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements.

- Even if we are able to advance any programs or development candidates, the programs and development candidates may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

Risks Related to Our Common Stock

- Our stock price may be volatile, and purchasers of our common stock could incur substantial losses.
- Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation.

PART I

Item 1. Business

General

We are a biopharmaceutical company utilizing a proprietary human memory B cell platform to discover and develop antibody therapeutics to improve patient care. Our discovery engine identifies novel therapeutic antibodies and their targets by leveraging the highly educated component of the immune system, memory B cells. Memory B cells are the key elements of a durable human immune response because they produce specific, high-affinity antibodies that bind to antigens produced in diseased cells and target them for destruction by other immune effector cells. We believe that our platform is different from those of other biotechnology companies because of our unbiased, broad, deep and efficient approach to identifying novel antibody-target pairs that may be useful in developing treatments for cancer and other diseases. Unlike some approaches that use deep sequencing of B cells to identify dominant clones that are common within and across patients, and which assume those clones are therapeutically relevant, we do not assume that any such genomic dominance is necessarily the hallmark of therapeutic utility.

Our primary focus area is oncology. Despite many elements that distinguish oncology from other diseases, the breadth of our platform has enabled the discovery of novel antibodies in non-oncology areas as well. We are currently advancing our lead oncology program: an antibody (IMM-ONC-01) against IL-38 , a novel immune modulator for the treatment of various solid tumors and identifying novel target-antibody pairs under the Collaboration Agreement with AbbVie. To date, we have processed memory B-cells isolated from hundreds of cancer patients and have generated several hundred thousand hybridomas, or stable, immortalized forms of B cell clones that each produce a single antibody for extended periods of time. We have successfully identified more than a thousand individual antibodies, which we refer to as “hits,” that appear to bind to either a cancer cell or a tumor extract with high-affinity and specificity. To date, after assessing only a fraction of these hits, we have identified over 70 potentially novel cancer targets. We believe that several of these antibody-target pairs could potentially form the basis of new therapies or diagnostics for a large number of oncology patients. One of these unique targets is interleukin 38, or IL-38, a novel immune modulator. An antibody directed at IL-38 is the current focus of our program IMM-ONC-01, which is in preclinical development stage. We are also studying the expression of IL-38 in various tumor types in order to select the most appropriate patient population for potential evaluation of IMM-ONC-01 clinical utility. We plan to submit our IND application for the IMM-ONC-01 program with the FDA by mid-2023.

We believe that our platform is useful in uncovering new insights into cancer biology itself. In analyzing over 70 cancer targets that we have identified to date, we observed a “functional clustering” of targets, indicating that different cancer patients appear to mount immune responses directed towards common processes in cancer biology, such as membrane dynamics and formation and function of exosomes. We are leveraging these insights to guide the discovery of future oncology pipeline assets and perhaps to enable future strategic collaborations and additional value creation. In addition, the platform can identify antibodies that can serve as potential candidates for other cancer treatment modalities, such as Antibody-Drug Conjugates or Bi-Specific Antibodies useful as T Cell Engagers by engaging unique targets expressed on cancer cell surface.

In the area of infectious diseases, we have advanced a product consisting of a cocktail of three antibodies (IMM-BCP-01) that bind and inactivate SARS-CoV2, which causes COVID-19. This program is aimed at advancing an

innovative therapeutic approach against the SARS-CoV2 virus into the clinic. We are conducting this program in collaboration with the DoD (U.S. Department of Defense's (DOD) Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) in collaboration with the Defense Health Agency (DHA). (Contract number: W911QY-20-9-0019). We generated a library of nearly 400 antibodies from the memory B-cells of patient "super-responders" who successfully cleared their SARS-CoV-2 infection having high circulating levels of high-affinity anti-viral antibodies. We submitted an IND application for the IMM-BCP-01 program to the U.S. FDA in November 2021 and initiated the Phase 1b study of IMM-BCP-01 in patients infected with SARS-CoV-2 in June 2022. On January 6, 2023, the Company announced that it successfully completed dosing of the first cohort of patients in a Phase 1b study with no significant treatment-related adverse events. The Company has decided to seek a partner in order to continue the trial and for any further development activities.

The Challenges Faced by Existing Antibody Therapies for Cancer

Despite significant advances in cancer therapeutics over the past 30 years, particularly in the realm of biologics including therapeutic antibodies, the five-year survival rate in patients with advanced malignancies of the lung, liver, stomach, pancreas, and other organs is less than 10%. We believe that a key issue undermining the wider effort to improve cancer therapeutics is a limited understanding of the diversity and complexity of human tumors. The discovery of new targets and novel therapeutics to neutralize them represent vitally important opportunities to help identify innovative and more effective cancer treatments. We are guided in our efforts by the immune responses generated by patients against their disease, and we leverage the wisdom of their memory B cells to illuminate the best routes forward.

Our Solution: Immunome's Discovery Engine

The below graphic in Figure 1 demonstrates the key components of our approach and discovery process using our proprietary discovery engine.

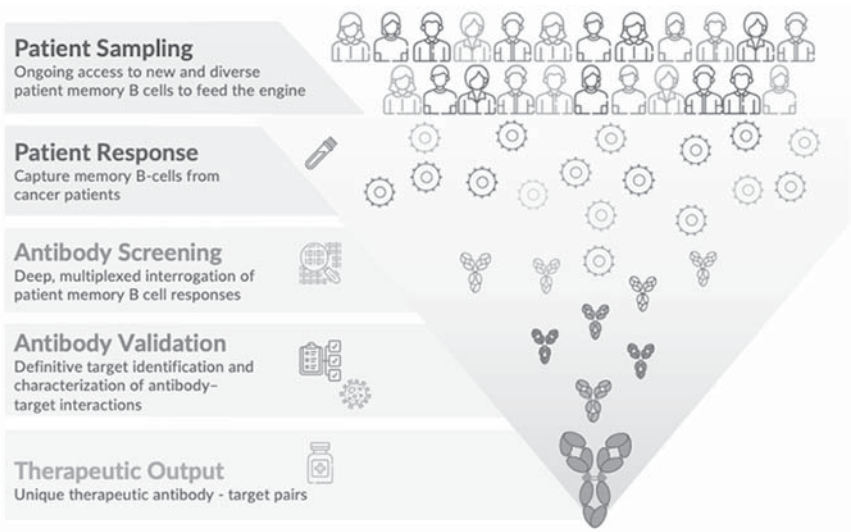

Figure 1. Key components of our discovery engine

Patient Sampling: Our discovery process begins with obtaining a patient's lymph node, tumor or blood sample and then purifying and expanding the memory B cell population. In oncology, patients sampled include those who are treatment naïve, treated with standard regimens, or have been treated with immunity enhancing therapies.

Patient Response: We fuse and immortalize thousands of these patient-derived memory B cells using proprietary methods, capturing them as hybridomas, each of which typically express an individual antibody in quantities sufficient for extensive functional screening.

Antibody Screening: For oncology, we screen individual antibodies by assessing their binding to intact cancer cells or normal cells, or by assessing their binding to a large number (typically 100) of different extracts of authentic tumor samples and cancer cell lines. Using our proprietary approach, we can screen up to 20,000 antibodies on a single array. Hybridomas producing antibodies that show both high-affinity binding, by typically binding at single digit nanomolar concentrations, and specific binding, by showing much higher binding to a subset of tumor cells compared to normal cells, are designated as screening "hits." Hybridomas producing those hits can be sequenced, their immunoglobulin genes can be cloned into expression vectors, and the individual antibodies can then be produced recombinantly.

Antibody Validation: The next step in our process is to identify the specific antigen to which the antibody appears to bind with high affinity and specificity. We use one of two complementary approaches for this activity: the first method involves an assessment of antibody binding to known human proteins spotted on a protein microarray with high selectivity. If the target is not represented on the array or no specific binding is seen, we attempt to use the antibody to "pull out" the antigen from its source using immunoprecipitation, and then identify the antigen sequence using mass spectrometry. Using these two approaches we are largely successful in identifying the antigen to which newly identified antibodies are binding. We then conduct experiments to assess whether the binding of the antibody to the specific antigen can produce a change in the biology of a cancer cell expressing the target, which we refer to as target validation. Additional tests, such as measurements of changes in cell growth, cell survival, cell migration, or internalization of the antigen after it has been bound by the antibody, are used to further assess the potential that the antibody could be of therapeutic interest.

Therapeutic Output: We believe our approach to the discovery of novel antibodies enables the following therapeutic modalities for cancer:

Unmodified Immunoglobulins: This therapeutic modality exploits antibodies where binding to the target antigen modifies cellular processes in way that directly induces a therapeutic benefit. This can occur when antibodies bind to antigens on tumor cells and disrupt cellular processes that are necessary for cancer cell growth and/or metastasis. Alternatively, binding of an antibody to its antigen may result in activation of the patient immune system to recognize and eliminate cancer cells.

Antibody-Drug Conjugates (ADCs): Certain target antigens have dense expression on the tumor cell surface as compared to normal tissues but binding of an antibody to that antigen does not induce a direct therapeutic effect. An ADC is an antibody to which a "tumor killing" payload is attached. If the antigen is rapidly internalized upon antibody binding the targeting selectivity of antibodies can be leveraged to deliver sufficient quantities of the "tumor killing" payload to kill the cancer cells. This approach uses known "tumor killing" agents and relies on their killing mechanisms for efficacy.

Bispecific Antibodies: Patient-derived antibodies bind to a single antigen. Antibodies can be engineered to engage two different target antigens. These bispecific antibodies can bind to two different tumor cell antigens and may induce therapeutic effects through simultaneous modulation of two cellular processes. Alternatively, bispecific antibodies can be engineered to bind to a tumor cell antigen as well as an antigen on the surface of an immune effector cell (e.g., T cell). This class of bispecific antibody, T cell engagers or TCEs, directs the immune effector cell to attack and destroy the tumor.

Key Attributes of Our Discovery Engine

Our discovery engine discovers innovative antibody-target pairs using an unbiased, broad, deep and efficient approach, as we are able to:

- Capture a large number (typically thousands) of patient-derived memory B cells and enrich and expand them using proprietary methods. We then convert memory B cells into stable human hybridomas, which typically express an antibody in quantities necessary for broad pre-clinical screening.

- Interrogate each antibody produced by the human memory B cell hybridomas against disease-related antigens, using function-based high-throughput screening approaches that include proprietary protein micro-array technologies that allow rapid screening of up to 20,000 antibodies in a single experiment.

- Simultaneously identify relevant, potentially novel, target antigens that are prevalent in a broader patient population, which we refer to as "public antigens," and antibodies that bind to them with high affinity. Therefore, we believe our platform can yield antibodies that may have the potential for use as therapeutics and/or diagnostics across a broad therapeutic landscape.

- Utilize an unbiased approach that spotlights biological processes of disease relevance, guided by the memory B-cell response. Further, identify antibodies that can be used in combination with other modalities resulting in novel therapeutics, such as Antibody-Drug Conjugates, Bi-specifics such as T cell engagers.

Our Current Programs

Oncology (IMM-ONC-01)

Our lead oncology program targets IL-38, which we believe is a novel, negative regulator of inflammation capable of promoting tumor evasion of the immune system. IL-38 was identified as the target of an antibody isolated from a hybridoma library generated from the memory B cells of a patient with squamous head and neck cancer. Query of public and proprietary (Tempus) databases of cancer gene expression revealed over-expression of IL-38 in multiple solid tumors. Further, a correlation with low levels of tumor-infiltrating immune effector cells, a hallmark of immune suppression in some of these patients' tumors, and high IL-38 expression was also observed, suggesting a role for IL-38 as an immune modulator. Data obtained from preclinical testing indicated that blocking IL-38 function using inhibitory antibodies increased the immune response to the tumor and resulted in anti-tumor activity in select animal models, suggesting that anti-IL-38 antibodies could have therapeutic utility as single agents or in combination with other therapeutic modalities. Our recent analysis further confirms IL-38 expression is frequently elevated in samples of select patient tumor subtypes, in cancers such as head and neck, lung and gastroesophageal. We believe that this information could potentially guide patient selection for early clinical testing and may improve the overall probability of demonstrating clinical utility, thereby improving the probability of clinical success. We plan to submit our IND application for the IMM-ONC-01 program by mid-2023.

SARS-CoV-2 (IMM-BCP-01)

We are developing an antibody cocktail derived from the B cells of COVID-19 patients who exhibited high neutralizing titers. IMM-BCP-01 targets non-overlapping regions of the Spike protein of SARS-CoV-2 which include highly conserved, subdominant epitopes. The cocktail promotes both ACE2 and non-ACE2 dependent neutralization and induces natural viral clearance mechanisms such as antibody dependent cellular cytotoxicity, complement activation and phagocytosis in pre-clinical testing. We are conducting this program in collaboration with the DoD. The IMM-BCP-01 program is broadly focused on the emerging variants of SARS-CoV-2. We submitted an IND application for the IMM-BCP-01 program to the U.S. FDA in November 2021 and initiated the Phase 1b study of IMM-BCP-01 in patients infected with SARS-CoV-2 in June 2022**.** On January 6, 2023, the Company announced that it successfully completed dosing of the first cohort of patients in a Phase 1b study with no significant treatment-related adverse events. The Company has decided to seek a partner in order to continue the trial and for any further development activities.

Other Programs and Platform

In addition to the already described current programs, we will continue to invest in our proprietary discovery engine to expand our pipeline. The high output of antibody-target pairs resulting from our discovery engine may provide us with additional insights into the immune response against cancer and other diseases. We intend to continue to invest in this platform, to evaluate novel antibody-target pairs and to develop a pipeline of antibody therapeutics as single agents or in combination with other therapeutics or technologies to yield programs and development candidates, such as Antibody-Drug Conjugates, or ADCs.

Additionally, we plan to expand our intellectual property estate and infrastructure needed to discover and advance our programs and development candidates. We may in-license or acquire complementary intellectual property as needed or required, and we may continue to build our know-how and trade secrets. We may pursue both therapeutic and diagnostic applications of our antibodies through composition of matter and/or method of use patents. While our initial focus areas are in oncology and other diseases, we may invest in intellectual property in other therapeutic areas as well.

Management

Our experienced management and leadership team has broad expertise in the field of discovering and developing therapeutics and includes highly capable, world-class immunologists and biologists.

Strategic Collaborations, License Agreements and Other Material Agreements

We believe that our technology has broad utility and could enable the formation of attractive strategic partnerships. Therefore, to maximize the value of our platform we may, from time to time, contemplate and enter into various forms of collaborative agreements related to our platform, our programs and/or development candidates with third parties, including other companies, government agencies, academic institutions and non-profit groups. Additionally, we may, from time to time, contemplate and enter into various forms of license agreements with third parties. The material collaborations, licensing and other related agreements entered into by us to date are described in greater detail below.

Collaboration with AbbVie

On January 4, 2023, the Company entered into a collaboration and option agreement, or the Collaboration Agreement, with AbbVie Global Enterprises Ltd., or AbbVie, pursuant to which the Company will use its proprietary discovery engine to discover and validate targets derived from patients with three specified tumor types, and antibodies that bind to such targets, which may be the subject of further development and commercialization by AbbVie. The research term is at least 66 months, subject to extension in certain circumstances by specified extension periods. Pursuant to the terms of the Collaboration Agreement, with respect to each novel target-antibody pair that the Company generates that meets certain mutually agreed criteria (each, a Validated Target Pair or VTP), the Company granted to AbbVie an exclusive option (up to a maximum of 10 in total) to purchase all rights in and to such Validated Target Pair, for all human and non-human diagnostic, prophylactic and therapeutic uses throughout the world, including without limitation the development and commercialization of certain products derived from the assigned Validated Target Pair and directed to the target comprising such VTP (Products). No rights are granted by the Company to AbbVie under any of Company's platform technology covering the Company's discovery engine. Until the expiration of the research term, the Company is not permitted to conduct any activities in connection with targets or antibodies derived from patients with the specified tumor types, whether independently or with other third parties, except in limited circumstances with respect to certain target-antibody pairs that are no longer subject to the collaboration with AbbVie. In addition, during the term of the Collaboration Agreement, the Company is not permitted to develop products directed to targets that are included in VTPs purchased by AbbVie, or to which AbbVie still has rights under the Collaboration Agreement, whether independently or with other third parties.

Under the Collaboration Agreement, AbbVie will pay the Company an upfront payment of $30.0 million, plus certain additional platform access payments in the aggregate amount of up to $70.0 million based on the Company's use of our discovery engine in connection with activities under each stage of the research plan, and delivery of VTPs to AbbVie. AbbVie will also pay an option exercise fee in the low single digit millions for each of the up to 10 VTPs for which it exercises an option. If AbbVie progresses development and commercialization of a Product, AbbVie will pay the Company development and first commercial sale milestones of up to $120.0 million per target, and sales milestones based on achievement of specified levels of net sales of Products of up to $150.0 million in the aggregate per target, in each case, subject to specified deductions in certain circumstances. On a Product-by-Product basis, AbbVie will pay the Company tiered royalties on net sales of Products at a percentage in the low single digits, subject to specified reductions and offsets in certain circumstances. AbbVie's royalty payment obligation will commence, on a Product-by-Product and country-by-country basis, on the first commercial sale of such Product in such country and will expire on the earlier of (a) (i) the ten (10)-year anniversary of such first commercial sale for such Product in such country, or (ii) solely with respect to a Product that incorporates an antibody comprising a VTP (or certain other antibodies derived from such

delivered antibody), the expiration of all valid claims of patent rights covering the composition of matter of any such antibody (whichever out of (i) or (ii) is later), and (b) the expiration of regulatory exclusivity for such Product in such country. The Company is potentially eligible to receive up to $2.8 billion from AbbVie under the Collaboration Agreement from the sources described above.

The Collaboration Agreement will expire upon the expiration of the last to expire royalty payment obligation with respect to all Products in all countries, subject to earlier expiration if all option exercise periods for all Validated Target Pairs expire without AbbVie exercising any option. In addition, the research term will terminate if AbbVie does not elect to make certain platform access payments at specified points during the research term, in order for the Company to continue the target discovery activities under the collaboration. The Collaboration Agreement may be terminated by (a) either party upon the other party's uncured material breach, or upon any insolvency event of the other party, (b) AbbVie for convenience upon a specified period prior written notice, or (c) AbbVie for the Company's breach of representations and warranties with respect to debarment or compliance with anti-bribery and anti-corruption laws. If AbbVie has the right to terminate the Collaboration Agreement for the Company's uncured material breach or a breach of representations and warranties with respect to debarment or compliance with anti-bribery and anti-corruption laws, AbbVie may elect to continue the Collaboration Agreement, subject to certain specified reductions applicable to certain of AbbVie's payment obligations (with a specified floor on such reductions).

Collaboration with the DoD

In July 2020, the Company entered into an Other Transaction Authority for Prototype Agreement, or the OTA Agreement, with the DoD to fund the Company's efforts in developing an antibody cocktail therapeutic to treat COVID-19. The amount of funding available to the Company under this expense reimbursement contract was originally $13.3 million. In May 2021, the Company and the DoD amended the OTA Agreement, pursuant to which the DoD award was increased from $13.3 million to $17.6 million. In January 2023, we modified the OTA Agreement to extend the completion date from December 30, 2022 to July 31, 2023, at no additional cost to the government. All other terms and conditions remain the same and are in full force and effect. The DoD may terminate the agreement in its entirety for convenience or in whole or in part for our material breach of the agreement.

As of December 31, 2022, the Company has received the maximum reimbursement amount of $17.6 million from the DoD to complete specific research activities for the project based on the estimated cost for such prototype. The $17.6 million was not sufficient to fund our full planned research and development phase 1B. Therefore, we have used our own funds to support completion of certain activities under the contract.

Pursuant to the OTA Agreement, ownership of any invention developed under the agreement follows inventorship under U.S. patent law. The Bayh-Dole Act does not apply to the OTA Agreement, and, as such, title to inventions will accrue to the inventor-organization. In addition, we own all study data generated under the OTA Agreement, whether generated by us or the DoD. We also obtained the right to negotiate a commercial license covering the DoD's interest in any invention solely owned by the DoD and developed under the agreement. Our rights to inventions and data are subject to standard government-retained rights.

Arrayjet License Agreements

In June 2019, we entered into an exclusive license agreement, or the Arrayjet Agreement, with Arrayjet Limited, or Arrayjet, amended on July 10, 2020 and on December 30, 2022. Pursuant to the Arrayjet Agreement, we obtained a royalty-bearing, exclusive license under certain licensed patents and know-how for all purposes, including to research, develop, make, have made, use, sell, offer for sale, market, and otherwise commercialize products in the United States, the United Kingdom, China, Germany, and Japan, for the screening of human derived hybridoma libraries against cancer cell lysate libraries where the antigen(s) of interest are unknown. We also obtained a right to license certain new intellectual property rights owned or acquired by Arrayjet during the term, subject to the negotiation of mutually agreeable license terms. The foregoing license grant includes a limited right to grant nonexclusive sublicenses. In connection with the Arrayjet Agreement, we are required to make annual license payments in the low-to-mid six figures to maintain such exclusivity. In the event we independently undertake certain development activities, we are also obligated to pay annual license fees in the mid six figures and annual sublicensing fees in the low six figures, and we are

obligated to pay a low single digit percentage of other sublicensing revenue received. During the term, we are obligated to pay Arrayjet a low single digit royalty on net sales of products by us and a low single digit to low teens royalty on net sales of products by sublicensees.

We have the right to terminate the Arrayjet Agreement upon specified written notice stating reasons for termination. Arrayjet may terminate the Arrayjet Agreement for our failure to meet certain diligence milestones, payment default, or failure to provide certain reports and information. Either party may terminate the Arrayjet Agreement for the other's material breach or insolvency.

Arrayjet Master Services Agreement and Quotation

On November 18, 2016, the Company entered into a Master Services Agreement with Arrayjet, which was subsequently amended on February 15, 2021, January 1, 2022 and December 30, 2022, referred to as the MSA. On December 30, 2022, the Company also entered into a Quotation & Contract of Sale, or the Quotation, with Arrayjet under the MSA, referred to as the Quotation.

Under the MSA, Immunome may engage Arrayjet to perform the services agreed upon between the parties pursuant to one or more quotations & contracts of sale. Per the MSA, unless otherwise provided in any quotation & contract of sale, Immunome may terminate any quotation & contract of sale without cause and Immunome may terminate the MSA at-will upon requisite advance notice.

Pursuant to the Quotation, the Company engaged Arrayjet to perform certain hybridoma screening services using a microarray assay for the period of time specified in the Quotation. These services may be performed pursuant to one or more Task Orders describing the specific services to be performed. The quotation may be terminated by either party for material breach of the other party, by Immunome at-will upon the requisite advance notice, by the parties' mutual agreement or automatically if the MSA is terminated.

Under the Quotation, the Company has agreed to pay Arrayjet an annual instrument access fee in the low six-figures and a screening fee based on the number of screening cycles ordered by the Company. The Company agreed to a minimum screening fee for the first year of the Quotation in the low six-figures and made a prepayment to Arrayjet for the first year of screening services.

Whitehead Patent License Agreement

In June 2009, we entered into an exclusive patent license agreement, or the Whitehead Agreement, with the Whitehead Institute for Biomedical Research, or Whitehead, and the Massachusetts Institute of Technology, or MIT, as licensing agent for Whitehead, pursuant to which we obtained from MIT and Whitehead a royalty-bearing exclusive license under certain patent rights of Whitehead and a royalty-bearing non-exclusive license under certain biological and chemical material of Whitehead that relate to our antibody screening platform, in each case to develop, manufacture, use, and commercialize licensed products and to develop and perform licensed processes and perform licensed services for all purposes in the United States. The foregoing license grant included the right to grant sublicenses with certain restrictions. Pursuant to the Whitehead Agreement, we are obligated to pay Whitehead up to $725,000 in the aggregate for certain development, regulatory and commercial milestones and up to $275,000 for each product or derivative that we discover using the licensed product or processes or Discovered Products. We are also obligated to pay Whitehead a low single digit royalty on net sales of licensed products and licensed processes when sold as a therapeutic or diagnostic product, a mid-single digit royalty on net sales of such licensed products or processes when sold as a research reagent, and a less than one percent royalty on net sales of Discovered Products when sold as a therapeutic or diagnostic product. Our obligation to pay royalties on net sales of Discovered Products is limited to a period of seven years from the first commercial sale of each Discovered Product. We are obligated to pay Whitehead a high single digit royalty on service income received in connection with the provision of licensed services the provision of which, absent the license granted under the Whitehead Agreement, would infringe a claim of a licensed patent. We are obligated to pay Whitehead a high first decile percentage of certain payments received from sublicensees, subject to certain reductions to single-digit percentages, and we are obligated to pay Whitehead a mid-teen percentage royalty on certain payments received from non-sublicensee corporate partners.

On November 17, 2022, the Company entered into a Letter Agreement, or Letter Agreement, with Whitehead, which became effective on January 4, 2023, upon the satisfaction of the conditions described therein. The Letter Agreement supplements the Whitehead Agreement. Pursuant to the Letter Agreement, Whitehead and the Company agreed that certain payments received by the Company from the Collaborator (as defined in the Letter Agreement) (i.e., a corporate partner, as defined in the License Agreement) would be excluded from the Company's payment obligations to Whitehead. The Company and Whitehead further agreed, among other things, that the Company will make certain payments to Whitehead (i) as Net Sales (as defined in the License Agreement) as long as the Company receives those payments from the Collaborator on a specified number of products purchased by the Collaborator and (ii) upon the achievement of certain milestones whether by the Company or the Collaborator.

We have the right to terminate the Whitehead Agreement upon specified prior written notice to Whitehead. Whitehead may terminate the Whitehead Agreement in the event of our uncured material breach or insolvency. Additionally, Whitehead may terminate the Whitehead Agreement if we or any of our affiliates or sublicensees challenges the validity, patentability, enforceability or non-infringement of the licensed patents.

TJU License Agreement

In June 2012, we entered into an exclusive license agreement, or the TJU Agreement, with Thomas Jefferson University, or TJU, pursuant to which we obtained from TJU a worldwide, royalty-bearing exclusive license under certain patent rights, know-how, and materials of TJU that relate to our antibody screening platform, in each case to research, develop, manufacture, use, commercialize, and improve licensed products and to practice licensed processes for all purposes. We are currently required to make an annual license maintenance payment in the low five figures, which amount may be credited against royalties payable in the same calendar year. We are also obligated to pay TJU $950,000 in the aggregate for certain development, regulatory and commercial milestones for licensed products. We are obligated to pay TJU a low single digit royalty on net sales of licensed products and licensed processes. The royalty rate is subject to certain specified reductions. Royalties are payable until expiration of the TJU Agreement. We are also obligated to pay TJU a high first decile percentage of any non-royalty sublicensing income received by us, subject to certain specified reductions. The TJU Agreement expires upon expiration of the last valid claim under the licensed patents.

Manufacturing

We produce our lead antibodies at the laboratory scale necessary for early research and development activities and some preclinical assessments. For later stage preclinical assessment, such as IND-enabling studies and safety assessment and early-stage clinical assessment, we use third-party manufacturers to produce our antibodies and any other necessary intermediates or reagents. We do not have, and we do not currently plan to acquire or develop the infrastructure, facilities or capabilities to conduct these manufacturing activities ourselves. We intend to continue to utilize third-party manufacturers to produce, package, label, test and release product for clinical and non-clinical testing and for future commercial use, as needed. We expect to continue to rely on such third parties to manufacture our products for the foreseeable future. Our expected future contractual manufacturing organizations will each have successful track records of producing clinical and commercial products for other companies under applicable compliance regulations, such as cGMP compliance in case of the FDA, and will have previously been inspected by regulatory authorities for compliance with cGMP standards.

Competition

We are aware of several companies that are developing antibody treatments for the therapeutic areas of cancer and other diseases. Many of these companies are well-capitalized and, in contrast to us, have significant clinical experience, and may include our potential future strategic partners. In addition, these companies compete with us in recruiting scientific and managerial talent. Our success will partially depend on our ability to obtain, maintain, enforce and defend patents and other intellectual property rights with respect to our antibodies that are proven to be safer and/or more effective or are less expensive than competing products. Our commercial opportunity and success will be reduced or eliminated if competing products that are safer, more effective, or less expensive than the antibodies we develop or if such products become available in the future.

In oncology, we expect to compete with antibody, biologic and other therapeutic platforms and development companies who are also pursuing similar antibody-based discovery approaches, including, but not limited to, companies such as AbCellera Biologics, Inc.; Adaptive Biotechnologies Corporation, or Adaptive; AIMM Therapeutics B.V.; Atreca, Inc.; IGM Biosciences, Inc.; OncoReponse, Inc; Neurimmune; Biocytogen; and Alchemab. In addition, we expect to compete with large, multinational pharmaceutical companies that discover, develop and commercialize antibodies and other therapeutics and modalities including Antibody-Drug Conjugates and T-Cell Engagers for use in treating cancer such as AstraZeneca; Amgen; Bristol-Myers Squibb Company; Genentech, Inc. (a member of Roche group); Merck & Co. Inc.; GlaxoSmithKline; Regeneron; Gilead; AbbVie; and Johnson & Johnson. If any programs or development candidates identified through our current lead programs are eventually approved for sale, they will likely compete with a range of treatments that are either in development or currently marketed for use in those same disease indications. In the area of infectious diseases, specifically our COVID-19 efforts, we made the decision to partner our IMM-BCP-01 program for further development and if a partner is successful in the future, they may encounter key competitors including other companies developing antibody-based therapeutics such as Regeneron; Glaxo SmithKline plc. and Vir Biotechnology (in collaboration); Invivyd; Eli Lilly and AbCellera (in collaboration); AbbVie; and AstraZeneca. Further, we expect the future market potential and need for our antibody cocktail product will be negatively influenced should any of the numerous vaccine products, by companies including Moderna, Inc.; Pfizer Inc. and BioNTech SE (in collaboration), AstraZeneca and Johnson and Johnson, continue to be safe and efficacious against COVID-19 and emerging variants of the virus.

Intellectual Property

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, whether developed internally, acquired or licensed from third parties. We will also seek to rely on regulatory protection afforded through orphan drug designations, inclusion in expedited development and review, data exclusivity, market exclusivity and patent term extensions where available.

We utilize various types of intellectual property assets to provide multiple layers of protection. For example, we seek a variety of patents to protect our inventions including, for example, compositions of matter and uses in treatment and diagnostic and methods for novel antibodies, including methods of treatment for diseases expressing novel targets. We believe our current layered patent estate, together with our efforts to develop and patent next generation technologies, provides us with substantial intellectual property protection.

As of March 1, 2023, we owned 68 pending national phase patent applications in the U.S and abroad, three pending PCT applications, and seven pending U.S. provisional patent applications, in total covering 12 patent families. Our portfolio includes claims directed to the composition of matter and methods of use for antibodies, including IMM-ONC-01 and IMM-BCP-01. Patent applications claiming the benefit of these PCT applications, if issued, are expected to expire between 2039 and 2042. Patents claiming priority to and the benefit of these provisional applications, if issued, are expected to expire in 2043. However, we recognize that the area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, which may affect those rights.

Our commercial success will depend in significant part upon obtaining and maintaining patent protection and trade secret protection of our programs and development candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges and operating without infringing on the proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents, or any patents granted to us in the future will be commercially useful in protecting our programs and development candidates, current programs and processes. For this and more comprehensive risks related to our intellectual property, please see the section titled “Risk Factors — Risks Related to Our Intellectual Property.”

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may potentially be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent taking into account delays on the part of the patentee or may be shortened if a patent is terminally disclaimed over an earlier expiring patent. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We expect to seek patent term extensions to all of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

In some instances, we file provisional patent applications directly in the USPTO. Provisional patent applications were designed to provide a lower-cost first patent filing in the United States. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. The corresponding non-provisional application benefits in that the priority date(s) of the patent application is/are the earlier provisional application filing date(s), and the patent term of the finally issued patent is calculated from the later non-provisional application filing date. This system allows us to obtain an early priority date, obtain a later start to the patent term and to delay prosecution costs, which may be useful in the event that we decide not to pursue examination in a subsequent non-provisional application. While we intend, as appropriate, to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such non-provisional patent applications will result in the issuance of patents that provide us with any competitive advantage.

We intend to file U.S. non-provisional applications and/or international Patent Cooperation Treaty, or PCT, applications that claim the benefit of the priority date of earlier filed provisional or non-provisional applications, when applicable. The PCT system allows for a single PCT application to be filed within 12 months of the priority filing date of a corresponding priority patent application, such as a U.S. provisional or non-provisional application, and to designate all of the 157 PCT contracting states in which national phase patent applications can later be pursued based on the PCT application. The PCT International Searching Authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to establish a patent application filing date in any of the member states and then seek patents through later-filed national-phase applications. No later than either 30 or 31 months from the first priority date of the PCT application, separate national phase patent applications can be pursued in any of the PCT member states, depending on the deadline set by individual contracting states. National phase entry can generally be accomplished through direct national filing or, in some cases, through a regional patent organization, such as the European Patent Organization. The PCT system delays application filing expenses, allows a limited evaluation of the chances of success for national/regional patent applications and allows for substantial savings in comparison to having filed individual countries rather than a PCT application in the event that no national phase applications are filed.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We file patents containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We may periodically reassess the number and type of patent applications, as well as the pending and issued patent claims to ensure that coverage and value are obtained for our processes, and compositions, given existing patent law and court decisions. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy subject matter, written description, and enablement requirements of the various patent jurisdictions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our programs and development candidates or for our technology platform. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

In addition to patent protection, we also rely on trademark registration, trade secrets, know how, other proprietary information and/or continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions.

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our products or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention.

When available to expand market exclusivity, our strategy is to obtain, or license additional intellectual property related to current or contemplated development platforms, core elements of technology and/or programs and development candidates.

For more information regarding the risks related to our intellectual property, see the section titled "Risk Factors — Risks Related to Our Intellectual Property."

Government Regulation

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with our third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our programs and development candidates.

U.S. Government Regulation of Biological Products

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations and biologics under the FDCA, the Public Health Service Act, or PHSA, and their implementing regulations. Both drugs and biologics 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 and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements may subject an applicant to administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications, or NDAs, or biologics license applications, or BLAs, or the agency's issuance of warning letters, or the imposition of fines, civil penalties, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution brought by the FDA and the U.S. Department of Justice or other governmental entities.

Nonclinical and Clinical Development

The data required to support a BLA is generated in two distinct development stages: nonclinical and clinical. Nonclinical studies include laboratory evaluation of product chemistry and formulation and may involve *in vitro* testing or *in vivo* animal studies to assess the potential for toxicity, adverse events, and other safety characteristics of the program or development candidate, and in some cases to establish a rationale for therapeutic use. The conduct of nonclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. The Consolidated Appropriations Act for 2023, signed into law on December 29, 2022, (P.L. 117-328) amended the FDCA and the Public Health Service Act to specify that nonclinical testing for drugs and biologics may, but is not required to, include *in vivo* animal studies. According to the amended language, a sponsor may fulfill nonclinical testing requirements by completing various *in vitro* assays (e.g., cell-based assays, organ chips, or microphysiological systems), *in silico* studies (i.e., computer modeling), other human or nonhuman biology-based tests (e.g., bioprinting), or *in vivo* animal studies.

The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, as well as other information, to the FDA as part of the IND. Some long-term nonclinical testing to further establish the safety profile of the program or development candidate, as well as manufacturing process development and product quality evaluation, continues after the IND is submitted.

Human clinical trials in support of an NDA or BLA

Prior to beginning the first clinical trial with a program or development candidate, the sponsor must submit an IND to the FDA. An IND is a request that FDA grant an exemption to federal law prohibiting interstate shipment of an investigational authorization to administer the program or development candidate to humans in accordance with a specific clinical trial protocol. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical trials. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions related to the proposed clinical trial and places the IND on a clinical hold . In such a case, the IND sponsor must resolve all outstanding concerns or questions posed by the FDA before the clinical trial can begin. Submission of an IND therefore may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that

the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, or DSMB, which provides authorization for whether a study may move forward at designated check points based on review of certain data from the study, to which only the DSMB has access, and may recommend halting the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the biologic, findings from animal or *in vitro* testing that suggest a significant risk for human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Sponsors of clinical trials of certain FDA-regulated products generally must register and disclose certain clinical trial information to a public registry maintained by the National Institutes of Health, or NIH. In particular, information related to the investigational product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. Although sponsors are also obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The NIH's Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and the government has brought enforcement actions against non-compliant clinical trial sponsors.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1/Phase 1b — The investigational product is initially introduced into healthy human subjects (Phase 1) or directly into patients with the target disease or condition (Phase 1b) for certain therapies targeting severe or life-threatening diseases where the investigational product may be too inherently toxic to administer ethically to healthy volunteers. In either case, these studies are designed to test safety, dosage tolerance, absorption, metabolism, distribution and excretion of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase 2 — The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to assess adverse events and potential side effects. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3 — The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and, if appropriate, to provide an adequate basis for product approval. These 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.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products. Concurrent with clinical trials, companies may complete additional nonclinical studies and develop additional information about the biological characteristics of the program or development candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the program or development candidate and, among other things, must develop methods for testing the identity, strength, quality and

purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the program or development candidate does not undergo unacceptable deterioration over its shelf life.

In the Consolidated Appropriations Act for 2023, Congress amended the FDCA to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug to support marketing authorization, to submit a diversity action plan for such clinical trial. The action plan must include the sponsor's diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. A sponsor must submit a diversity action plan to FDA by the time the sponsor submits the trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect Phase 3 trial planning and timing or what specific information FDA will expect in such plans, but if FDA objects to a sponsor's diversity action plan and requires the sponsor to amend the plan or take other actions, it may delay trial initiation.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials, along with information relating to the product's chemistry, manufacturing, and controls and proposed labeling, are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. A BLA must contain sufficient evidence of the biological program or development candidate's safety, purity, potency and efficacy for its proposed indication or indications. 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. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, as amended, or PDUFA, each BLA must be accompanied by a significant user fee, and the sponsor of an approved BLA is also subject to an annual program fee. The FDA adjusts the PDUFA user fees on an annual basis. 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 BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

According to the goals and policies for original BLAs agreed to by the FDA under PDUFA, the FDA has ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with priority review. For all original BLAs, the ten and six-month time periods run from the filing date; for all other submissions, including resubmissions, efficacy supplements and other supplements, the FDA's stated review time periods, ranging from two to ten month, run from the submission date. Despite these review goals, it is not uncommon for FDA review of a BLA to extend beyond the goal date.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews a BLA to determine, among other things, whether the proposed product is safe, pure, potent and effective for its intended use, and whether the facility (or facilities) in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. Most such applications are meant to be reviewed within ten months from the date it is accepted for filing, and most applications for "priority review" products are meant to be reviewed within six months from the date the application is accepted for filing. The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

The FDA likely will re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process.

The FDA may refer applications for novel biological products or biological products that 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. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making final decisions on approval.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities comply with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more treatment sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL generally outlines the deficiencies that the FDA identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional clinical or other data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing . If a CRL is issued, the applicant may choose to either resubmit the NDA or BLA addressing all of the deficiencies identified in the letter or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA grants regulatory approval of a product, such approval is limited to the conditions of use (e.g., patient population, indication) described in the application and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a risk evaluation and mitigation strategy, or REMS, to ensure the benefits of the product outweigh its risks and to assure the safe use of the drug or biological product. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and 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. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required. The FDA also may condition approval on, among other things, changes to proposed labeling (e.g., the addition of specific contraindications, warnings or precautions) or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the BLA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections and the sponsor pays any required user fees upon submission of the first section of the NDA. In addition, fast track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging from the clinical trial process.

In addition, the FDA may designate a drug or biologic as a "breakthrough therapy" upon a request made by the IND sponsor. A breakthrough therapy is 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. Drugs or biologics designated as breakthrough therapies are also eligible for accelerated approval of their respective marketing applications. The FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings with and providing advice to the product sponsor, which are intended to expedite the development and review of an application for approval of a breakthrough therapy.

Finally, the FDA may designate a product for priority review if it is a drug or biologic that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness over existing therapy. The FDA determines at the time that the marketing application is submitted, on a case- by-case basis, whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months for an original BLA from the date of filing.

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 decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, breakthrough therapy designation and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

Accelerated Approval Pathway

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval from the FDA and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug or biologic when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA will require that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trials to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to expedited withdrawal procedures. Drugs and biologics

granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

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. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug or biologic, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints but has indicated that such endpoints generally may support accelerated approval when the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate long-term clinical benefit of a drug or biologic.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a program or development candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to establish the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, would allow the FDA to withdraw approval of the drug. As part of the Consolidated Appropriations Act for 2023, Congress provided FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under the act's amendments to the FDCA, the FDA may require the sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports are published on FDA's website. The amendments also give FDA the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product.

All promotional materials for programs or development candidates being considered and approved under the accelerated approval program are subject to prior review by the FDA.

Pediatric Trials

Under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of such data or full or partial waivers. The FDCA requires that a sponsor who is planning to submit a marketing application for a drug or biologic product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA, if there is no such meeting, as early as practicable before the initiation of Phase 3 or Phase 2/3 clinical trials. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs. Unless otherwise required by regulation, the PREA does not apply to any product for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic 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 available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use will be disclosed publicly by the FDA; the posting will also indicate whether the drug or biologic is no longer designated as an orphan drug. More than one program or development candidate may receive an orphan drug designation for the same indication. 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 drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to seven years of orphan product exclusivity. During the seven-year exclusivity period, the FDA may not approve any other applications to market a product containing the same active moiety for the same disease, except in very limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A product is clinically superior if it is safer, more effective or makes a major contribution to patient care. Thus, orphan drug exclusivity could block the approval of one of our potential products for seven years if a competitor obtains approval of the same product as defined by the FDA and we are not able to show the clinical superiority of our program or development candidate or if our program or development candidate's indication is determined to be contained within the competitor's product orphan indication. In addition, the FDA will not recognize orphan drug exclusivity if a sponsor fails to demonstrate upon approval that the product is clinically superior to a previously approved product containing the same active moiety for the same orphan condition, regardless of whether or not the previously approved product was designated an orphan drug or had orphan drug exclusivity. A product that has received orphan drug designation may not receive orphan exclusivity if it is approved for a use that is broader than the indication for which it received the designation. Orphan exclusivity does not prevent the FDA from approving a different drug or biological product for the same disease or condition, or the same product for a different disease or condition.

Recent court cases have challenged FDA's approach to determining the scope of orphan drug exclusivity; however, at this time the agency continues to apply its long-standing interpretation of the governing regulations and has stated that it does not plan to change any orphan drug implementing regulations.

Post-Approval Requirements

Any products that we may manufacture or distribute pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, monitoring and record-keeping requirements, reporting of adverse experiences with the product, periodic reporting requirements, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, as well as advertising and promotion requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as off-label use), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the Internet. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval of a new BLA or a supplement, which may require the applicant to develop additional data or conduct additional pre-clinical studies and clinical trials. The FDA may also place other conditions on approvals, including the requirement for a 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.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the quality and long-term stability of the product. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing facilities for our programs and development candidates must meet cGMP requirements and satisfy the FDA or comparable foreign regulatory authorities before any product is approved and our commercial products can be manufactured. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in

accordance with cGMP regulations. These third-party manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers, including third-party manufacturers, and other entities involved in the manufacture and distribution of approved biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our CMOs that may disrupt production or distribution or require substantial resources to correct. In addition, the discovery of conditions that violate these rules, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, voluntary recall and regulatory sanctions as described below.

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, could result in adverse consequences to the Company. Examples of these consequences include, without limitation, the following: 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; complete withdrawal of the product from the market or other limits on marketing or manufacture of the product; imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA 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. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Pediatric exclusivity

Pediatric exclusivity is a type of non-patent marketing exclusivity available in the United States and, if granted, it provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patents. This six-month exclusivity may be granted if a sponsor submits pediatric data that fairly responds to a Written Request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. The issuance of a Written Request does not require the sponsor to undertake the described studies.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic without such alteration or switch. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product, although to date no such products have been approved for marketing in the United States. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed. As part of the Consolidated Appropriations Act for 2023, Congress amended the PHSA in order to permit multiple interchangeable products approved on the same day to receive and benefit from this one-year exclusivity period. If pediatric studies are performed and accepted by the FDA as responsive to a Written Request, the 12-year exclusivity period will be extended for an additional six months. In addition, the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a supplement for the reference product for a subsequent application filed by the same sponsor or manufacturer of the reference product (or licensor, predecessor in interest or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

Other U.S. Health Care Laws and Compliance Requirements

Although we currently do not have any products on the market, our business operations and current and future arrangements with investigators, health care professionals, consultants, third-party payors and customers may be subject to regulation and enforcement by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, or HHS, (such as the Office of Inspector General and the Health Resources and Service Administration), the Department of Justice, or the DOJ, and individual U.S. Attorney offices within the DOJ, and state

and local governments. For example, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal health care programs. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers and purchasers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Further, courts have found that if "one purpose" of remuneration is to induce referrals, the federal Anti-Kickback statute is violated. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices, including our arrangements with physicians, may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

The federal false claims and civil monetary penalty laws, including the False Claims Act, or FCA, which can be enforced by private citizens through civil qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal health care programs, including Medicare and Medicaid, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other health care companies have been, and continue to be, prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. A violation of the Anti-Kickback Statute makes any claim submitted as a result of the violation of the Anti-Kickback Statute a false claim under the FCA. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any health care benefit program, including private third-party payors, willfully obstructing a criminal investigation of a health care offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Like the federal Anti-Kickback Statute, under HIPAA 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.

Also, many states have similar, and typically more prohibitive, fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Additionally, to the extent that our products are approved by and sold in a foreign country, we may be subject to similar foreign laws.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information on certain health care providers, health care clearinghouses, and health plans, known as covered entities, as well as independent contractors, or agents of covered entities that create, receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity, known as a business associates. Among other things, the passage of HITECH made HIPAA's privacy

and security standards directly applicable to business associates. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians, as broadly defined by such law, certain advanced non-physician health care practitioners, and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, such individuals or entities, and to report annually certain ownership and investment interests held by physicians and their immediate family members. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other health care entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Ensuring business arrangements with third parties comply with applicable health care laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state health care laws described above or any other current or future governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual 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, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and integrity oversight if we become subject to a corporate integrity agreement or other 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. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The complex compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a health care company may run afoul of one or more of the requirements.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any programs or development candidates for which we may obtain regulatory approval. In the United States and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the United States,

third-party payors include federal and state health care programs, private managed care providers, health insurers and other organizations. Coverage and adequate reimbursement from governmental health care programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance.

Third-party payors decide which therapeutics they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS. CMS decides whether and to what extent our products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is a covered benefit under its health plan, safe, effective and medically necessary, appropriate for the specific patient, cost-effective and neither experimental nor investigational.

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, we cannot be sure that the level of reimbursement will be adequate. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Limited coverage and less than adequate reimbursement may reduce the demand for, or the price of, any product for which we obtain regulatory approval.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies, and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and biologics, as well as drugs and biologics administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our programs and development candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Additionally, in the United States there is no uniform policy among third-party payors for coverage or reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, one third-party payor's determination to provide coverage for a product does not ensure that other payors will also provide coverage for the product. Adequate third-party payor reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any program or development candidate that we successfully develop.

Many pharmaceutical manufacturers must calculate and report certain price reporting metrics, such as average sales price and best price, to the government, such as average sales price and best price. These prices for drugs or biologics may be reduced by mandatory discounts or rebates required by government health care programs or private payors and by any future relaxation of laws that presently restrict imports of drugs or biologics from countries where drugs may be sold at lower prices than in the United States. Further, certain of our products, if approved, may be administered by a physician. Under currently applicable U.S. law, certain products that are not self-administered by the patient (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain drug and biological products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs or biologicals, the manufacturer is required to participate in other government health care programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires biopharmaceutical 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 therapeutic products furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular program or development candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any programs or development candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide coverage and adequate reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the United States has increased, and we expect will continue to increase, the pressure on health care pricing. The downward pressure on the rise in health care costs has become very intense. Coverage policies and third-party 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.

Health Care Reform

In the United States and some jurisdictions outside the United States, there have been, and continue to be, proposed legislative and regulatory changes to the current health care systems that could prevent or delay marketing approval of programs and development candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell programs and development candidates for which marketing approval is obtained. The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product and therapeutic candidates. 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 otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. Moreover, among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and/or expanding access.

For example, the ACA was enacted in March 2010 and has had a significant impact on the health care industry in the United States. The ACA expanded coverage for the uninsured while at the same time containing overall health care costs. With regard to biopharmaceutical products, the ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program. Additionally, the Creating and Restoring Equal Access to Equivalent Samples Act was enacted on December 20, 2019 to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic product developers access to samples of brand products. Because generic product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on any of our future commercial products are unknown.

Following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court upheld the ACA when it dismissed a legal challenge to the ACA's constitutionality. Further legislative and regulatory changes under the ACA remain possible, but it is unknown what form any such changes or any law would take, and how or whether it may affect the biopharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other health care reform measures, especially with regard to health care access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the United States.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA that affect health care expenditures. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and was extended by the Consolidated Appropriations Act for 2023 and will remain in effect through 2032 unless additional Congressional action is taken.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. In May 2019, DHHS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified a DHHS policy change that was effective January 1, 2019.

More recently, in August 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers, or PBMs, and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services, including any future drug products for which we secure marketing approval.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that

continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Employees and Human Capital Resources

As of December 31, 2022, we had 37 full-time employees, including 25 who hold advanced degrees. Of these employees, 24 were engaged in research and development activities and 13 were engaged in general and administrative activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, training, incentivizing and integrating our existing and new employees, advisors and consultants. We offer a competitive total rewards package, updated in 2022 based on market research. During 2020 through 2022, we also adjusted our practices and processes to support employees in a pandemic environment. We incentivize high performers through an annual bonus program based on our performance for which all employees are eligible. We also offer equity incentive plans, the purpose of which are to attract, retain and reward personnel through the granting of share-based compensation awards in order to increase stockholder value and the success of our company by motivating team members to perform to the best of their abilities and achieve our objectives.

Facilities

We currently lease 11,000 square feet of office and laboratory space in Exton, Pennsylvania under a lease that expires on March 31, 2024. We believe the leased space is sufficient to meet our immediate facility needs, and that any additional space we may require will be available on commercially reasonable terms.

Item 1A. Risk Factors

As noted throughout this Annual Report, we are subject to a number of risks and uncertainties. You should consider and read carefully all the risks and uncertainties described below, as well as other information included in this Annual Report, including our financial statements and related notes appearing at the end of this Annual Report and our "Management's Discussion and Analysis of Financial Conditions and Results of Operations." The risks and uncertainties described below are not the only ones facing us. The occurrence of any of the following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition or results of operations. In such case, the trading price of our common stock could decline, and you may lose all or part of your investment. This Annual Report also contains forward-looking statements and estimates. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks and uncertainties described below.

Risks Related to Our Business

We are a biopharmaceutical company with a history of losses. We expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We are a biopharmaceutical company with a history of losses. Since our inception, we have devoted substantially all of our resources to research and development, raising capital, building our management team and building our intellectual property portfolio, and we have incurred significant operating losses. As of December 31, 2022, we had an accumulated deficit of $116.0 million. Our net loss was $36.9 million and $24.7 million for the years ended December 31, 2022 and 2021, respectively. Substantially all our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. To date, we have not generated any revenue from product sales, and we have not identified or sought or

obtained regulatory approval for the marketing or sale of any product. Furthermore, we do not expect to generate any revenue from product sales for the foreseeable future, and we expect to continue to incur significant operating losses for the foreseeable future due to the cost of research and development activities and the regulatory approval process for our programs and development candidates.

We expect our net losses to increase substantially as we continue our operations; however, the amount of our future losses is uncertain. Our ability to achieve or sustain profitability, if ever, will depend on, among other things, successfully identifying and developing our programs and development candidates, obtaining regulatory approvals for marketing and commercialization, manufacturing on commercially reasonable terms, performance as anticipated by our vendors, entering into additional potential future strategic partnerships and performing and meeting milestones on strategic partnerships, establishing a sales and marketing organization or suitable third-party alternatives for any approved product and raising sufficient funds to finance business activities. If we, or our potential future partners, are unable to commercialize one or more of our programs or development candidates, or if sales revenue from any program or development candidate that receives approval is insufficient, we will not achieve or sustain profitability, which could have a material and adverse effect on our business, financial condition, results of operations and prospects. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

We will need to raise substantial additional funds to advance development of our programs and development candidates and our discovery engine, and we cannot guarantee that we will have sufficient funds available in the future to develop and commercialize them.

The research and development of biopharmaceutical products is capital-intensive. If our programs and development candidates continue to advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our development, regulatory, manufacturing, marketing and sales capabilities. We have used substantial funds to develop our discovery engine and will require significant funds to continue to develop our discovery platform and conduct further research and development, including preclinical studies and clinical trials, to seek regulatory approvals and to manufacture and market products, if any, that are approved for commercial sale. In addition, we incur additional costs associated with operating as a public company.

As of December 31, 2022, we had $20.3 million in cash, which does not include the $30.0 million received in January 2023 upon entry into the Collaboration Agreement with AbbVie. Based on our current operating plan, we believe that our cash as of December 31, 2022, together with the $30.0 million upfront payment received from AbbVie under the Collaboration Agreement, will be sufficient to fund our operations for at least 12 months from the filing date of this Annual Report on Form 10-K. Our future capital requirements and the period for which we expect our existing resources to support our operations may vary significantly from what we expect. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of biopharmaceutical products is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. The timing and amount of our operating expenditures will depend largely on factors discussed in these Risk Factors, including the following:

- the scope, number, timing and progress of preclinical and clinical development activities;
- the price and pricing structure that we are able to obtain from our third-party contract manufacturers to manufacture our preclinical study and clinical trial materials and supplies and other vendors relevant to advancement of our programs;
- the costs involved in obtaining, maintaining, enforcing and defending patents and other intellectual property rights and the resources needed to pursue regulatory approvals;
- our efforts to enhance operational systems, secure sufficient laboratory space and hire additional personnel, including personnel to support development of our programs and development candidates and satisfy our obligations as a public company.

To date, we have primarily financed our operations through the sale of equity securities and our other transaction authority contract with the DoD. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, additional collaborations, strategic alliances, licensing arrangements, government contracts and other marketing arrangements. We cannot assure you that we will be successful in acquiring additional funding at levels sufficient to fund our operations on terms favorable to us. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our preclinical studies, clinical trials, research and development programs or commercialization efforts. Because of the numerous risks and uncertainties associated with the development and commercialization of our programs and development candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated preclinical studies and clinical trials. To the extent that we raise additional capital through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights, future revenue streams or research programs or to grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

We do not expect to realize revenue from product sales (either directly or through our collaborators) in the foreseeable future, if at all, and unless and until they are clinically tested, approved for commercialization and successfully marketed.

We may be unable to advance any of our programs and development candidates through clinical development, obtain regulatory approval and ultimately commercialize them, or we may experience significant delays in doing so, either ourselves or through a partner.

Other than IMM-BCP-01 and IMM-ONC-01, we have no identified development candidates at this time, and we may never identify any or advance them to IND-enabling studies or clinical-stage development. We have no products on the market that have gained regulatory approval and do not currently have any active clinical trials. Our ability to generate revenue and achieve and sustain profitability depends on our ability to continue to identify programs and nominate development candidates, advancing them into preclinical and clinical development and obtaining regulatory approvals for and successfully commercializing them, either alone or through a collaboration.

Before obtaining regulatory approval for the commercial distribution of any programs or development candidates, we, either alone or with or through a collaborator, must conduct extensive preclinical studies, followed by clinical trials to demonstrate their safety and efficacy in humans. We cannot be certain of the timely completion or outcome of our research and development activities or our planned clinical studies, and we cannot predict the actions of the FDA or other regulatory authorities or if further research and development activities will ultimately support the further advancement of our programs and development candidates. Our programs and development candidates are in the early stages, and we are subject to the risks of failure inherent in novel approaches, targets and mechanisms of action.

We submitted an IND for the IMM-BCP-01 program to the FDA in November 2021. In March 2022, the FDA communicated that the clinical study can be initiated for our antibody cocktail for the treatment of SARS-CoV-2 following a brief clinical hold, and we initiated the Phase 1b study of IMM-BCP-01 in patients infected with SARS-CoV-2 in June 2022. On January 6, 2023, we announced that we successfully completed dosing of the first cohort of patients in a Phase 1b study with no significant treatment-related adverse events. We have decided to seek a partner in order to continue the trial and for any further development activities. No assurance can be given that we will be able to find a suitable partner for IMM-BCP-01, that any potential partner will offer us satisfactory partnering terms or that any such partner will have success in its development and commercialization efforts.

We expect to prepare and submit to the FDA an IND for IMM-ONC-01 by mid-2023. However, there can be no assurance that we will be able to do so as anticipated or that we will not face regulatory hurdles.

We may not have the financial resources to continue development of, or to enter into new collaborations for, our programs and development candidates. This may be exacerbated by one or more of the following:

- negative or inconclusive results from our clinical trials or the clinical trials of others for programs and development candidates similar to ours, leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon a program;
- product-related side effects experienced by participants in our clinical trials or by individuals using drugs or therapeutic antibodies similar to ours;
- delays in IND submissions or comparable foreign applications, or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- inadequate supply or quality of components or materials or other supplies necessary for the conduct of our clinical trials;
- poor effectiveness of our development candidates during clinical trials;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial or manufacture site; failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- the FDA or other regulatory agencies interpreting our data differently than we do; or
- adverse impacts caused by the COVID-19 pandemic, which could heighten any of the foregoing risks.

Further, we and any potential future partners may never receive necessary marketing and commercialization approvals from regulatory authorities. Even if we or a potential future partner obtains regulatory approval, the approval may be for targets, disease indications or patient populations not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We or a potential future partner may be subject to post-marketing testing requirements to maintain regulatory approval.

We may not be successful in our efforts to use and expand our discovery engine to build a pipeline.

A key element of our strategy is to use and expand our discovery engine to build a pipeline and progress the pipeline through preclinical and clinical development for the treatment of various diseases. Our scientific research that forms the basis of our discovery efforts based on our discovery engine is ongoing. Further, the scientific evidence to support the feasibility of developing therapeutic antibodies based on our platform has not been established. Our discovery engine may not be proven to be superior to competing technologies. Even if we are successful in building our pipeline, the programs and development 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 products that will receive marketing approval from regulatory authorities or achieve market acceptance. If we or our collaborators do not successfully develop and commercialize programs and development candidates, we will not be able to generate product revenue in the future.

We may pursue particular programs or development candidates; these decisions may prove to be wrong and may adversely impact our business.

In the natural course of progressing our programs and development candidates, we may make decisions about the prioritization of programs and development candidates that may prove to be incorrect. In addition, because we have limited financial and other resources, we may be limited in our ability to pursue all potential programs and development candidates of interest, even if we would otherwise choose to do so if these limitations did not exist. For these reasons,

we may fail to capitalize on viable opportunities. If we do not accurately evaluate the commercial potential or target market for a program or development candidate, we may relinquish valuable rights to it through partnership, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

To date, we have not identified a partner for the IMM-BCP-01 program, and we may not be able to find such a suitable partner in the future, which could impair our ability to derive value from the IMM-BCP-01 program.

We have decided to seek a partner in order to continue our Phase 1b trial for the IMM-BCP-01 program and for any further development activities. As a result of this determination, the primary path available to derive value from the IMM-BCP-01 program is to find a suitable partner for the program. We currently have no agreements or commitments to engage in any specific partnerships. There can be no assurance that we will enter into any partnership as a result of this effort or that a partnership will be able to be consummated upon favorable terms. Furthermore, if we enter into a partnership relating to the IMM-BCP-01 program, our business objectives may change depending upon the nature of the partnership. We cannot predict the impact that a partnership might have on our stock price. We also cannot predict the impact on our stock price if we fail to enter into such a partnership. If we do enter into a partnership regarding the IMM-BCP-01 program, there is no assurance that the partner will be successful in the development of the program as any potential partner would be subject to many of the same risks associated with clinical development set forth in this "Risk Factors" section.

We have obtained rights to use human samples in furtherance of our research and development. However, if we failed to obtain appropriate permission to use these samples or exceed the scope of the permissions given, our program could be adversely affected.

Our discovery process involves gathering tissue samples from humans. While we attempt to ensure that we and our vendors have obtained these samples with all necessary permissions, there is a risk that one or more individuals from whom samples were collected, or their representatives may assert that we have either failed to obtain appropriate permission or exceeded the scope of permission granted. In such circumstances, we could be required to pay monetary damages, to pay a continuing royalty on any products created or invented by analyzing the person's sample or even to cease using the sample and any and all materials derived from or created through analysis of the sample, any of which could result in a change to our business plan and materially harm our business, financial condition, results of operations and prospects. Further, in some cases, these penalties could materially impact the performance, availability, or validity of studies conducted by us or on our behalf. Even in the absence of violations resulting in penalties, regulatory and other authorities may refuse to authorize the conduct or to accept the results of studies for regulatory or ethical reasons, which could impact our ability to progress our program into clinical trials, and peer-reviewed journals may refuse to publish scientific findings, which could limit our ability to disseminate information related to this program.

Clinical trials are expensive, time-consuming and difficult to design and implement.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our programs and development candidates are based on new technologies and discovery approaches, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. For example, IMM-BCP-01 includes a combination of antibodies to prevent or treat the SARS-CoV-2 virus, which complicates the clinical development program, for example by requiring factorial study design to determine the relative contribution of each antibody to the therapeutic activity and require us or our CROs to conduct additional or more complex clinical trials. In addition, costs to treat study participants and to treat potential side effects that may result from our development candidates may be significant. Accordingly, our clinical trial costs are likely to be high and could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Clinical development has an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

It is impossible to predict when or if any of our programs or development candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities, we must, as applicable, complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy in humans. Clinical testing can take many years to complete, and its outcome is inherently uncertain. The results of preclinical studies and early clinical trials of any of our programs and development candidates may not be predictive of the results of later-stage clinical trials. In addition, development candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of pharmaceutical companies have suffered significant setbacks in advanced clinical trials due to lack of efficacy or safety profiles, notwithstanding promising results in earlier trials.

We do not know whether planned preclinical studies and clinical trials will be completed on schedule or at all, or whether planned clinical trials will begin on time, need to be redesigned, enroll participants on time or be completed on schedule, if at all. Our development programs may be delayed for a variety of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- delays in developing suitable assays for screening participants for eligibility for trials with respect to certain programs and development candidates;
- delays in reaching agreement with the FDA, EMA or other regulatory authorities as to the design or implementation of our clinical trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining institutional review board, or IRB, approval at each clinical trial site;
- recruiting suitable participants to participate in a clinical trial and having participants complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites, CROs or other third parties deviating from trial protocol or dropping out of a trial;
- failure to perform in accordance with the FDA's GCP requirements, or applicable regulatory guidelines in other countries;
- any unresolved ethical issues associated with enrolling patients in clinical trials in lieu of prescribing existing treatments that have established safety and efficacy profiles.
- addressing participant safety concerns that arise during the course of a trial, including occurrence of adverse events that are viewed to outweigh potential benefits; or
- having inadequate supply or quality of components or materials or other supplies necessary for the conduct of our preclinical studies or clinical trials.

Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we expect to enter into agreements governing their committed activities, we have limited influence over their actual performance.

As noted above, our IMM-BCP-01 Phase 1b clinical study was suspended. Any additional clinical trial may be suspended or terminated by us, our partners, the IRBs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug or therapeutic biologic, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of any of our programs, the commercial prospects will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval.

If we encounter difficulties enrolling participants in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may not be able to initiate or continue clinical trials for our programs or development candidates if we are unable to locate and enroll a sufficient number of eligible participants to participate in these trials as required by the FDA or other regulatory authorities. The enrollment of participants depends on many factors, including:

- the severity of the disease under investigation;
- the eligibility criteria defined in the clinical trial protocol and the size of the population required for analysis of the trial's primary endpoints;
- the existence of approved antibody therapies, or ones available under Emergency Use Authorizations, for treating similar populations may limit recruitment into the clinical trial;
- the willingness or availability of eligible individuals to participate in our clinical trials;
- the proximity and availability of clinical trial sites;
- the referral practices of physicians;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- perceptions as to the potential advantages of the candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain participant consents; and
- the risk that those enrolled in clinical trials will drop out of the trials before completion.

In addition, our future clinical trials will compete with other clinical trials for programs and development candidates that are in the same therapeutic areas as those being pursued by us, and this competition will reduce the number and types of participants available to us, because some participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is

limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of participants who are available for our clinical trials at such clinical trial sites. Additionally, because we anticipate that some of our oncology clinical trials will be in patients with advanced solid tumors, the patients are typically in the late stages of the disease and may experience disease progression or adverse events independent from our programs and development candidates, making them unevaluable for purposes of the trial and requiring additional enrollment. Delays in enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our pipeline.

Preliminary results from our preclinical studies and clinical trials that we announce or publish from time to time may change as more data becomes available and as the data undergoes audit and verification procedures.

From time to time, we may publish preliminary results from our preclinical studies and clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as enrollment continues and more data becomes available. Preliminary or top-line results 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, interim and preliminary data should be viewed with caution until the final data is available. Differences between preliminary or interim data and final data could significantly affect our business prospects.

If we are unable to obtain approval via the accelerated approval pathway, we may be required to conduct additional preclinical studies or clinical trials. Even if we receive accelerated approval from the FDA, the FDA may seek to withdraw accelerated approval.

We may seek an accelerated approval development pathway (see "Expedited Development and Review Programs" section for discussion about the accelerated approval pathway).

If we choose to pursue accelerated approval, we intend to seek feedback from the FDA or will otherwise evaluate our ability to seek and receive such accelerated approval. After our evaluation of the feedback from the FDA or other factors, we may decide not to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Furthermore, if we submit an application for accelerated approval, there can be no assurance that such application will be accepted or that approval will be granted on a timely basis, or at all. The FDA also could require us to conduct further studies or trials prior to considering our application or granting approval of any type. We might not be able to fulfill the FDA's requirements in a timely manner, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA.

Even if we receive accelerated approval from the FDA, we will be subject to rigorous post-marketing requirements, including the completion of confirmatory post-market clinical trials to verify the clinical benefit of the product, and submission to the FDA of all promotional materials prior to their dissemination. The FDA could seek to withdraw accelerated approval for multiple reasons, including if we fail to conduct any required post-market study with due diligence; a post-market study does not confirm the predicted clinical benefit; other evidence shows that the product is not safe or effective under the conditions of use; or we disseminate promotional materials that are found by the FDA to be false and misleading.

A failure to obtain accelerated approval or any other form of expedited development, review or approval for a program or development candidate that we may choose to develop would delay our commercialization, could increase the cost of development and could harm our competitive position in the marketplace.

We may not elect or be able to take advantage of any expedited development or regulatory review and approval processes available to programs and development candidates granted breakthrough therapy or fast track designation by the FDA.

We intend to evaluate and discuss with the FDA on regulatory strategies that could enable us to take advantage of expedited development pathways for certain of our programs and development candidates. Potential expedited

development pathways that we could pursue include breakthrough therapy and fast track designation (see discussion about those pathways in our "Expedited Development and Review Programs" section).

We cannot assure you that any of our programs or development candidates would be eligible for, or be granted, breakthrough therapy or fast track designation. Breakthrough therapy designation and fast track designation do not change the standards for product approval, and there is no assurance that such designation or eligibility will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the breakthrough therapy designation or fast track designation. Thus, even if we do receive breakthrough therapy or fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw breakthrough therapy or fast track designation if it believes that the product no longer meets the qualifying criteria. Our business may be harmed if we are unable to avail ourselves of, or to maintain, these or any other expedited development and regulatory pathways.

The market may not be receptive to our programs and development candidates, and we may not generate any revenue from their sale, partnering or licensing.

Even if regulatory marketing approval is obtained, we may not generate or sustain revenue from sales of the corresponding product. Market acceptance will depend on, among other factors:

- the timing of our receipt of any marketing and commercialization approvals and the terms of such approvals;
- safety and efficacy;
- limitations or warnings contained in any labeling approved by the FDA or other regulatory authority;
- relative convenience and ease of administration;
- the availability of coverage and adequate government and third-party payor reimbursement and the pricing of our products, particularly as compared to alternative treatments; and
- availability of alternative effective treatments for the disease indications that our programs or development candidates are intended to treat and the relative risks, benefits and costs of those treatments.

If any program or development candidate we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations and prospects.

If the market opportunities for our programs and development candidates are smaller than we believe they are, our future product revenues may be adversely affected, and our business may suffer.

Our understanding of the number of people who suffer from certain types of medical conditions that may be able to be treated with antibodies that have been and may in the future be identified by our discovery engine is based on estimates. These estimates may prove to be incorrect, and new studies may reduce the estimated incidence or prevalence of these diseases. The number of patients in the United States or elsewhere may turn out to be lower than expected or may not be otherwise amenable to treatment. Additionally, patients may become increasingly difficult to identify and access, all of which would adversely affect our business prospects and financial condition. In particular, the treatable population for various oncology indications may further be reduced if our estimates of addressable populations are erroneous or sub-populations of patients do not derive benefit from our programs and development candidates.

Further, there are several factors that could contribute to making the actual number of participants in clinical studies less than the potentially addressable market. These include the lack of widespread availability of, and limited reimbursement for, new therapies in many underdeveloped markets.

If we or others identify undesirable side effects caused by a program or development candidate undergoing clinical trials, our ability to market and derive revenue from the program or development candidate could be compromised.

Undesirable side effects caused by any programs or development candidates could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these side effects. In such an event, our trials could be suspended or terminated, and the FDA or other regulatory authorities could order us to cease further development of or deny approval of a program or development candidate for any or all targeted indications. Such side effects could also affect recruitment or the ability of enrolled participants to complete the trial or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business and financial condition and impair our ability to generate revenues.

Further, clinical trials by their nature utilize a sample of the potential population. With a limited number of participants and limited duration of exposure, rare and severe side effects of a program or development candidate may only be uncovered when a significantly larger number of participants are exposed to the program and development candidate or when participants are exposed for a longer period of time.

In the event that any of our programs or development candidates receive regulatory approval and we or others identify undesirable side effects caused by one of these products, any of the following adverse events could occur, which could result in the loss of significant revenue to us and materially and adversely affect our results of operations and business:

- regulatory authorities may withdraw their approval of the product, seize the product or additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be required to recall the product, change the way the product is administered, conduct additional preclinical studies or clinical trials or change the labeling of the product;
- we may be sued, subject to fines, injunctions or the imposition of civil or criminal penalties; and
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication or a limitation on the indications for use or impose restrictions on the distribution in the form of a Risk Evaluation and Mitigation Strategy, or REMS, in connection with approval.

If any of our programs or development candidates is approved for marketing and commercialization in the future and we are unable to develop sales, marketing and distribution capabilities on our own or enter into agreements with third parties to perform these functions on acceptable terms, we will be unable to successfully commercialize any such future products.

We currently have no sales, marketing or distribution capabilities or experience. We will need to develop internal sales, marketing and distribution capabilities to commercialize each program and development candidate that gains FDA approval, which would be expensive and time-consuming, or enter into strategic partnerships with third parties to perform these services. If we decide to market any approved products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market any approved products or decide to co-promote products with partners, we will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for any approved product. If we are not successful in commercializing any product approved in the future, either on our own or through third parties, our business and results of operations could be materially and adversely affected.

Additional regulatory burdens and other risks and uncertainties in foreign markets may limit our growth.

Our future growth may depend, in part, on our ability to engage in development and commercialization efforts in foreign markets for which we may rely on strategic partnership with third parties. We will not be permitted to market or promote any program or development candidate before we receive regulatory approval from the applicable regulatory authority in a foreign market, and we may never receive such regulatory approval. To obtain separate regulatory approval in foreign countries, we generally must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of a program or development candidate, and we cannot predict success in these jurisdictions. If we obtain approval of any of our programs or development candidates and ultimately commercialize any such program or development candidate in foreign markets, we would be subject to risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries.

Our business entails a significant risk of product liability, which may not be sufficiently covered by our insurance.

As we move into conducting preclinical studies and clinical trials, we will be exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of antibody 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 investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs and potentially 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, substantial monetary awards to trial participants or patients and a decline in our stock price. 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, our partners or 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 a material and adverse effect on our business, financial condition, results of operations and prospects.

If we choose to pursue strategic transactions, we may not be able to enter into such transactions on acceptable terms, if at all, which could adversely affect our development and commercialization activities, impact our cash position, increase our expense, and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as collaborations like our recently announced Collaboration Agreement with AbbVie, acquisitions of companies, asset purchases, joint ventures and out- or in-licensing. For example, we will evaluate and, if strategically attractive, may seek to enter into collaborations, including with biotechnology or biopharmaceutical companies or hospitals. The competition for partners is intense, and the negotiation process is time-consuming and complex. If we desire to enter into strategic transactions but are not able to do so, we may not have access to the required liquidity or expertise to further develop our programs and development candidates or our discovery engine. Any such collaboration, or other strategic transaction, may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. We may acquire additional technologies and assets, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business, but we may not be able to realize the benefit of acquiring such assets. Conversely, any new collaboration that we do enter into may be on terms that are not optimal for us. These transactions would entail numerous operational and financial risks, including:

- exposure to unknown liabilities and higher-than-expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses; and

- disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, programs or technologies, including impairment of relationships

with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and our business could be materially harmed by such transactions. Conversely, any failure to enter any collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our programs and development candidates and have a negative impact on the competitiveness of any program or development candidate that reaches market.

In addition, to the extent that AbbVie or any of our future partners were to terminate a collaboration agreement, we may be forced to independently develop our programs and development candidates, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and maintaining, enforcing and defending intellectual property rights, or, in certain instances, abandoning any program or development candidate altogether, any of which could result in a change to our business plan and materially harm our business, financial condition, results of operations and prospects.

There is no guarantee that our collaboration with AbbVie will result in the successful discovery and validation of targets for further development and commercialization by AbbVie.

Related to the AbbVie collaboration, there is no guarantee that our discovery engine will successfully discover and validate targets, or that such targets may become the subject of further successful development and commercialization by AbbVie. Additionally, if there is any conflict, dispute, disagreement, or issue of nonperformance between us and AbbVie regarding our rights or obligations under the Collaboration Agreement, AbbVie may have a right to terminate the agreement or reduce the payments due to us thereunder.

If third parties on which we intend to rely to conduct our current and future preclinical and clinical studies do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our programs could be delayed with material and adverse impacts on our business and financial condition.

We intend to continue to rely on third-party clinical investigators, contract research organizations, or CROs, clinical data management organizations and consultants to design, conduct, supervise and monitor certain preclinical studies and any clinical trials. Because we intend to rely on these third parties and will not have the ability to conduct certain preclinical studies or clinical trials independently, we will have less control over the timing, quality and other aspects of such preclinical studies and clinical trials than we would have had we conducted them on our own. These investigators, CROs and consultants will not be our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

The FDA requires certain preclinical studies to be conducted in accordance with good laboratory practices and clinical trials must be conducted in accordance with good clinical practices, including for designing, conducting, recording and reporting the results of preclinical studies and clinical trials to ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control will not relieve us of these responsibilities and requirements. Any adverse development or delay in our clinical trials could have a material and adverse impact on our commercial prospects and may impair our ability to generate revenue.

Because we may rely on third parties for manufacturing, supply and testing, some of which may be sole source vendors, for preclinical and clinical development materials and commercial supplies, our supply may become limited or interrupted or may not be of satisfactory quantity or quality.

We rely on third-party contract manufacturers for our preclinical and future clinical trial product materials and commercial supplies. We do not intend to produce any meaningful quantity of materials needed for preclinical and clinical development through our internal resources, and we do not currently own manufacturing facilities for producing such supplies. While we intend to try to avoid sole-source arrangements with any of our manufacturing, supply and testing vendors, it may not always be possible to do so. We cannot assure you that our preclinical or future clinical development product supplies and commercial supplies will not be limited or interrupted, especially with respect to any sole source third-party manufacturing and supply partners or will be of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a program or development candidate is subject to FDA and other regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMP. In the event that any of our future manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on reasonable terms, or at all. In some cases, the technical skills or technology required for manufacture may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our materials. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop in a timely manner or within budget.

If we are unable to obtain or maintain third-party manufacturing for any program or development candidate, or to do so on commercially reasonable terms, we may not be able to complete our development and commercialization efforts successfully. Our or a third party's failure to execute on our manufacturing requirements and comply with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials;
- delay in submitting regulatory applications, or receiving regulatory approvals;
- loss of the cooperation of a potential future partner;
- subjecting third-party manufacturing facilities or our potential future manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches; and
  in the event of approval to market and commercialize a product, an inability to meet commercial demands.

We may be unable to successfully scale manufacturing in sufficient quality and quantity, which would delay or prevent us from completing our development and commercialization efforts, if any.

In order to conduct our research and development efforts, including clinical trials, for our programs and development candidates, we will need to manufacture large quantities. If any programs or development candidates are commercialized, we will need to scale up our manufacturing efforts even further. We currently expect to continue to use third parties for our manufacturing needs, as we do not currently have, nor do we currently intend to establish, our own manufacturing capacity. Our manufacturing partners may be unable to successfully increase the manufacturing capacity for any program or development candidate in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities and our manufacturers may fail to perform under their contracts with us, which could result in an unexpected need to change manufacturers. If we or our manufacturing partners are unable to successfully

scale the manufacture at any stage, in sufficient quality and quantity, the development, testing and clinical trials of that program or development candidate may be delayed or infeasible, and regulatory approval or commercial launch of any potential resulting product may be delayed or not obtained, which could significantly harm our business.

Our significant reliance on third-party vendors could impair our ability to implement our business plan.

We rely on, and expect to continue to rely on, third-party vendors for many aspects of our business. We depend on these third parties, and likely will continue to depend on them, to perform their obligations in a timely manner consistent with contractual and regulatory requirements. We may also need to rely on certain vendors as our sole source for manufacturing or other services, establishing additional or replacement sole source vendors, if required, may not be accomplished quickly. If we are unable to make arrangements with a vendor for a particular need, or maintain our relationship with that vendor, on commercially reasonable terms, we may not be able to develop and commercialize our programs or development candidates successfully or operate our business as we intend, which could harm our business, result of operations, financial condition and prospects.

Any inability to attract and retain qualified key management, technical personnel and employees would impair our ability to implement our business plan.

Our success largely depends on the continued service of key management, advisors and other specialized personnel. While we have a written employment agreement with our management team and each of our key employees, those employment arrangements are at-will and could be terminated at any time. The loss of one or more members of our executive team, management team or other key employees or advisors could delay our research and development programs and have a material and adverse effect on our business, financial condition, results of operations and prospects. We do not currently maintain "key man" insurance on any of our executive officers.

The relationships that our key management team members have cultivated within our industry make us particularly dependent upon their continued employment with us. We are dependent on the continued service of our technical personnel because of the highly technical nature of our programs, development candidates and technologies and the specialized nature of the regulatory approval process. Our future success will depend in large part on our continued ability to attract and retain other highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation and commercialization. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations.

As of December 31, 2022, we had 37 full-time employees. Our focus on the development of our programs and development candidates will require adequate staffing. We may need to hire and retain new employees to execute our future clinical development and manufacturing plans. We cannot provide assurance that we will be able to hire or retain adequate staffing levels to advance our platform, develop our programs or development candidates or run our operations or to accomplish our objectives.

We may experience difficulties in managing our growth and expanding our operations.

We have limited experience in product development or clinical trials. As our programs and development candidates enter and advance through preclinical studies and any clinical trials, we will need to expand our development, regulatory and manufacturing capabilities or contract with other organizations to provide these capabilities for us. We may also experience difficulties in the discovery and development of new programs and development candidates using our discovery engine if we are unable to meet demand as we grow our operations. In the future, we also expect to have to manage additional relationships with collaborators, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures and secure adequate facilities for our operational needs. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls.

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

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state health care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, 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. Such misconduct 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. For example, individuals conducting the non-interventional clinical studies that we sponsor through which we obtain antibodies for development into potential antibody-based therapeutics may violate applicable laws and regulations regarding personal data. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business and financial condition, including the imposition of significant criminal, civil, and administrative fines or other sanctions, such as monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded health care programs, such as Medicare and Medicaid, integrity obligations, reputational harm and the curtailment or restructuring of our operations.

A cyber-attack or breach of our information technology systems could cause substantial costs, significant liabilities, harm to our brand and business disruption and/or a material adverse effect on our business.

In connection with the Immunome discovery engine and efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. Although we have extensive measures in place to prevent the sharing and loss of personal data in our sample collection process associated with our discovery platform, any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by HITECH), and international law (e.g., the GDPR). We rely on information technology and other internal infrastructure systems that we or our third-party vendors operate to process, transmit and store electronic information in our day-to-day operations. The size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy, systems failure or other significant disruption. Additionally, we are aware that hackers have been targeting health care organizations and businesses working to develop treatments for COVID-19 and vaccines against the SARS-CoV2 virus. Our prior work to develop IMM-BCP-01 may make us a more attractive target for a cyber-attack. A successful attack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. We have invested in our systems and the protection and recoverability of our data to reduce the risk of an intrusion or interruption, and we monitor and test our systems on an ongoing basis for any current or potential threats. There can be no assurance that these measures and efforts will prevent future interruptions or breakdowns. If we or our third-party vendors fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to these systems, we or our third-party vendors could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with physicians, clinical trial participants and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research, development and manufacturing involve the use of hazardous materials and various flammable and toxic chemicals. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe our procedures for storing, handling and disposing of these materials in our facilities comply with the relevant guidelines of the Commonwealth of Pennsylvania and the Occupational Safety and Health Administration of the U.S. Department of Labor, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for substantial resulting damages. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of animals and biohazardous materials. Our workers' compensation insurance may not provide adequate coverage against costs and expenses we may incur due to injuries to our employees resulting from the use of these materials. Our current environmental liability insurance covering certain of our facilities could be inadequate for all environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Our current laboratory operations are concentrated in one location, and we or the third parties upon whom we depend on may be adversely affected by natural or other disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current business operations are concentrated in the greater Philadelphia area. Any unplanned event, such as flood, fire, explosion, extreme weather condition, medical epidemics, including any potential effects from a pandemic, such as the COVID-19 pandemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities or the manufacturing facilities of our third-party contract manufacturers, or lose our repository of blood-based and other valuable laboratory samples, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development efforts or interruption of our business operations. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. In addition, terrorist acts or acts of war targeted at the United States, and specifically the greater Philadelphia area, could cause damage or disruption to us, our employees, facilities, partners and suppliers, The disaster recovery and business continuity plan we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business and financial condition.

A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, could materially and adversely affect our business and our financial results and cause a disruption to our research, development and commercialization efforts.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. Notably, the COVID-19 pandemic continues to evolve. The extent to which COVID-19 impacts our operations or those of our collaborators, vendors and other material business relations will depend on future developments, which are highly

uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the virus and the actions to contain it or treat its impact, among others.

We previously implemented work-from-home policies to support the community efforts to reduce the transmission of COVID-19 and protect employees, and these work-from-home policies continue in effect to the degree that we believe to be appropriate, tailored to the role of each team member; this policy continues to evolve as the specific conditions associated with COVID-19 evolve. We also implemented a number of measures to ensure employee safety and business continuity. While many restrictions in Pennsylvania and other locations in which we have employees or independent contractors have been lifted or continue to be relaxed and phased re-openings were implemented, these restrictions may be re-implemented, or new restrictions imposed if rates or incidence of infection increase.

The spread of COVID-19 could also have adverse economic impacts to us. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic, have been, and continue to be, difficult to assess or predict, the spread of COVID-19 has caused a broad impact globally.

The ongoing COVID-19 pandemic continues to evolve. The extent to which the COVID-19 pandemic may impact our business continues to be highly uncertain and cannot be predicted with confidence.

Unfavorable global economic and political conditions could adversely affect our business, financial condition or results of operations.

The results of our operations could be adversely affected by general conditions in the global economy, the global financial markets and the global political conditions. The United States and global economies are facing growing inflation, higher interest rates and potential recession. Furthermore, a severe or prolonged economic downturn, including a recession or depression or political disruption such as the war between Ukraine and Russia could result in a variety of risks to our business, including weakened demand for our programs and development candidates, if approved, relationships with any vendors or business partners located in affected geographies and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

In addition, actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Furthermore, concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult to acquire financing on acceptable terms or at all. Any decline in available funding or access to cash and liquidity resources could, among other risks, adversely impact our and our vendors', collaborators' and other business relations' ability to meet operating expenses, financial obligations or fulfill other obligations, potentially resulting in breaches of financial and/or contractual obligations and/or result in violations of federal or state wage and hour laws. Any of these impacts could have material adverse impacts on our business operations, financial condition and results of operations.

The impact of the Russian invasion of Ukraine on the global economy, energy supplies and raw materials is uncertain, but may prove to negatively impact our business and operations.

The short and long-term implications of Russia's invasion of Ukraine are difficult to predict at this time. We continue to monitor any adverse impact that the outbreak of war in Ukraine and the subsequent institution of sanctions against Russia by the United States and several European and Asian countries may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and customers. For example, a prolonged conflict may result in challenges associated with timely receipt of customer payments and banking

transactions, supply-chain issues, increased inflation, escalating energy prices and constrained availability, and thus increasing costs, of raw materials. We will continue to monitor this fluid situation and develop contingency plans as necessary to address any disruptions to our business operations as they develop. To the extent the war in Ukraine may adversely affect our business as discussed herein, it may also have the effect of heightening many of the other risks described herein. Such risks include, but are not limited to, adverse effects on macroeconomic conditions, including inflation; disruptions to our global technology infrastructure, including through cyber-attack, ransom attack, or cyber-intrusion; adverse changes in international trade policies and relations; our ability to maintain or increase our product prices; disruptions in global supply chains; our exposure to foreign currency fluctuations; and constraints, volatility, or disruption in the capital markets, any of which could negatively affect our business and financial condition.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our technology, programs and development candidates, or if our intellectual property rights are inadequate, we may not be able to compete effectively.

Our success depends in part on our ability to obtain and maintain protection for our owned and in-licensed intellectual property rights and proprietary technology. We rely on patents and other forms of intellectual property rights, including in-licenses of intellectual property rights and biologic materials of others, to protect our discovery engine, pipeline, manufacturing methods, and methods for treating patients.

We in-license exclusive rights, including patents and patent applications, relating to the Immunome discovery engine Patent applications for this in-licensed technology are still pending before the U.S. Patent and Trademark Office and other national patent offices. There is no guarantee that such patent applications will be issued as patents, nor any guarantee that issued patents will provide adequate protection for the in-licensed technology or any meaningful competitive advantage.

We also own 13 national phase patent applications, including in the United States, on our own technology relating to the Immunome discovery engine. There is no guarantee that any patent covering this technology will issue from the patent application we own, or, if it does, that the issued claims will provide adequate protection for the Immunome discovery engine or any meaningful competitive advantage.

In addition, under our collaboration agreements, we may be required to disclose and assign certain inventions that we conceive or reduce to practice in performing the agreement. If we fail to strictly follow these requirements, or if there is a dispute with regard to ownership of inventions under any collaboration agreement, the Company could be subject to adverse consequences, such as termination or reductions in economics to the Company.

We currently own 68 and in-license 14 pending national phase non-provisional patent applications in connection with our pipeline. We have filed seven provisional patent applications in the United States and three Patent Cooperation Treaty, or PCT, patent applications in connection with antibodies identified by the Immunome discovery engine, related antibody variants, and their methods of use. Subject matter disclosed in a United States provisional patent application is not eligible to be issued in a patent until, among other things, we file a corresponding non-provisional patent application within 12 months of the filing date of the provisional patent application. If we do not timely file non-provisional patent applications, we may lose our priority dates with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. A PCT patent application is an international patent application and a type of non-provisional patent application but one that does not directly mature into a granted patent. A PCT patent application must enter the national phase, be filed in the patent office of a PCT member country or region where it is examined and from which a country patent may or may not be granted. If a PCT national phase application is not filed in a PCT member country or region, no patent will result in that country or region from that particular PCT patent application. We expect to file PCT national phase applications in commercially appropriate countries or regions based upon factors such as the invention that is the subject of the application, likely patentability, country laws regarding patent eligibility and business opportunity but do not expect to file PCT national phase applications in all PCT member countries or regions and may forgo national phase filing for a given PCT patent application. Moreover, there is no guarantee that any current or future patent applications will result in the issuance of patents that will effectively protect

the Immunome discovery engine or our programs or development candidates or will effectively prevent others from commercializing competitive products.

The patent prosecution process is expensive, complex and time-consuming. Patent license negotiations also can be complex and protracted, with uncertain results. We may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own, or in-license may fail to result in issued patents, and, even if they do issue as patents, such patents may not cover our current or future technologies, programs or development candidates in the United States or in other countries or provide sufficient protection from competitors. In addition, because the coverage claimed in a patent application can be significantly reduced before the patent is issued, any patent that issues may not provide sufficient scope to exclude competitors, which may materially harm our business.

We may be unaware of prior art that could be used to invalidate an issued patent or to prevent our owned or in-licensed pending patent applications from being issued as patents. While we strive to ensure patentability, there is no guarantee that all relevant prior art relating to our owned or in-licensed patents and patent applications has been found. For example, publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, and in some cases not at all. We also cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or in-licensed patents or pending applications, or that we or our licensors were the first to file for patent protection of such inventions. Prior art may be used to invalidate our patents or narrow their scope of protection. Any such invalidation or narrowing of our patent rights, including in-licensed patent rights, could materially harm our business.

The patent positions of biopharmaceutical companies are generally uncertain because they may involve complex legal and factual considerations that have, in recent years, been the subject of legal development and change. As a result, the issuance, scope, validity, enforceability and commercial value of our pending patent rights are uncertain. The standards applied by the United States Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always certain and moreover, are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in patents. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our owned or in-licensed patents or narrow the scope of our patent protection.

Even if patents do successfully issue and even if such patents cover our current or any future technologies, programs or development candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful development and commercialization of any current or future technologies, programs or development candidates that we may develop. Likewise, if patent applications we own or have in-licensed fail to issue, if their breadth or strength is threatened, or if they fail to provide meaningful exclusivity, other companies could be dissuaded from collaborating with us. Lack of valid and enforceable patent protection could threaten our ability to commercialize current or future products and could prevent us from maintaining exclusivity with respect to the invention or feature claimed in the patent applications. Any failure to obtain or any loss of patent protection could have a material adverse impact on our business and ability to achieve profitability. We may be unable to prevent competitors from entering the market with a product that is similar to or the same as our programs or development candidates.

The filing of a patent application or the issuance of a patent is not conclusive as to its ownership, inventorship, scope, patentability, validity or enforceability. Issued patents and patent applications may be challenged in the courts and in the patent office in the United States and abroad. For example, our applications or applications filed by our licensors may be challenged through third-party submissions, opposition or derivation proceedings. By further example, our issued patents or the issued patents we in-license may be challenged through reexamination, *inter partes* review or post-grant review proceedings before the patent office, or in declaratory judgment actions or counterclaims. An adverse determination in any such submission, proceeding or litigation could prevent the issuance of, reduce the scope of, invalidate or render unenforceable our owned or in-licensed patent rights; limit our ability to stop others from using or

commercializing similar or identical platforms and products; allow third parties to compete directly with us without payment to us; or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or in-licensed patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize programs or development candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, some of our owned and in-licensed patents and patent applications are or may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent application, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. We may need the cooperation of any such co-owners of our patents to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business prospects and financial conditions.

Our in-licensed patent rights from academic institutions are subject to a standard research purpose reservation of rights by one or more third parties. In addition, the academic institutions may co-own rights with a governmental entity. As a result, the U.S. government may have certain rights, including so-called march-in rights, to such patent rights and any products or technology developed from such patent rights. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a nonexclusive license authorizing the U.S. government to use the invention for non-commercial purposes. These rights may permit the U.S. government to disclose our confidential information to third parties and to exercise march-in rights to use or to allow third parties to use our licensed technology. The U.S. government can exercise its march-in rights if it determines that action is necessary because we fail to achieve the practical application of government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in any such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the U.S. government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

If we fail to comply with our obligations under any license, collaboration or other intellectual property-related agreements, we may be required to pay damages and could lose intellectual property rights that may be necessary for developing, commercializing and protecting our current or future technologies or we could lose certain rights to grant sublicenses.

We are reliant upon in-licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the Immunome discovery engine and advancement of our programs and development candidates.

Our current license agreements impose, and any future license agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license. License termination could result in a material adverse effect on our inability to develop, manufacture and sell products that are covered by the licensed technology or could enable a competitor to gain access to the licensed technology. In certain circumstances, our licensed patent rights are subject to our reimbursing our licensors for their patent prosecution and maintenance costs. For example, our license agreements with Whitehead and TJU each require us to bear the costs of filing and maintaining patent applications, and our agreement with Arrayjet requires us to reimburse Arrayjet for applicable patent costs.

Furthermore, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications that we license from third parties. For example, pursuant to our license agreements with Whitehead and TJU, while we may comment on patent applications and may lead enforcement of the patents and patent applications, the licensing institution is responsible for the preparation, filing, prosecution and

maintenance and defense of the patents and patent applications; Arrayjet also retains prosecution and enforcement rights of the patents we license from Arrayjet. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, and defended in a manner consistent with the best interests of our business. If our licensors and future licensors fail to prosecute, maintain, enforce and defend patents we may license, or lose rights to licensed patents or patent applications, our license rights may be reduced or eliminated. In such circumstances, our right to develop and commercialize any of our programs or development candidates that is the subject of such licensed rights could be materially adversely affected.

Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor's intellectual property rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products if infringement or misappropriation were found, those amounts could be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to disagreement regarding 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 impact on our business and ability to achieve profitability. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize any affected programs or development candidates, which could have a material adverse effect on our business and financial conditions.

Patent terms may not be able to protect our competitive position for an adequate period of time with respect to our current or future technologies, programs or development candidates.

Patents have a limited lifespan. In the United States, the standard patent term is typically 20 years after filing. Various extensions may be available. Even so, the life of a patent and the protection it affords are limited. As a result, our owned and in-licensed patent portfolio provides us with limited rights that may not last for a sufficient period of time to exclude others from commercializing products similar or identical to ours. For example, given the large amount of time required for the research, development, testing and regulatory review of new programs and development candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Extensions of patent term are available, but there is no guarantee that we would succeed in obtaining any particular extension — and no guarantee any such extension would confer patent term for a sufficient period of time to exclude others from commercializing products similar or identical to ours. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). A patent term extension cannot extend the remaining term of a patent beyond 14 years from the date of product approval; only one patent may be extended; and extension is available for only those claims covering the approved drug, a method for using it, or a method for manufacturing it. The applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. An extension may not be granted or may be limited where there is, for example, a failure to exercise due diligence during the testing phase or regulatory review process, failure to apply within applicable deadlines, failure to apply before expiration of relevant patents, or some other failure to satisfy applicable requirements. If this occurs, our competitors may be able to launch their products earlier by taking advantage of our investment in development and clinical trials along with our clinical and preclinical data. This could have a material adverse effect on our business and ability to achieve profitability.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current or any future technologies, programs or development candidates.

Changes in either the patent laws or interpretation of the patent laws in the United States or elsewhere could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. The United States has enacted and implemented wide-ranging patent reform legislation. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law, which could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation and switch the U.S. patent system from a "first-to-invent" system to a "first-to-file" system. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. These provisions also allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to challenge the validity of a patent by the USPTO administered post grant proceedings, including derivation, reexamination, *inter partes* review, post-grant review and interference proceedings. The USPTO developed additional regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and, in particular, the first-to-file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our issued owned or in-licensed patents, all of which could have a material adverse impact on our business prospects and financial condition.

As referenced above, for example, courts in the United States continue to refine the heavily fact-and-circumstance-dependent jurisprudence defining the scope of patent protection available for therapeutic antibodies, narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This creates uncertainty about our ability to obtain patents in the future and the value of such patents. We cannot provide assurance that future developments in U.S. Congress, the federal courts and the USPTO will not adversely impact our owned or in-licensed patents or patent applications. The laws and regulations governing patents could change in unpredictable ways that could weaken or prevent our and our licensors' ability to obtain new patents or to enforce our existing owned or in-licensed patents and patents that we might obtain or in-license in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may have a material adverse effect on our and our licensors' ability to obtain new patents or to protect and enforce our owned or in-licensed patents or patents that we may obtain or in-license in the future.

Other companies or organizations may challenge our or our licensors' patent rights or may assert patent rights that prevent us from our development and commercialization efforts.

As the field of antibody-based therapeutics continues to mature, patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue, and, if they do, when, to whom, and with what claims. In addition, third parties may attempt to invalidate our or our licensors' intellectual property rights. Even if such rights are not directly challenged, disputes could lead to the weakening of our or our licensors' intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management, and could have a material and adverse impact on our profitability, financial condition and prospects or ability to successfully compete.

Further, we cannot guarantee that we are aware of all patents and patent applications potentially relevant to our technology or products. We may not be aware of potentially relevant third-party patents or applications for several reasons. For example, U.S. applications filed before November 29, 2000, and certain U.S. applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such

earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our programs, development candidates or platform technologies could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform, our programs or development candidates, or the use of our technologies.

Thus, it is possible that one or more third parties will hold patent rights to which we will need a license, which may not be available on reasonable terms or at all. If such third parties refuse to grant us a license to such patent rights on reasonable terms or at all, we may be required to expend significant time and resources to redesign our technology, programs, development candidates or the methods for manufacturing them, or to develop or license replacement technology, all of which may not be commercially or technically feasible. In such case, we may not be able to market such technology programs or development candidates and may not be able to perform research and development or other activities covered by these patents. This could have a material adverse effect on our ability to commercialize and our business and financial condition.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents on current or future technologies, programs or development candidates in all countries throughout the world would be prohibitively expensive. Competitors or other third parties may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export infringing products to territories where we have patent protection or licenses, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Additionally, the laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States. Many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, including certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our owned and in-licensed patents or the marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our owned or in-licensed intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and could divert our efforts and attention from other aspects of our business. Such proceedings could also put our owned or in-licensed patents at risk of being invalidated or interpreted narrowly, could put our owned or in-licensed patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuits or other adversarial proceedings that we or our licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our and our licensors' efforts to enforce such intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or in-license.

Further, 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 its patents. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business prospects may be materially adversely affected.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse impact on the success of our business.

Our commercial success depends, in part, upon our ability or the ability of our potential future collaborators to develop, manufacture, market and sell any programs or development candidates and to use our and their proprietary technologies without infringing, misappropriating or violating the proprietary and intellectual property rights of third

parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights.

We or our licensors, or any future strategic partners, may be party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights. In some instances, we may be required to indemnify our licensors for the costs associated with any such adversarial proceedings or litigation. Third parties may assert infringement claims in litigation or other adversarial proceedings against us, our licensors or our strategic partners based on existing patents or patents that may be granted in the future, regardless of their merit. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a material adverse impact on our ability to utilize the Immunome discovery engine or to commercialize any programs or development candidates. Further, we cannot guarantee that we will be able to successfully settle or otherwise resolve such adversarial proceedings or litigation. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or to continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in our marketing efforts. If we, or our licensors, or any future strategic partners are found to infringe, misappropriate or violate a third-party patent or other intellectual property rights, we could be required to pay damages, including treble damages and attorney's fees, if we are found to have willfully infringed. In addition, we, or our licensors, or any future strategic partners may choose to seek, or be required to seek, a license from a third party, which may not be available on commercially reasonable terms, if at all. Even if a license can be obtained on commercially reasonable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us, and we could be required to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease utilizing, developing, manufacturing and commercializing the Immunome discovery engine or programs or development candidates deemed to be infringing. We may be forced to redesign current or future technologies or products. Any of the foregoing could have a material adverse effect on our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

In addition, we or our licensors may find it necessary to pursue claims or to initiate lawsuits to protect or enforce our owned or in-licensed patent or other intellectual property rights. The cost to us in defending or initiating any litigation or other proceeding relating to our owned or in-licensed patent or other intellectual property rights, even if resolved in our favor, could be substantial, and any litigation or other proceeding could divert our management's attention. Such litigation or proceedings could materially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Some of our competitors may be able to more effectively sustain the costs of complex patent litigation because they may have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and materially limit our ability to continue our operations. Furthermore, because of the substantial amount of discovery required in connection with certain such proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, such announcements could have a material adverse effect on the price of our common stock.

If we or our licensors were to initiate legal proceedings against a third party to enforce a patent covering one of our programs or development candidates or our technology, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, claiming patent-ineligible subject matter, lack of novelty, indefiniteness, lack of written description, non-enablement, anticipation or obviousness. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome of such invalidity and unenforceability claims is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we or our licensors and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection for one or more of our programs or development candidates or certain aspects of our platform technology. Such a loss of patent protection could have a material adverse effect on our business, financial condition, results of operations and prospects. Patents and other intellectual property rights also will not protect our programs, development candidates and

technologies if competitors or third parties design around them without legally infringing, misappropriating or violating our owned or in-licensed patents or other intellectual property rights.

Intellectual property rights of third parties could adversely affect our ability to commercialize our technologies, programs or development candidates, and we might be required to litigate or obtain licenses from third parties to engage in development or marketing efforts, which may not be available on commercially reasonable terms or at all.

Because the antibody therapeutics landscape is still evolving, it is difficult to conclusively assess our freedom to operate without infringing, misappropriating or violating third-party rights. There are numerous companies that have pending patent applications and issued patents broadly covering antibodies generally or covering antibodies directed against the same targets as, or targets similar to, those we are pursuing. Our competitive position may materially suffer if patents issued to third parties or other third-party intellectual property rights cover our technologies programs and development candidates or elements thereof or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize current or future technologies, programs and development candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by our current or future technologies or programs and development candidates. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our current or future technologies or programs and development candidates. Additionally, claims in pending patent applications, subject to certain limitations, can be amended in a manner that could cover the Immunome discovery engine, our programs and development candidates, or the use of our technologies. If a third-party infringement claim should successfully be brought, we may be required to pay substantial damages or be forced to abandon our current or future technologies or programs and development candidates or to seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

Third party intellectual property right holders may also actively bring infringement, misappropriation or violation or other claims alleging violations of intellectual property rights against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or to continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our programs and development candidates. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our current or future technologies or programs and development candidates that are held to be infringing, misappropriating or otherwise violating third-party intellectual property rights. We might, if possible, also be forced to redesign current or future technologies or programs and development candidates so that we no longer infringe, misappropriate or violate the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business, which could have a material adverse effect on our financial condition and results of operations.

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

We consider trade secrets, including confidential and unpatented know-how, important to the maintenance of our competitive position. However, trade secrets and know-how can be difficult to protect. We protect and plan to protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants under which they are obligated to maintain confidentiality and to assign their inventions to us. Despite these efforts, we may not obtain these agreements in all circumstances. Moreover, individuals with whom we have such agreements may breach such agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for any such breaches. We may also become involved in inventorship disputes relating to inventions

and patents developed by our employees or consultants under such agreements. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret or securing title to an employee- or consultant-developed invention if a dispute arises, is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions disfavor or are unwilling to protect trade secrets. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent that competitor from using the technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be materially and adversely harmed.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets or other proprietary information of our employees' or consultants' former employers or their clients.

Many of our employees or consultants and our licensors' employees or consultants were previously employed at universities or biotechnology or biopharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that one or more of these employees or consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of former employers. Litigation or arbitration may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or may be enjoined from using such intellectual property. Any such proceedings and possible aftermath would likely divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. A loss of key research personnel or their work product could limit our ability to commercialize, or prevent us from commercializing, our current or future technologies or programs and development candidates, which could materially harm our business. Even if we are successful in defending against any such claims, litigation or arbitration could result in substantial costs and could be a distraction to management.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government 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 government fees on patents or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and in-licensed patents or applications and any patent rights we may own or in-license in the future. The USPTO and various non-U.S. government patent agencies require compliance with several 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 with these requirements, and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our in-licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance 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. In such an event, potential competitors might be able to enter the market with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition.

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.

Our trademarks or trade names may be challenged, infringed, circumvented, 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 or may be forced to stop using these names, which we use for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be materially adversely affected. Additionally, while we own trademark registrations for the IMMUNOME mark, if such mark were challenged and found to be generic or merely descriptive, we could lose the ability to enforce our name against other parties, including competitors. Furthermore, if a party challenges our trademark rights in the IMMUNOME mark, we would need to expend resources defending our rights.

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

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. The following examples are illustrative:

- others may be able to make compounds or formulations that are similar to our programs and development candidates, but that are not covered by the claims of any patents that we own, license or control;
- we or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own, license or control;
- we or our licensors might not have been the first to file patent applications covering certain of our owned and in-licensed inventions;
- others may independently develop the same, similar, or alternative technologies without infringing, misappropriating or violating our owned or in-licensed intellectual property rights;
- it is possible that our owned or in-licensed pending patent applications will not lead to issued patents;
- issued patents that we own, in-license, or control may not provide us with any competitive advantages, or may be narrowed or held invalid or unenforceable, including as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- 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 trade secrets or know-how; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse impact on our business and financial condition.

Risks Related to Government Regulation

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business.

We and our current and potential collaborators may be subject to federal, state and foreign data protection laws and regulations (*i.e.*, laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws (*e.g.*, the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH), state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (*e.g.*, Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH, or other privacy and data security laws. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose protected health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. However, determining whether protected health

information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation.

If we are unable to properly protect the privacy and security of protected health information or other personal, sensitive, or confidential information in our possession, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face significant administrative, civil and criminal penalties. Enforcement activity can also result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal and outside resources. Furthermore, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

Many state laws govern the privacy and security of personal information and data in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts. For example, in 2018, California enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places 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. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. In addition, the California Consumer Rights Act, or CPRA, was recently enacted to strengthen elements of the CCPA and became effective on January 1, 2023. A number of other states have considered similar privacy proposals, with states like Virginia and Colorado enacting their own privacy laws. The Virginia Consumer Data Protection Act became effective on January 1, 2023, and the Colorado Privacy Act is scheduled to come into effect on July 1, 2023. These privacy laws may impact our business activities and exemplify the vulnerability of our business to the evolving regulatory environment related to personal data.

In the EU, we may be subject to the General Data Protection Regulation (GDPR) which went into effect in May 2018, and which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR applies to any company established in the European Economic Area, or EEA, (which includes the EU Member States plus Iceland, Liechtenstein, and Norway) and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR establishes stringent requirements applicable to the processing of personal data, including strict requirements relating to the validity of consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct data protection impact assessments for "high risk" processing, limitations on retention of personal data, special provisions affording greater protection to and requiring additional compliance measures for "special categories of personal data" including health and genetic information of data subjects, mandatory data breach notification (in certain circumstances), "privacy by design" requirements, and direct obligations on service providers acting as processors. The GDPR also prohibits the international transfer of personal data from the EEA to countries outside of the EEA unless made to a country deemed to have adequate data privacy laws by the European Commission or a data transfer mechanism has been put in place. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

The GDPR may also impose additional compliance obligations relating to the transfer of data between us and our subsidiaries or other business partners. For example, on July 16, 2020, the Court of Justice of the European Union (CJEU), issued a landmark opinion in the case *Maximilian Schrems vs. Facebook* (Case C-311/18), called *Schrems II.* This decision (a) calls into question commonly relied upon data transfer mechanisms as between the EU Member States and the United States (such as the Standard Contractual Clauses) and (b) invalidates the EU-U.S. Privacy Shield on

which many companies had relied as an acceptable mechanism for transferring such data from the EU to the United States. The CJEU is the highest court in Europe and the *Schrems II* decision heightens the burden on data importers to assess U.S. national security laws on their business and future actions of EU data protection authorities are difficult to predict. Some customers or other service providers may respond to these evolving laws and regulations by asking us to make certain privacy or data-related contractual commitments that we are unable or unwilling to make. This could lead to the loss of current or prospective customers or other business relationships.

Relatedly, following the United Kingdom's withdrawal from the EU (i.e., Brexit), and the expiry of the Brexit transition period, which ended on December 31, 2020, the EU GDPR has been implemented in the United Kingdom (as the UK GDPR). The UK GDPR sits alongside the UK Data Protection Act 2018 which implements certain derogations in the EU GDPR into UK law. Under the UK GDPR, companies not established in the UK but who process personal data in relation to the offering of goods or services to individuals in the UK, or to monitor their behavior will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to £17.5 million or 4% of global turnover.

Compliance with U.S. and international data protection laws and regulations 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. We must continue to monitor and devote significant resources to understanding and complying with this changing landscape. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity 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. 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.

Health care legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain health care costs. See our discussion of those initiatives under "Health Care Reform" section in the Government Regulation.

Those new laws and initiatives may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our future customers and accordingly, our financial operations. 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 otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services, which could result in reduced demand for our programs and development candidates or additional pricing pressures.

If we or potential future partners, manufacturers or service providers fail to comply with health care laws and regulations, we or they could be subject to enforcement actions, which could affect our ability to develop, market and sell our products and may harm our reputation.

Health care providers, physicians and third-party payors, among others, will play a primary role in the prescription and recommendation of any programs or development candidates for which we obtain marketing approval. Our current and future arrangements with third-party payors, providers and customers, among others, may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial

arrangements and relationships through which we market, sell and distribute our programs and development candidates for which we obtain marketing approval. These laws and regulations, include:

- the federal Anti-Kickback Statute;
- federal civil and criminal false claims laws and civil monetary penalties laws, including the federal False Claims Act;
- HIPAA, as amended by HITECH, and their respective implementing regulations, including the Final Omnibus Rule;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, created as part of the ACA; and
- analogous local, state and foreign laws and regulations.

See our discussion of these laws under "Other U.S. Health Care Laws and Compliance Requirements" in the Government Regulation section.

Ensuring that our future business arrangements with third parties comply with applicable health care laws and regulations could involve substantial costs. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a health care company may run afoul of one or more of the requirements. If our operations are found to be in violation of any such requirements, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, individual imprisonment, disgorgement, contractual damages, reputational harm, exclusion from participation in government health care programs, integrity obligations, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government, refusal to allow us to enter into supply contracts, including government contracts, additional reporting requirements and oversight if 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.

We intend to develop and implement a comprehensive corporate compliance program prior to the commercialization of our programs and development candidates. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources. Moreover, federal, state or foreign laws or regulations are subject to change, and while we, our collaborators, manufacturers and/or service providers currently may be compliant, that could change due to changes in interpretation, prevailing industry standards or other reasons.

Any programs or development candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

Even if we are successful in achieving regulatory approval to commercialize a program or development candidate ahead of our competitors, our programs and development candidates may face competition from biosimilar products. In the United States, our antibody-based programs and development candidates are expected to be regulated by the FDA as biological products, and we intend to seek approval for these programs and development candidates pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for FDA approval of biosimilar and interchangeable biological products based on a previously licensed reference product. Under the BPCIA, an application for a biosimilar biological product cannot be approved by the FDA until 12 years after the original reference biological product was approved under a BLA. The law is complex and is still being interpreted

and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our programs and development candidates.

We believe that any of our programs and development candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity available to reference biological products. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our programs and development candidates to be reference biological products pursuant to its interpretation of the exclusivity provisions of the BPCIA for competing products, potentially creating the opportunity for generic follow-on biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing including whether a future competitor seeks an interchangeability designation for a biosimilar of one of our products. Under the BPCIA as well as state pharmacy laws, only interchangeable biosimilar products are considered substitutable for the reference biological product without the intervention of the health care provider who prescribed the original biological product. However, as with all prescribing decisions made in the context of a patient-provider relationship and a patient's specific medical needs, health care providers are not restricted from prescribing biosimilar products in an off-label manner. In addition, a competitor could decide to forego the abbreviated approval pathway available for biosimilar products and to submit a full BLA for product licensure after completing its own preclinical studies and clinical trials. In such a situation, any exclusivity for which our products candidates may be eligible under the BPCIA would not prevent the competitor from marketing its biological product as soon as it is approved.

In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved.

If competitors are able to obtain marketing approval for biosimilars referencing our programs and development candidates, if approved, our future products may become subject to competition from such biosimilars, whether or not they are designated as interchangeable, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our programs and development candidates may have received approval.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, 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 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, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the Securities and Exchange Commission, or SEC, and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including beginning on December 22, 2018, , the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Additionally, the FDA and regulatory authorities outside the United States imposed and may continue to impose various restrictions or other policy measures in response to the COVID-19 pandemic. Although the FDA lifted restrictions relating to COVID-19

and affecting its inspection and other compliance operations in July 2022, the agency currently faces a significant backlog on compliance monitoring and enforcement activities for both domestic and foreign manufacturers, which may affect the scheduling of necessary pre-approval inspections of manufacturing facilities for drug and biological programs and development candidates.

If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review 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 or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Even if we receive regulatory approval of our programs and development candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements.

If our programs and development candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities must comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing applications, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we receive for our programs and development candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the program and development candidate. The FDA may also require a REMS program as a condition of approval of our programs and development candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician 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 or a comparable foreign regulatory authority approves our programs and development candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP for any clinical trials that we conduct post-approval.

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.

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 other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;

- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our programs and development 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.

Even if we are able to commercialize any program or development candidate, the program and development candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our programs and development candidates or assure that coverage and reimbursement will be available for any product that we may develop. The regulations that govern marketing approvals, pricing and reimbursement for new drug and biological products vary widely from country to country. Some countries require approval of the sale price of a drug or biologic before it can be marketed. In many countries, the pricing review period begins after marketing or product approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. We are monitoring these regulations as several of our programs move into later stages of development; however, many of our programs are currently in the earlier stages of development and we will not be able to assess the impact of price regulations for a number of years. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that could delay our commercial launch of the product and negatively impact any potential revenues we may be able to generate from the sale of the product in that country and potentially in other countries due to reference pricing.

Our ability to commercialize any products successfully will also depend in part on the extent to which coverage and adequate reimbursement/payment for these products and related treatments will be available from government health administration authorities, private payors and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered medically necessary and/or cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. At this time, we are unable to determine their cost effectiveness or the likely level or method of reimbursement for our programs and development candidates. Increasingly, third-party payors, such as government and private insurance plans, are requiring that biopharmaceutical companies provide them with predetermined discounts from list prices and are seeking to reduce the prices charged or the amounts paid for biopharmaceutical products. If the price we are able to charge for any products we develop, or the payments provided for such products, is inadequate in light of our development and other costs, our return on investment could be adversely affected.

We currently expect that any drugs we develop may need to be administered under the supervision of a physician on an outpatient basis. Under currently applicable U.S. law, certain therapeutic products that are not usually self-administered (such as most injectable drugs and biologics) may be eligible for coverage under the Medicare Part B program if:

- they are incident to a physician's services;
- they are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice; and
- they have been approved by the FDA and meet other requirements of the statute.

There may be significant delays in obtaining coverage for newly-approved biologics, and coverage may be more limited than the indications for which the biologic is approved by the FDA or comparable foreign regulatory authorities. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to pay all or part of the costs associated with their prescription medications. Patients are

unlikely to use our products unless coverage is provided, and payment is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate payment is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Moreover, eligibility for coverage does not imply that any of our products, if approved, will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs or biologics, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs or biologics may be reduced by mandatory discounts or rebates required by government health care programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates. However, no uniform policy requirement for coverage and reimbursement for drug or biologic products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug and biologic products can differ significantly from payor to payor. 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 applied consistently or obtained in the first instance. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for new products we develop and for which we obtain regulatory approval could adversely affect our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

We believe that the efforts of governments and third-party payors to contain or reduce the cost of health care and legislative and regulatory proposals to broaden the availability of health care will continue to affect the business and financial condition of pharmaceutical and biopharmaceutical companies. A number of legislative and regulatory changes in the health care system in the United States and other major health care markets have been proposed and/or adopted in recent years, and such efforts have expanded substantially in recent years.

In particular, in March 2010, the ACA was signed into law. This legislation changed the system of health care insurance and benefits and was intended to broaden access to health care coverage, enhance remedies against fraud and abuse, add transparency requirements for the health care and health insurance industries, impose taxes and fees on the health care industry, impose health policy reforms, and control costs. This law also contains provisions that would affect companies in the pharmaceutical industry and other health care related industries by imposing additional costs and changes to business practices. Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA. The uncertainty around the future of the ACA, and in particular the impact to reimbursement levels, may lead to uncertainty or delay in the purchasing decisions of our customers, which may in turn negatively impact on our product sales. We continue to evaluate the effect that the ACA has or any potential changes to the ACA could have on our business. Additional federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the United States to increase pressure on drug and biologic pricing and reimbursement. Such reforms could have an adverse effect on anticipated revenues from programs and development candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop programs and development candidates.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We interact with officials and employees of government agencies and government-affiliated hospitals, universities and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities abroad or to obtain necessary permits, licenses and other

regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

We adopted a Code of Business Conduct and Ethics and implemented training programs, policies and procedures to ensure compliance with such code. The Code of Business Conduct and Ethics mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. However, we cannot assure you that our employees and third-party intermediaries will comply with this code or such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

Risks Related to Our Common Stock

Our stock price may be volatile, and purchasers of our common stock could incur substantial losses.

The trading price of our common stock has been volatile, and it may continue to be volatile, with the trading price seeing significant increases and decreases from time to time. The market price for our common stock may be influenced by many factors, including the other risks described in this section, titled "Risk Factors." In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that has been often unrelated to the operating performance of the issuer, including recently in connection with the ongoing COVID19 pandemic, which has resulted in decreased or increased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These broad market and industry factors and other adverse effects may seriously harm the market price of our common stock, regardless of our operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition.

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.

Based on the beneficial ownership of our capital stock as of December 31, 2022, our executive officers and directors, together with holders of 5% or more of our capital stock and their respective affiliates, beneficially owned approximately 29.7% of our common stock on an as-converted basis. As a result, these stockholders, if acting together, have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction.

The interests of these stockholders may not be the same as, and may even conflict with, your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this Annual Report lapse, the trading price of our common stock could decline. At December 31, 2022, we have outstanding a total of 12,128,843 shares of common stock, assuming no exercise of any warrants to purchase shares of common stock. However, warrant holders have started to exercise their warrants and we expect this to continue in the future. Of these shares, only the shares of common stock sold in the IPO have been freely tradable without restriction in the public market.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our 2008 Plan, 2018 Plan and 2020 Plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act. If these additional shares of common stock 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.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our 2020 Plan, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including further development of the Immunome discovery engine, preparing IND filings, conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. In this regard, we filed a shelf registration statement on Form S-3, which was declared effective by the SEC on October 14, 2021, pursuant to which we may issue from time to time securities with an aggregate value of up to $200.0 million in one or more offerings at prices and terms to be determined at the time of sale, including one or more "at the market" offerings pursuant to the ATM Agreement (as defined below) with Jefferies Group LLC (which provides that, upon the terms and subject to certain conditions and limitations therein, we may elect, from time to time, to offer and sell common shares under the registration statement having an aggregate offering price of up to $75.0 million through Jefferies Group LLC). If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

Pursuant to our 2020 Plan, our management is authorized to grant stock options to our employees, directors and consultants. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under our 2020 Plan is 2,000,000 shares. Additionally, the number of shares of our common stock reserved for issuance under our 2020 Plan will automatically increase on January 1 of each year, beginning on January 1, 2021 and continuing through and including January 1, 2030, by 4% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

We are an "emerging growth company" and our election of reduced reporting requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, or Section 404, reduced disclosure obligations regarding executive compensation in this Annual Report and our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, as an

emerging growth company, we are only required to provide two years of audited financial statements and two years of selected financial data in this Annual Report. We could be an emerging growth company for up to five years following the completion of our IPO, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30, or if we have total annual gross revenue of $1.07 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we could still qualify as a "smaller reporting company," which would allow us 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 and reduced disclosure obligations regarding executive compensation in this Annual Report and our other 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 share price may be more volatile.

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 an exemption that allows us to delay adopting new or revised accounting standards until such time as those standards apply to private companies. As a result, we will not be subject to the same new or revised accounting standards as other public companies that comply with the public company effective dates, including but not limited to the new lease accounting standard. We have also elected to take advantage of certain of the reduced disclosure obligations in this Annual Report and may elect to take advantage of other reduced reporting requirements in future filings. As a result of these elections, the information that we provide to our stockholders may be different than you might receive from other public reporting companies. However, if we later decide to opt out of the extended period for adopting new accounting standards, we would need to disclose such decision and it would be irrevocable.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors. However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation.

We have incurred substantial losses since our inception. Unused U.S. federal net operating losses, or NOLs, for taxable years beginning before January 1, 2018, may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or the Tax Act, as modified by legislation enacted on March 27, 2020, entitled the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, U.S. federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such U.S. federal NOLs in taxable years beginning after December 31, 2020, is

limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. Our NOL carryforwards and R&D credits are subject to review and possible adjustment by federal and state tax authorities.

As of December 31, 2022, we had federal and state net operating loss carryforwards of $81.0 million and $81.4 million, respectively, which are available to reduce future taxable income. If not utilized, the federal and state net operating loss carryforwards expire starting in 2027. Included in the federal net operating loss carryforwards are $64.0 million of net operating loss generated from 2018 to 2022 that will not expire and are limited to offset 80% of our taxable income for years beginning after December 31, 2020. Certain federal and state net operating loss carryforwards expire at various dates through 2042. As of December 31, 2022, we had cumulative federal R&D tax credits of $2.7 million. These tax credit carryforwards will expire at various dates through 2042.

Under Sections 382 and 383 of the Code, changes in our ownership may limit the amount of our net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. Private placements, the IPO and other transactions that have occurred since our inception may trigger such an ownership change pursuant to Sections 382 and 383. Any such limitation, whether as the result of prior issuances of securities by us, sales of our common stock by our existing stockholders or additional sales of our common stock by us, could have a material adverse effect on our results of operations in future years.

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

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, 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 realities 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 or insufficient disclosures due to error or fraud may occur and not be detected.

If we experience future material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations.

If, in the future, we identify material weaknesses in our internal controls over financial reporting, we may not detect errors on a timely basis, and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company, we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Select Market or other adverse consequences that would materially harm our business. In addition, we could become subject to investigations by Nasdaq, the SEC, and other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and our financial condition, or divert financial and management resources from our core business.

An independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting in accordance with the provision of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, because no such evaluation has been required. Had an independent registered public accounting firm

performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, material weaknesses may have been identified.

Capital appreciation, if any, will be a stockholder's sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be an Immunome stockholder's sole source of gain for the foreseeable future.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may delay or prevent an acquisition of our company or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a prohibition on actions by our stockholders by written consent;
- a requirement that special meetings of stockholders, which our company is not obligated to call more than once per calendar year, be called only by the chairman of our board of directors, our chief executive officer, or our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors;
- advance notice requirements for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings;
- division of our board of directors into three classes, serving staggered terms of three years each; and
- the authority of the board of directors to issue preferred stock with such terms as the board of directors may determine.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, as amended, or DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with u-s for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions would apply even if the proposed merger or acquisition could be considered beneficial by some stockholders.

The choice of forum provision in our certificate of incorporation limits our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our certificate of incorporation or our bylaws; or 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. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions.

The choice of forum provision in our certificate of incorporation 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 and may discourage these types of lawsuits. Alternatively, a stockholder may nevertheless seek to bring a claim in a venue other than that designated in the exclusive forum provision. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provision of our certificate of incorporation. If a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur significant additional costs associated with resolving such action in other jurisdictions.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently lease 11,000 square feet of office and laboratory space in Exton, Pennsylvania under a lease that expires on March 31, 2024. We believe the leased space is sufficient to meet our immediate facility needs, and that any additional space we may require will be available on commercially reasonable terms.

Item 3. Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of the outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

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

Our common stock has been publicly traded on the Nasdaq Global Market under the symbol "IMNM" since October 2, 2020.

Holders

As of March 13, 2023, the Company had approximately 62 record holders of its common stock. A substantially greater number of holders are beneficial owners whose shares are held of record by banks, brokers and other nominees.

Dividends

The Company has not declared or paid any dividends since its inception, nor does it expect to pay dividends in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

The information under the heading "Securities Authorized for Issuance Under Equity Compensation Plans" will be filed in the Company's definitive proxy statement for the 2023 annual meeting of stockholders and is incorporated herein by reference.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. Selected Financial Data

Not required.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, our actual results could differ materially from the results described in or implied by these forward-looking statements. You should carefully read the "Risk Factors" section of this Annual Reports to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Overview

Since our inception in 2006, we have devoted substantially all our resources to research and development, raising capital, building our management team and building our intellectual property portfolio. To date, we have financed our operations primarily through sales of our common stock, Series A convertible preferred stock and warrants, warrant exercises, the issuance of convertible promissory notes, the Paycheck Protection Program loan, or the PPP loan, that was forgiven in May 2021, and strategic partnerships with AbbVie and the Department of Defense, or the DoD. In January 2023, we received a $30.0 million upfront payment from AbbVie under the Collaboration Agreement. In addition, we received $17.6 million in expense reimbursement from the DoD under the OTA Agreement through December 31, 2022.

To date, we have not generated any revenue from product sales and do not expect to generate revenue from the sale of products for the foreseeable future. Since inception we have incurred significant operating losses. Our net losses were $36.9 million and $24.7 million for the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, we had a cash and cash equivalent balance of $20.3 million, which does not include the $30.0 million upfront payment that we received in January 2023 from AbbVie under the Collaboration Agreement. We expect to continue to incur losses for the foreseeable future. We expect to continue to incur significant expenses and increasing operating losses in connection with ongoing research and development activities related to our portfolio of programs as we continue advancement of our programs and development candidates. We also plan to perform research activities as we seek to discover and develop additional programs and development candidates; carry out maintenance, expansion, enforcement, defense, and protection of our intellectual property portfolio; and hire research and development, clinical and administrative personnel. If we cannot obtain the necessary funding to support these activities on favorable terms, if at all, we will need to delay, scale back or eliminate some or all of our research and development programs. We may also need to consider other various strategic alternatives, including a merger or sale of the Company; or reduce or cease operations. If we engage in collaborations, we may receive lower consideration upon commercialization of such products or technologies than if we had not entered into such arrangements or if we entered into such arrangements at later stages in the research and development process. Other than the current and potential future sources of funding under the Collaboration Agreement with AbbVie, we currently have no other sources of revenue, and our ability to continue to fund our future business plans is dependent on our ability to raise capital to fund our present and future business plans. Additionally, volatility in the capital markets, the competitive landscape and general economic conditions in the United States may be a significant obstacle to raising the required funds.

We expect to continue to incur significant expenses and increasing operating losses in connection with ongoing activities, particularly if and as we:

- continue research and development activities;
- pursue regulatory approvals and implement other regulatory strategies for our programs and development candidates;
- take additional steps to advance our discovery engine and our existing and future pipeline;

- obtain, maintain, expand and protect our intellectual property portfolio;
- hire additional research and development, clinical and administrative personnel;
- scale up and expand our clinical and regulatory capabilities; and
- add operational, financial and management information systems and infrastructure to support our research and development programs, and any future commercialization efforts.

As a result of these anticipated expenditures and potential unanticipated expenditures, we will need substantial additional financing to support our continuing operations and pursue our growth strategy. Until such time as we generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of any stockholder 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 stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market programs and development candidates that we would otherwise prefer to develop and market ourselves. We may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all. The inability to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

Through December 31, 2022, we raised an aggregate of $125.1 million in gross proceeds from sales of our common stock, Series A convertible preferred stock and warrants, warrant and stock option exercises, the issuance of convertible promissory notes, and the PPP loan. In addition, in July 2020, the Company entered into an Other Transaction Authority for Prototype Agreement, or the OTA Agreement, with the Department of Defense, or the DoD, to fund the Company's efforts in developing an antibody cocktail therapeutic to treat COVID-19. As of December 31, 2022, the Company has received $17.6 million in expense reimbursement from the DoD under the OTA Agreement.

On October 1, 2021, we entered into an Open Market Sale Agreement, or the ATM Agreement, with Jefferies Group LLC, which provides that, upon the terms and subject to the conditions and limitations in the ATM Agreement, we may elect, from time to time, to offer and sell shares of common stock under our existing shelf registration statement having an aggregate offering price of up to $75.0 million through Jefferies Group LLC acting as sales agent. The Company has not sold any shares under the ATM Agreement or the shelf registration statement as of December 31, 2022.

In addition, on January 4, 2023, we entered into the Collaboration Agreement with AbbVie directed to the discovery of up to 10 novel target-antibody pairs leveraging our discovery engine. The Company is potentially eligible to receive up to $2.8 billion from AbbVie under the Collaboration Agreement from the sources described in Note 15 to the financial statements. We have received the $30.0 million upfront payment in January 2023. There are no assurances that we will receive additional payments from AbbVie beyond the $30.0 million upfront payment.

We expect that our cash as of December 31, 2022, together with the $30.0 million upfront payment that we received in January 2023 from AbbVie under the Collaboration Agreement, will be sufficient to fund our operations at least 12 months from the filing date of this Annual Report on Form 10-K. We have based these estimates on assumptions that may prove to be imprecise, and we may exhaust our available capital resources sooner than we currently expect. See "Liquidity and capital resources." Due to the numerous risks and uncertainties associated with the research and development of our programs, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our programs and development candidates.

Our current programs and strategic collaborations

Oncology (IMM-ONC-01)

Our lead oncology program targets IL-38, which we believe is a novel, negative regulator of inflammation capable of promoting tumor evasion of the immune system. IL-38 was identified as the target of an antibody isolated from a hybridoma library generated from the memory B cells of a patient with squamous head and neck cancer. Query of public and proprietary (Tempus) databases of cancer gene expression revealed over-expression of IL-38 in multiple solid tumors. Further, a correlation with low levels of tumor-infiltrating immune effector cells, a hallmark of immune suppression in some of these patients' tumors, and high IL-38 expression was also observed, suggesting a role for IL-38 as an immune modulator. Data obtained from preclinical testing indicated that blocking IL-38 function using inhibitory antibodies increased the immune response to the tumor and resulted in anti-tumor activity in select animal models, suggesting that anti-IL-38 antibodies could have therapeutic utility as single agents or in combination with other therapeutic modalities. Our recent analysis further confirms IL-38 expression is frequently elevated in samples of select patient tumor subtypes, in cancers such as head and neck, lung and gastroesophageal. We believe that this information could potentially guide patient selection for early clinical testing and may improve the overall probability of demonstrating clinical utility, thereby improving the probability of clinical success. We plan to submit our IND application for the IMM-ONC-01 program by mid-2023.

SARS-CoV-2 (IMM-BCP-01)

We are developing an antibody cocktail derived from the B cells of COVID-19 patients who exhibited high neutralizing titers. IMM-BCP-01 targets non-overlapping regions of the Spike protein of SARS-CoV-2 which include highly conserved, subdominant epitopes. The cocktail promotes both ACE2 and non-ACE2 dependent neutralization and induces natural viral clearance mechanisms such as antibody dependent cellular cytotoxicity, complement activation and phagocytosis in pre-clinical testing. We are conducting this program in collaboration with the DoD. The IMM-BCP-01 program is broadly focused on the emerging variants of SARS-CoV-2. We submitted an IND application for the IMM-BCP-01 program to the U.S. FDA in November 2021 and initiated the Phase 1b study of IMM-BCP-01 in patients infected with SARS-CoV-2 in June 2022**.** On January 6, 2023, the Company announced that it successfully completed dosing of the first cohort of patients in a Phase 1b study with no significant treatment-related adverse events. The Company has decided to seek a partner in order to continue the trial and for any further development activities.

Other Programs and Platforms

In addition to the already described current programs, we will continue to invest in our proprietary discovery engine to expand our pipeline. The high output of antibody-target pairs resulting from our discovery engine may provide us with additional insights into the immune response against cancer and other diseases. We intend to continue to invest in this platform, to evaluate novel antibody-target pairs and to develop a pipeline of antibody therapeutics as single agents or in combination with other therapeutics or technologies to yield programs and development candidates, such as Antibody-Drug Conjugates (ADCs).

Additionally, we plan to expand our intellectual property estate and infrastructure needed to discover and advance our programs and development candidates. We may in-license or acquire complementary intellectual property as needed or required, and we may continue to build our know-how and trade secrets. We may pursue both therapeutic and diagnostic applications of our antibodies through composition of matter and/or method of use patents. While our initial focus areas are in oncology and other diseases, we may invest in intellectual property in other therapeutic areas as well.

Collaboration with AbbVie

On January 4, 2023, the Company and AbbVie entered into the Collaboration Agreement, pursuant to which the Company will use its proprietary discovery engine to discover and validate targets derived from patients with three specified tumor types, and antibodies that bind to such targets, which may be the subject of further development and commercialization by AbbVie. For a more comprehensive discussion regarding the Collaboration Agreement, please see Note 15 to the financial statements.

COVID-19 pandemic

The ongoing COVID-19 pandemic continues to affect economies and businesses around the world. The extent and duration of such effects remain uncertain and difficult to predict, particularly as virus variants continue to spread. We are actively monitoring and managing our response and assessing actual and potential impacts to our operating results and financial condition, as well as developments in our business, which could further impact the developments, trends and expectations described below. See the risk factor related to the impact of the COVID-19 pandemic, "A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, could materially and adversely affect our business and our financial results and cause a disruption to our research, development and commercialization efforts," described in "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K.

Components of our results of operations

Research and development expenses

Research and development expenses consist of costs incurred in performing research and development activities, which include:

- personnel-related expenses, including salaries, bonuses, benefits and share-based compensation for employees engaged in research and development functions;
- expenses incurred in connection with the advancement of our programs and development candidates, including under agreements with consultants, contractors, contract research organizations and other third-party vendors and suppliers;
- expenses to conduct clinical trials including regulatory and quality assurance;
- the cost of developing and validating our manufacturing process for use in our preclinical studies and clinical trials;
- laboratory supplies and research materials and other infrastructure-related expenses; and
- facilities, depreciation and amortization and other expenses which include direct and allocated expenses.

We expense research and development costs as incurred. Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the benefits are consumed.

Research and development activities are central to our business model. We expect that our research and development expenses will increase substantially in connection with the continuation of our activities.

In July 2020, we entered into the OTA Agreement with the DoD to fund the development of IMM-BCP-01 to treat COVID-19. The OTA Agreement was modified in May 2021 to increase such funding. In connection with the OTA Agreement, we record expense reimbursements received from the DoD as contra-research and development expenses in the same period the underlying expenses are incurred.

Under the provisions of the CARES Act signed into law on March 27, 2020 and the subsequent extension of the CARES Act, the Company was deemed eligible to receive the employee retention credit subject to certain criteria. The Company recognized the employee retention credit as contra-expense to personnel related costs in research and development expenses in the statements of operations.

General and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs, including share-based compensation for personnel in our executive, business development, and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters, professional fees for accounting, auditing, tax and consulting services, insurance costs, travel, direct and allocated facility related expenses and other operating costs.

We anticipate that our general and administrative expenses will increase in the future to support increased and progressed research and development activities.

Under the provisions of the CARES Act signed into law on March 27, 2020 and the subsequent extension of the CARES Act, the Company was eligible for a refundable employee retention credit subject to certain criteria. The Company recognized the employee retention credit as contra-expense to personnel related costs in general and administrative expenses in the statements of operations.

Interest income (expense), net

Interest expense consists of interest expense related to our equipment loan payable. Interest income consists of interest income earned on our cash.

Other income

In April 2020, the Company received a $0.5 million loan, or the PPP Loan, pursuant to the Paycheck Protection Program, or the PPP, under the Coronavirus Aid, Relief, and Economic Security Act implemented by the U.S. Small Business Administration. The loan was forgiven on May 21, 2021 and recorded as other income in the statement of operations.

Results of operations

The ultimate extent of the impact of any epidemic, pandemic, outbreak, or other public health crisis on our results of operations will depend on future developments, which are highly uncertain, including new information that may emerge concerning the severity of COVID-19 and its variants or other public health crisis and actions taken to contain or prevent the further spread, among others. Accordingly, we cannot fully predict the extent to which our business and results of operations will be affected by the pandemic.

Comparison of the years ended December 31, 2022 and 2021:

	YEAR ENDED DECEMBER 31,		
	2022	2021	Change
		(in thousands)	
Operating expenses:			
Research and development	$ 23,272	$ 14,110	$ 9,162
General and administrative	13,629	11,094	2,535
Total operating expenses	36,901	25,204	11,697
Loss from operations	(36,901)	(25,204)	(11,697)
Other income (expense):			
Other income	—	503	(503)
Interest income (expense), net	5	(10)	15
Total other income	5	493	(488)
Net loss	$ (36,896)	$ (24,711)	$ (12,185)

Research and development expenses

Research and development expenses were $23.3 million and $14.1 million, net of DoD reimbursement of $0.6 million and $15.2 million for the years ended December 31, 2022 and 2021, respectively.

Research and development expenses increased by $9.2 million for the year ended December 31, 2022. Of the $9.2 million increase in research and development expenses, BCP-01 program related expenses increased by $6.8 million as a result of receiving the maximum reimbursement amount of $17.6 million from the DoD under the OTA Agreement during 2022 and using our own funds to support our clinical activities. Prior to receiving the maximum reimbursement amount, contra-research and development expenses offset the expenses recognized for the period under the DoD agreement. ONC-01 program related expenses increased by $2.3 million in connection with the advancement of our program. Personnel-related costs increased by $0.7 million due to an increase of $0.5 million in share-based compensation and $0.2 million in personnel compensation. These increases were offset by $0.6 million decrease in general expenses and facility related costs.

General and administrative expenses

General and administrative expenses increased by $2.5 million from $11.1 million for the year ended December 31, 2021 to $13.6 million for the year ended December 31, 2022. This increase is primarily as a result of a $2.5 million increase in personnel-related costs due to an increase of $1.4 million in share-based compensation and $1.1 million in personnel-related costs. Personnel-related costs increased as a result of an increase in wages and issuance of annual share-based awards.

Other income

Other income for the year ended December 31, 2021 primarily consists of the forgiveness of the PPP Loan.

Interest income (expense), net

Interest expense, net consists of interest expense related to our equipment loan payable which were paid in full as of December 31, 2021. Interest income consists of interest earned on our cash balances held with financial institutions.

Liquidity and capital resources

Since our inception, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we continue advancement of our programs and development candidates. Through December 31, 2022, we raised an aggregate of $125.1 million in gross proceeds from sales of our common stock, Series A convertible preferred stock and warrants, warrant and stock option exercises, the issuance of convertible promissory notes, and the PPP loan that was forgiven in May 2021. As of December 31, 2022, we had $20.3 million in cash and cash equivalents which does not include the $30.0 million that we received from AbbVie under the Collaboration Agreement.

On October 1, 2021, we entered into an Open Market Sale Agreement, or the ATM Agreement, with Jefferies Group LLC, which provides that, upon the terms and subject to the conditions and limitations in the ATM Agreement, we may elect, from time to time, to offer and sell common shares under the registration statement having an aggregate offering price of up to $75.0 million through Jefferies Group LLC acting as sales agent. We filed a shelf registration statement on Form S-3, which was declared effective by the SEC on October 14, 2021, pursuant to which we may issue from time-to-time securities with an aggregate value of up to $200.0 million. The Company has not sold any shares under the ATM Agreement or the shelf registration statement as of December 31, 2022.

In addition, on January 4, 2023, we entered into the Collaboration Agreement with AbbVie directed to the discovery of up to 10 novel target-antibody pairs leveraging our discovery engine. Under the terms of the Collaboration Agreement, Immunome will grant AbbVie the option to purchase worldwide rights for up to 10 novel target-antibody pairs arising from the selected tumors. AbbVie will pay the Company an option exercise fee in the low single digit

millions for each of the validated target pairs for which it exercises an option. We received an upfront payment of $30.0 million in January 2023 and will be eligible to receive additional platform access payments in the aggregate amount of up to $70.0 million based on AbbVie's election for us to continue research using our discovery engine. We are also eligible to receive development and first commercial sale milestones of up to $120.0 million per target with respect to certain products derived from target-antibody pairs that AbbVie elects to purchase, sales-based milestones based on achievement of specified levels of net sales of products up to $150.0 million in the aggregate per target, and tiered low single digit royalties on net sales of products. The Company is potentially eligible to receive up to $2.8 billion from AbbVie under the Collaboration Agreement from the sources described above. There are no assurances that we will receive additional payments from AbbVie beyond the $30.0 million upfront payment.

We will need to raise additional capital before we exhaust our current cash to continue to fund our research and development, including our plans to continue advancement of our programs and product candidates and new product development, as well as to fund operations. As and if necessary, we will seek to raise additional funds through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations, or, if such funds are available to us, that such additional financing will be sufficient to meet our needs.

Cash flows

The following table summarizes our sources and uses of cash for the years ended December 31, 2022 and 2021:

	YEARS ENDED DECEMBER 31,	
	2022	2021
	(in thousands)	
Cash used in operating activities	$ (28,690)	$ (18,226)
Cash used in investing activities	(248)	(79)
Cash provided by financing activities	32	27,768
Net (decrease) increase in cash and cash equivalents and restricted cash	$ (28,906)	$ 9,463

Operating activities

Net cash used in operating activities for the year ended December 31, 2022 was $28.7 million, consisting primarily of our net loss of $36.9 million and decreases in accrued expenses and other liabilities, accounts payable, and other long-term liabilities of $2.8 million, offset by net noncash charges of $6.0 million for depreciation and amortization expense and share-based compensation expense and a $5.1 million decrease in prepaids expenses and other assets.

Net cash used in operating activities for the year ended December 31, 2021 was $18.2 million, consisting primarily of our net loss of $24.7 million and increases of prepaid expenses and other assets of $4.3 million, offset by net noncash charges of $3.7 million for depreciation and amortization expense, share-based compensation expense, and forgiveness of PPP loan, and an increase in accounts payable and accrued expenses and other liabilities of $7.1 million due to our growth in expenditures.

Investing activities

During the years ended December 31, 2022 and 2021, we used $0.2 million and $0.1 million, respectively, for the purchase of property and equipment.

Financing activities

During the year ended December 31, 2022, financing activities provided $32,000 from exercise of stock options.

During the year ended December 31, 2021, cash provided by financing activities was $27.8 million, consisting primarily of $26.7 million of net proceeds received from the private investment in public equity (PIPE) funding, $1.4 million of proceeds from the exercise of common stock warrants and stock options, offset by $0.2 million of offering costs in connection with the Company's shelf registration statement and $0.1 million for payments related to our equipment loan payable.

Funding requirements

Our operating expenses are expected to increase substantially as we continue to advance our discovery engine and programs.

Specifically, our expenses will increase if and as we:

- further develop our discovery engine;
- continue our research and development programs for our programs and development candidates from our current programs;
- seek to identify additional programs and development candidates;
- maintain, expand, enforce, defend, and protect our intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio;
- seek marketing approvals for any of our programs and development candidates that successfully complete clinical trials;
- establish a sales, marketing, and distribution infrastructure to commercialize any medicines for which we may obtain marketing approval;
- hire additional personnel including research and development, clinical and administrative personnel;
- add operational, financial, and management information systems and personnel, including personnel to support our product development;
- acquire or in-license products, intellectual property, and technologies; and
- continue to operate as a public company.

We expect that our existing cash at December 31, 2022, together with the $30.0 million upfront payment we received in January 2023 from AbbVie under the Collaboration Agreement, will enable us to fund our current and planned operating expenses and capital expenditures at least 12 months from the filing date of this Annual Report on Form 10-K. The Company will need additional financing to support its continuing operations and pursue its research and development strategy. We have based these estimates on assumptions that may prove to be imprecise, and we may exhaust our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of our programs, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our programs and development candidates.

Our future funding requirements will depend on many factors including:

- the costs of continuing to develop our discovery engine;
- the costs of acquiring licenses, should we choose to do so, for the expansion of product development;

- the scope, progress, results, and costs of discovery, preclinical development, laboratory testing, manufacturing and clinical trials for programs and development candidates;

- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights, and defending intellectual property-related claims and the success of our intellectual property portfolio;

- the costs, timing, and outcome of regulatory review of the programs and development candidates we may develop;

- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, distribution, coverage and reimbursement for any programs or development candidates for which we receive regulatory approval;

- the success of our license agreements and our collaborations;

- our ability to establish and maintain additional collaborations on favorable terms, if at all;

- the achievement of milestones or occurrence of other developments that trigger payments under any additional collaboration agreements we obtain;

- the extent to which we acquire or in-license products, intellectual property, and technologies; and

- the costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of any purchaser 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 equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market programs and development candidates that we would otherwise prefer to develop and market ourselves.

Critical accounting policies and significant judgments

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our 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 an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in Note 2 to our audited financial statements appearing elsewhere in this Annual Report, we believe that the following accounting policies are the most critical to the judgments and estimates used in the preparation of our financial statements.

Share-based compensation

We recognize the grant-date fair value of share-based awards issued as compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. The fair value of stock options is estimated at the time of grant using the Black-Scholes option pricing model, which requires the use of inputs and assumptions such as the fair value of the underlying common stock, exercise price of the option, expected term, risk-free interest rate, expected volatility and dividend yield.

The inputs and assumptions used to estimate the fair value of share-based payment awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and management uses different inputs and assumptions, our share-based compensation expense could be materially different for future awards.

Expected volatility is a subjective assumption based on the historical stock volatility of several of our comparable publicly traded companies over a period of time equal to the expected term.

Accrued research and development expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders and communicating with 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 on a pre-determined schedule or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments, if necessary. 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.

Recently adopted accounting standards

ASC Topic 842, Leases

On January 1, 2022, the Company adopted ASC 842, which supersedes the lease accounting guidance under ASC 840. The standard generally requires lessees to recognize operating and finance lease liabilities and corresponding right-of-use (ROU) assets in the balance sheets and provide enhanced disclosures on the amount, timing, and uncertainty of cash flows arising from lease arrangements. The Company adopted ASC 842 using the modified retrospective approach. The Company elected the package of practical expedients available for existing contracts, which allowed the Company to carry forward its historical assessments of lease identification, lease classification, and initial direct costs. The Company also elected a policy to not apply the recognition requirements of ASC 842 for short-term leases with a term of 12 months or less.

As of January 1, 2022, the effective date, the Company identified one operating lease arrangement relating to the Company's headquarters facility and one short-term lease relating to laboratory equipment. The adoption of ASC 842 resulted in a recognition of an ROU asset and lease liability of $0.5 million in the Company's balance sheets relating to the lease as of January 1, 2022. The adoption of the standard did not have a material effect on the Company's statements of operations and statements of cash flows.

ASU Topic 832, Government Assistance

In November 2021, the FASB issued ASU 2021-10, *Government Assistance*, or Topic 832, which requires enhanced disclosures of transactions with governments that are accounted for by applying a grant or contribution model. The new

pronouncement requires entities to provide information about the nature of the transaction, terms and conditions associated with the transaction and financial statement line items affected by the transaction. The Company adopted the standard for the annual period beginning January 1, 2022. The DoD expense reimbursement contract and the employee retention credit received under the CARES Act qualify as government assistance programs under Topic 832 and resulted in enhanced required disclosures, as described in Note 5.

ASU 2021-04, Earnings Per Share

In May 2021, the FASB issued ASU 2021-04 *Earnings Per Share (Topic 260), Debt— Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging— Contracts in Entity's Own Equity (Subtopic 815-40)*, or ASU 2021-04, that requires the issuer to treat a modification of an equity-classified written call option (i.e., a warrant) that does not cause the option to become liability-classified as an exchange of the original option for a new option. An issuer should measure the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately before modification or exchange. The Company adopted the standard for interim periods beginning January 1, 2022. As described in Note 11, in September 2022, the Company modified its Series B Warrants which resulted in a reduction in exercise price from $45.00 per share to $10.00 per share. The Company recognized a deemed dividend of $0.6 million which was recorded in the Company's statement of operations as an increase to the net loss attributable to common stockholders for purposes of computing net loss per share, basic and diluted. The net impact to the statements of changes in stockholders' equity was zero because the warrants were equity classified before and after the modification.

JOBS Act

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies, including reduced disclosure about our executive compensation arrangements, exemption from the requirements to hold non-binding advisory votes on executive compensation and golden parachute payments and exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until the last day of the fiscal year following the fifth anniversary of our initial public offering or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company earlier if we have more than $1.07 billion in annual revenue, we have more than $700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or we issue more than $1.0 billion of non-convertible debt securities over a three-year period. For so long as we remain an emerging growth company, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. We may choose to take advantage of some, but not all, of the available exemptions. 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. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. Therefore, the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required.

Item 8. Financial Statements and Supplementary Data

The information required by this Item is set forth on pages 85 through 108 hereto.

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

On September 30, 2022, the Audit Committee, or the Committee, of the Board of Directors of the Company elected to terminate its engagement with Deloitte & Touche LLP, or Deloitte, as the Company's independent registered public accounting firm, effective immediately.

The audit report of Deloitte on the financial statements of the Company as of and for the year ended December 31, 2021 did not contain any adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope, or accounting principles.

During the fiscal year ended December 31, 2021 and the subsequent interim periods through March 31, 2022 and June 30, 2022, there were no "disagreements," as that term is defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions, between the Company and Deloitte, on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreements, if not resolved to the satisfaction of Deloitte, would have caused Deloitte to make reference in connection with their opinion to the subject matter of the disagreement.

During the fiscal year ended December 31, 2021 and the subsequent interim periods through March 31, 2022 and June 30, 2022, there were no "reportable events" as that term is defined in Item 304(a)(1)(v) of Regulation S-K.

On September 30, 2022, the Committee appointed Ernst & Young LLP, or EY, as its independent registered public accounting firm, which became effective on October 4, 2022. During the fiscal year ended December 31, 2021 and the subsequent interim periods through March 31, 2022 and June 30, 2022, neither the Company, nor anyone on its behalf, has consulted EY with respect to: (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, and neither a written report was provided to the Company nor oral advice was provided to the Company that EY concluded was an important factor considered by the Company in reaching a decision as to the accounting, auditing or financial reporting issue; or (ii) any matter that was either the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) or a reportable event (as defined in Item 304(a)(1)(v) of Regulation S-K).

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of December 31, 2022, our disclosure controls and procedures were effective as of December 31, 2022 to ensure the timely disclosure of required information in our SEC filings.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. The Company's internal control over financial reporting is a process designed, as defined in Rule 13a-15(f) under the Exchange Act, 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. The Company's internal control over financial reporting is supported by written policies and procedures that:

- Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Company's assets;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of the Company's management and directors; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

In connection with the preparation of the Company's annual financial statements, management of the Company has undertaken an assessment of the effectiveness of the Company's internal control over financial reporting based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included an evaluation of the design of the Company's internal control over financial reporting and testing of the operational effectiveness of the Company's internal control over financial reporting. Based on this assessment, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2022.

Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements prepared for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control Over Financial Reporting

No changes in our internal control over financial reporting occurred during the year ended December 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

The information required by Item 10 of Form 10-K is incorporated by reference to the information contained in our definitive proxy statement for the 2023 annual meeting of stockholders.

Item 11. Executive Compensation

The information required by Item 11 of Form 10-K is incorporated by reference to the information contained in our definitive proxy statement for the 2023 annual meeting of stockholders.

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

The information required by Item 12 of Form 10-K is incorporated by reference to the information contained in our definitive proxy statement for the 2023 annual meeting of stockholders.

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

The information required by Item 13 of Form 10-K is incorporated by reference to the information contained in our definitive proxy statement for the 2023 annual meeting of stockholders.

Item 14. Principal Accountant's Fees and Services

The information required by Item 14 of Form 10-K is incorporated by reference to the information contained in our definitive proxy statement for the 2023 annual meeting of stockholders.

Part IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements

See Index to the Financial Statements on page 85 of this Annual Report.

(a)(2) Financial Statement Schedules

None, as all information required in these schedules is included in the Notes to the Financial Statements.

(a)(3) Exhibits

See Exhibit Index or Page 109 of this Annual Report.

Immunome, Inc.

INDEX TO FINANCIAL STATEMENTS

Report of independent registered public accounting firm

To the Shareholders and the Board of Directors of Immunome, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Immunome, Inc. (the Company) as of December 31, 2022, the related statement of operations, changes in stockholders' equity and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022, and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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 audit 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 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 audit 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 audit included performing procedures to assess the risks of material misstatement of the 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 financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2022.

Philadelphia, Pennsylvania

March 16, 2023

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Immunome, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Immunome, Inc. (the "Company") as of December 31, 2021, the related statement of operations, changes in stockholders' equity, and cash flow, for the year ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021, and the results of its operations and its cash flow for the year ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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 audit 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 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 audit, 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 audit included performing procedures to assess the risks of material misstatement of the 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 financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Philadelphia, Pennsylvania

March 28, 2022

We began serving as the Company's auditor in 2019. In 2022 we became the predecessor auditor.

Immunome, Inc.
Balance sheets
(in thousands, except share and per share amounts)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 20,323	$ 49,229
Prepaid expenses and other current assets	2,326	7,409
Total current assets	22,649	56,638
Property and equipment, net	681	855
Operating right-of-use asset, net	284	—
Restricted cash	100	100
Deferred offering costs	332	332
Total assets	$ 24,046	$ 57,925
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,400	$ 3,077
Accrued expenses and other current liabilities	4,931	6,651
Total current liabilities	7,331	9,728
Other long-term liabilities	62	12
Total liabilities	7,393	9,740
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued or outstanding at December 31, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 12,128,843 shares issued and outstanding at December 31, 2022 and 12,110,373 shares issued and outstanding at December 31, 2021	1	1
Additional paid-in capital	132,653	127,289
Accumulated deficit	(116,001)	(79,105)
Total stockholders' equity	16,653	48,185
Total liabilities and stockholders' equity	$ 24,046	$ 57,925

The accompanying notes are an integral part of these financial statements.

Immunome, Inc.
Statements of operations
(in thousands, except share and per share amounts)

	Year ended December 31,	
	2022	2021
Operating expenses:		
Research and development	$ 23,272	$ 14,110
General and administrative	13,629	11,094
Total operating expenses	36,901	25,204
Loss from operations	(36,901)	(25,204)
Other income (expense):		
Other income	—	503
Interest income (expense), net	5	(10)
Total other income	5	493
Net loss	$ (36,896)	$ (24,711)
Deemed dividend arising from warrant modification	(622)	—
Net loss attributable to common stockholders	$ (37,518)	$ (24,711)
Per share information:		
Net loss per common share, basic and diluted	$ (3.09)	$ (2.14)
Weighted-average common shares outstanding, basic and diluted	12,126,573	11,538,668

The accompanying notes are an integral part of these financial statements.

Immunome Inc.
Statements of changes in stockholders' equity
(in thousands, except share amounts)

	Stockholders' equity				
	Common stock		Additional paid-in capital	Accumulated deficit	Total
	Shares	Amount			
Balance at January 1, 2021	10,634,245	1	95,738	(54,394)	41,345
Sale of common stock and common stock warrants, net of $559 in offering costs	1,014,115	—	26,666	—	26,666
Share-based compensation expense	—	—	3,448	—	3,448
Exercise of common stock warrants	200,979	—	1,338	—	1,338
Exercise of stock options and vesting of restricted stock	261,034	—	99	—	99
Net loss	—	—	—	(24,711)	(24,711)
Balance at December 31, 2021	12,110,373	1	127,289	(79,105)	48,185
Share-based compensation expense	—	—	5,332	—	5,332
Exercise of stock options	18,470	—	32	—	32
Net loss	—	—	—	(36,896)	(36,896)
Balance at December 31, 2022	12,128,843	$ 1	$ 132,653	$ (116,001)	$ 16,653

The accompanying notes are an integral part of these financial statements.

Immunome Inc.
Statements of cash flows
(in thousands)

	Year ended December 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (36,896)	$ (24,711)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	422	755
Amortization of right-of-use asset	209	—
Share-based compensation	5,332	3,448
Deferred rent	—	4
Forgiveness of PPP Loan	—	(500)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	5,071	(4,281)
Accounts payable	(677)	1,780
Accrued expenses and other current liabilities	(1,922)	5,279
Other long-term liabilities	(229)	—
Net cash used in operating activities	(28,690)	(18,226)
Cash flows from investing activities:		
Purchases of property and equipment	(248)	(79)
Net cash used in investing activities	(248)	(79)
Cash flows from financing activities:		
Proceeds from exercise of stock options	32	99
Proceeds from exercise of common stock warrants	—	1,338
Proceeds from sale of common stock and common stock warrants	—	27,225
Payment of issuance costs related to the sale of common stock and common stock warrants	—	(559)
Payment of equipment loan payable	—	(113)
Payment of offering costs	—	(222)
Net cash provided by financing activities	32	27,768
Net (decrease) increase in cash and cash equivalents and restricted cash	(28,906)	9,463
Cash and cash equivalents and restricted cash at beginning of year	49,329	39,866
Cash and cash equivalents and restricted cash at end of year	$ 20,423	$ 49,329
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ —	$ 14
Supplemental disclosures of non-cash investing and financing activities:		
Operating lease right-of-use asset and lease liability recorded upon adoption of ASC 842	$ 492	$ —
Offering costs included in accounts payable	$ —	$ 110

The accompanying notes are an integral part of these financial statements.

Immunome, Inc.
Notes to financial statements

1. Nature of the business

Organization

Immunome, Inc., the Company or Immunome, is a biopharmaceutical company. The Company was incorporated as a Pennsylvania corporation on March 2, 2006 and was converted to a Delaware corporation on December 2, 2015. The Company is utilizing a proprietary human memory B cell platform to discover and develop antibody therapeutics to improve patient care. The Company's primary focus areas are oncology and other diseases, including COVID-19.

Since its inception, the Company has devoted substantially all its resources to research and development, raising capital, building its management team and extending its intellectual property portfolio. The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, risks associated with the successful research, development and manufacturing of programs and development candidates, uncertain results of preclinical and clinical testing, development of new technological innovations and products by competitors, dependence on key personnel and third-party vendors, protection of proprietary technology, compliance with government regulations, regulatory approval of programs and development candidates and the ability to secure additional capital to fund operations.

Liquidity

The Company has incurred net losses since inception, including net losses of $36.9 million and $24.7 million for the years ended December 31, 2022 and 2021, respectively, and it expects to generate losses from operations for the foreseeable future primarily due to research and development costs for its programs and development candidates. As of December 31, 2022, the Company had an accumulated deficit of $116.0 million. The Company expects to generate operating losses for the foreseeable future.

Through December 31, 2022, the Company raised an aggregate of $125.1 million in gross proceeds from sales of our common stock, Series A convertible preferred stock and warrants, warrant and stock option exercises, the issuance of convertible promissory notes, and the Payment Protection, or PPP, loan that was forgiven in May 2021. In addition, in July 2020, the Company entered into an Other Transaction Authority for Prototype Agreement, or the OTA Agreement, with the Department of Defense, or the DoD, to fund the Company's efforts in developing an antibody cocktail therapeutic to treat COVID-19. As of December 31, 2022, the Company has received $17.6 million in expense reimbursement from the DoD under the OTA Agreement.

On October 1, 2021, the Company entered into an Open Market Sale Agreement, or the ATM Agreement, with Jefferies Group LLC, which provides that, upon the terms and subject to the conditions and limitations in the ATM Agreement, the Company may elect, from time to time, to offer and sell shares of common stock under the registration statement having an aggregate offering price of up to $75.0 million through Jefferies Group LLC acting as sales agent. The Company filed a shelf registration statement on Form S-3, which was declared effective by the Securities and Exchange Commission, or the SEC, on October 14, 2021, pursuant to which the Company may issue from time-to-time securities with an aggregate value of up to $200.0 million. The Company has not sold any shares under the ATM Agreement or the shelf registration statement as of December 31, 2022.

On January 4, 2023, the Company entered into a collaboration and option agreement, or the Collaboration Agreement, with AbbVie Global Enterprises Ltd, or AbbVie, directed to the discovery of up to 10 novel target-antibody pairs leveraging our discovery engine. Under the terms of the Collaboration Agreement, Immunome will grant AbbVie the option to purchase worldwide rights for up to 10 novel target-antibody pairs arising from the selected tumors. AbbVie will pay the Company an option exercise fee in the low single digit millions for each of the validated target pairs for which it exercises an option. The Company received a non-refundable upfront payment of $30.0 million in January 2023 and will be eligible to receive additional platform access payments in the aggregate amount of up to $70.0 million based on AbbVie's election for the Company to continue research using its discovery engine. The Company is also

eligible to receive development and first commercial sale milestones of up to $120.0 million per target with respect to certain products derived from target-antibody pairs that AbbVie elects to purchase, sales-based milestones based on achievement of specified levels of net sales of products up to $150.0 million in the aggregate per target, and tiered low single digit royalties on net sales of products. The Company is potentially eligible to receive up to $2.8 billion from AbbVie under the Collaboration Agreement from the sources described above. However, there are no assurances that the Company will receive additional payments from AbbVie beyond the $30.0 million upfront payment.

The Company expects that its cash as of December 31, 2022, together with the $30.0 million received in January 2023 from AbbVie under the Collaboration Agreement, will be sufficient to fund its operations for at least 12 months from the filing date of this Annual Report on Form 10-K. Beyond that date, more funding will be necessary to fund additional research and development activities and operations in order to pursue the Company's growth strategy.

If the Company cannot obtain the necessary funding, it will need to delay, scale back or eliminate some or all of its research and development programs or enter into collaborations with third parties relative to potential programs, products or technologies that it might otherwise seek to progress independently (or enter into these collaborations sooner than it might otherwise have intended to); consider various other strategic alternatives, including a possible merger or sale of the Company; or reduce or cease operations. If the Company engages in collaborations under these circumstances, it may receive lower consideration than if it had not entered into such arrangements or if it entered into such arrangements at later stages in the research and development process. Additionally, volatility in the capital markets generally and the biotechnology sector specifically, as well as general economic conditions in the United States may be a significant obstacle to raising the required funds on satisfactory terms, if at all.

Operations of the Company are subject to certain risks and uncertainties including various internal and external factors that will affect whether and when the Company's programs and development candidates become approved drugs and how significant their market share will be, many of which are outside of the Company's control. The length of time and cost of developing and commercializing these programs and development candidates and/or failure of them at any stage of the drug approval process will materially affect the Company's financial condition and future operations. The Company is also subject to risks and uncertainties as a result of the ongoing COVID-19 pandemic. Although there is uncertainty as to the extent of the continued impact of the COVID-19 pandemic, including the continued impact to capital markets and economies worldwide in the form of economic slowdowns or recession, there has not been a significant impact to the Company's operations or financial statements to date.

2. Summary of significant accounting policies

Basis of presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted, or GAAP, in the United States. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification, or ASC, and Accounting Standards Updates, or ASU, promulgated by the Financial Accounting Standards Board, or FASB.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses. The Company bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the expected volatility used to estimate fair value of stock options and accrued research and development expenses. Estimates and assumptions are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from these estimates.

Segment and geographic information

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or CODM, or decision-making group, in deciding how to allocate resources and in assessing performance. The CODM is the Company's Chief Executive Officer. The Company views its operations as and manages its business in one operating segment operating exclusively in the United States.

Cash and cash equivalents

Cash and cash equivalents consist of standard checking accounts and a money market account. 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.

Restricted cash

Restricted cash represents collateral provided for a letter of credit issued as a security deposit in connection with the Company's lease of its corporate facilities. Cash will be released from restriction upon termination of the lease. Restricted cash was $100,000 at both December 31, 2022 and 2021, respectively. The following table provides a reconciliation of the components of cash and cash equivalents and restricted cash presented in the statements of cash flows:

(in thousands)	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 20,323	$ 49,229
Restricted cash	100	100
	$ 20,423	$ 49,329

Concentration of credit risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. As of December 31, 2022, the Company held deposits at Silicon Valley Bank ("SVB") in excess of government insured limits. On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation ("FDIC") was appointed as receiver. No losses were incurred by the Company on the Company's deposits that were held at SVB. Subsequent to this event the Company's deposits were transferred to a financial institution that management believes to be of high credit quality, therefore management believes that the Company currently is not exposed to significant credit risk.

Property and equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

Asset category	Estimates useful life
Lab equipment	5 years
Leasehold improvements	Lesser of lease term or 5 years
Computer equipment	3 years
Office equipment	5 years
Furniture and fixtures	5 years

Expenditures for repairs and maintenance of assets are charged to expense as incurred, while major betterments are capitalized. Upon retirement or sale, the cost and related accumulated depreciation and amortization of assets disposed of are removed from the accounts and any resulting gain or loss is included in the statements of operations.

Impairment of long-lived assets

The Company evaluates its long-lived assets, which consist primarily of property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. There were no impairment losses recognized during the years ended December 31, 2022 and 2021.

Equity issuance costs

The Company capitalized costs that were directly associated with establishing the ATM Agreement and shelf registration statement in 2021. These costs will remain capitalized until such financings are consummated, at which time such costs will be recorded against the gross proceeds from the applicable financing. If a financing is abandoned, deferred offering costs are expensed. Ongoing costs that are directly associated with the ATM Agreement are expensed as incurred.

Deferred offering costs were $0.3 million as of each of December 31, 2022 and 2021, respectively, in the balance sheets.

Government assistance programs

The Company accounts for amounts received under the DoD expense reimbursement contract as contra-research and development expenses in the statements of operations. The Company accounts for the employee retention credit received under the U.S. Department of Treasury Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, as contra-expense to personnel related costs within research and development and general and administrative expenses in the statements of operations.

Research and development costs

Research and development costs are charged to expense as incurred. Research and development costs consist of costs incurred in performing research and development activities, including salaries and bonuses, share-based compensation, employee benefits, facilities costs, laboratory supplies, depreciation and amortization, preclinical and clinical development expenses, including manufacture and testing of clinical supplies, consulting and other contracted services. Additionally, under the terms of the license agreements described in Note 9, the Company is obligated to make future payments should certain development, regulatory, and sales milestones be achieved. Costs for certain research and development activities are recognized based on the terms of the individual arrangements, which may differ from the timing of receipt of invoices and payment of invoices and are reflected in the financial statements as a prepaid or accrued expense.

Share-based compensation

The Company’s share-based compensation program allows for grants of stock options and restricted stock awards. Grants are awarded to employees and non-employees, including directors.

The Company accounts for its share-based compensation awards granted to employees and non-employees based on the estimated fair value on the date of grant and recognized compensation expense of those awards over the requisite service period, which is the vesting period of the respective award. The Company accounts for forfeitures as they occur. For share-based awards with service-based vesting conditions, the Company recognized compensation expense on a straight-line basis over the service period. The Company classified share-based compensation expense in its statements of operations in the same manner in which the award recipient’s payroll costs are classified or in which the award recipient’s service payments are classified.

The Company estimates the fair value of options granted using the Black-Scholes option pricing model for stock option grants to both employees and non-employees. The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of Company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and biopharmaceutical industry focus. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The Company uses the simplified method to calculate the expected term for options granted to employees and non-employees whereby, the expected term equals the arithmetic average of the vesting term and the original contractual term of the options due to its lack of sufficient historical data. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock. The exercise price is the fair value of the common stock as of the measurement date.

Patent costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses in the accompanying statements of operations.

Leases

Effective January 1, 2022, the Company adopted ASU No. 2016-02, *Leases*, or ASC 842, using the modified retrospective approach by applying the new standard to all leases existing on the adoption date. The results for reporting periods beginning after January 1, 2022 are presented in accordance with ASC 842, while prior period amounts are not adjusted and continue to be reported under the accounting standards that were in effect prior to January 1, 2022.

At the inception of an arrangement, the Company determines whether an arrangement contains a lease based on facts and circumstances present in the arrangement. An arrangement is or contains a lease if the arrangement conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Typically, lessees are required to recognize leases with a term greater than one year in the balance sheets as an operating or finance lease liability and right-of-use asset. Right-of-use assets represent the Company's right to use an underlying asset during the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. The Company has elected the practical expedient to not recognize leases with a term of 12 months or less. The Company does not have any financing leases as of December 31, 2022.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on their present value of lease payments over the remaining lease term. Options to extend the lease term are included in the Company's assessment of the lease term only if there is a reasonable assessment that the Company will renew. Leases are discounted to its present value using either the interest rate implicit in the Company's lease or its incremental borrowing rate, which reflects the fixed rate in which the Company could borrow on a collateralized basis the amount of lease payments in the same currency, for a similar term, in a similar economic environment.

Income taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the Company's financial statements and tax returns. Deferred tax assets and liabilities are determined based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards, using enacted tax rates expected to be in effect in the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that these assets may not be realized. The Company determines whether it is more likely than not that a tax position will be sustained upon examination. If it is not more likely than not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the

more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes.

Fair value of financial instruments

ASC Topic 820, *Fair Value Measurement* (ASC 820), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the assets or liability and are developed based on the best information available in the circumstances. ASC 820 identifies fair value as the price that would be received to sell an asset or paid to transfer a liability, in an orderly transaction between market participants at the measurement date. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tiered value hierarchy that distinguishes between the following:

- Level 1: Quoted market prices in active markets for identical assets or liabilities.
- Level 2: Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.
- Level 3: Unobservable inputs for the asset or liability (i.e., supported by little or no market activity). Level 3 inputs include management's own assumptions about the assumptions that market participants would use in pricing the asset or liability (including assumptions about risk).

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgement. Accordingly, the degree of judgement exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Cash and cash equivalents are Level 1 assets for the years ended December 31, 2022 and 2021.

Net loss per share

Basic net loss per share of common stock is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net loss per share of common stock is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share of common stock is computed by dividing the diluted net loss by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of common stock equivalents.

The following potentially dilutive securities outstanding as of December 31, 2022 and 2021 have been excluded from the computation of diluted weighted-average shares of common stock outstanding, as they would be anti-dilutive:

	Year ended December 31,	
	2022	2021
Stock options[(1)]	2,519,405	2,005,756
Common stock warrants[(1)]	1,303,112	1,303,112
	3,822,517	3,308,868

(1) Represents common stock equivalents

In periods in which the Company reports a net loss per share of common stock, diluted net loss per share of common stock is the same as basic net loss per share of common stock since dilutive common shares are not assumed to have

been issued if their effect is anti-dilutive. The Company reported a net loss per share of common stock for the years ended December 31, 2022 and 2021.

Recently adopted accounting standards

ASC Topic 842, Leases

On January 1, 2022, the Company adopted ASC 842 which supersedes the lease accounting guidance under ASC 840. The standard generally requires lessees to recognize operating and finance lease liabilities and corresponding right-of-use, or ROU, assets in the balance sheets and provide enhanced disclosures on the amount, timing, and uncertainty of cash flows arising from lease arrangements. The Company adopted ASC 842 using the modified retrospective approach. The Company elected the package of practical expedients available for existing contracts, which allowed the Company to carry forward its historical assessments of lease identification, lease classification, and initial direct costs. The Company also elected a policy to not apply the recognition requirements of ASC 842 for short-term leases with a term of 12 months of less. As of January 1, 2022, the effective date, the Company identified one operating lease arrangement relating to the Company's headquarters facility and a short-term lease relating to laboratory equipment. The adoption of ASC 842 resulted in a recognition of an ROU asset and lease liability of $0.5 million in the Company's balance sheets relating to the lease as of January 1, 2022. The adoption of the standard did not have a material effect on the Company's statements of operations and statements of cash flows.

ASU Topic 832, Government Assistance

In November 2021, the FASB issued ASU 2021-10, *Government Assistance*, or Topic 832, which requires enhanced disclosures of transactions with governments that are accounted for by applying a grant or contribution model. The new pronouncement requires entities to provide information about the nature of the transaction, terms and conditions associated with the transaction and financial statement line items affected by the transaction. The Company adopted the standard for the annual period beginning January 1, 2022. The DoD expense reimbursement contract and the employee retention credit received under the CARES Act qualify as government assistance programs under Topic 832 and resulted in enhanced required disclosures, as described in Note 5.

ASU 2021-04, Earnings Per Share

In May 2021, the FASB issued ASU 2021-04 *Earnings Per Share (Topic 260), Debt— Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)*, or ASU 2021-04, that requires the issuer to treat a modification of an equity-classified written call option (i.e., a warrant) that does not cause the option to become liability-classified as an exchange of the original option for a new option. An issuer should measure the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately before modification or exchange. The Company adopted the standard for interim periods beginning January 1, 2022. As described in Note 11, in September 2022, the Company modified its Series B Warrants which resulted in a reduction in exercise price from $45.00 per share to $10.00 per share. The Company recognized a deemed dividend of $0.6 million which was recorded in the Company's statement of operations as an increase to the net loss attributable to common stockholders for purposes of computing net loss per share, basic and diluted. The net impact to the statements of changes in stockholders' equity was zero because the warrants were equity classified before and after the modification.

3. Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following:

(in thousands)	December 31, 2022	December 31, 2021
Prepaid subscriptions, prepaid service contracts and short-term deposits	$ 876	$ 492
CARES Act employee retention credit receivable	847	—
Research and development advance payments	445	586
Prepaid insurance	158	2,019
Reimbursement receivable from the DoD	—	2,674
Unbilled reimbursement receivable from the DoD	—	1,638
	$ 2,326	$ 7,409

4. Property and equipment, net

Property and equipment consisted of the following:

(in thousands)	December 31, 2022	December 31, 2021
Lab equipment	$ 3,681	$ 3,513
Leasehold improvements	194	193
Computer equipment	235	156
Office equipment and furniture and fixtures	22	22
	4,132	3,884
Less accumulated depreciation and amortization	(3,451)	(3,029)
Property and equipment, net	$ 681	$ 855

Depreciation and amortization expense was $0.4 million and $0.8 million for the years ended December 31, 2022 and 2021, respectively. There were no assets under capital leases as of December 31, 2022 and 2021.

5. Government assistance programs

DoD expense reimbursement contract

In July 2020, the Company entered into the OTA Agreement with the DoD to fund the Company's efforts in developing an antibody cocktail therapeutic to treat COVID-19. The amount of funding originally made available to the Company under the OTA Agreement was $13.3 million. In May 2021, the Company and the DoD amended the OTA Agreement, pursuant to which the DoD award was increased from $13.3 million to $17.6 million. In January 2023, the Company and the DoD modified the OTA Agreement to extend the termination date of the agreement to July 2023, at no additional cost to the government. All other terms and conditions remain the same and are in full force and effect.

Under the OTA Agreement, the DoD is required to pay the Company, upon submission of invoices for approved budgeted supplies delivered and services rendered in carrying out the prototype project, within 30 calendar days of receipt of request for payment. As of December 31, 2022, the Company has received the maximum $17.6 million in expense reimbursement from the DoD under the OTA Agreement.

The Company recorded contra-research and development expense of $0.6 million and $15.2 million for the years ended December 31, 2022 and 2021, respectively, in the statements of operations. There was no expense reimbursement receivable due from the DoD as of December 31, 2022. The Company had an expense reimbursement receivable balance

of $2.7 million due from the DoD in prepaid expenses and other current assets as of December 31, 2021 in the accompanying balance sheets. DoD reimbursable services that have been performed but not yet billed are recorded as an unbilled receivable in prepaid expenses and other current assets in the accompanying balance sheets. There was no unbilled receivable from the DoD as of December 31, 2022. As of December 31, 2021, the Company had an unbilled receivable of $1.6 million from the DoD.

Costs that have been reimbursed by the DoD but not yet expensed by the Company are recorded as a deferred research obligation liability for the period. The deferred research obligation liability is inconsequential for the year ended December 31, 2022. As of December 31, 2021, the deferred research liability of $2.0 million is included in accrued expenses and other liabilities in the accompanying balance sheets.

CARES Act employee retention credit

Under the CARES Act, the Company met eligibility criteria for a $0.8 million refundable employee retention credit. The Company recorded contra-expense to personnel related costs within research and development expense of $0.6 million and general and administrative expense of $0.2 million for the year ended December 31, 2022. No such amounts were recorded for the year ended December 31, 2021.

The Company had an employee retention credit receivable due from the U.S. Department of Treasury of $0.8 million in prepaid expenses and other current assets as of December 31, 2022 in the accompanying balance sheets. There was no employee retention credit receivable due from the U.S. Department of Treasury as of December 31, 2021.

6. Accrued expenses and other liabilities

Accrued expenses and other liabilities consisted of the following:

	December 31,	
(in thousands)	2022	2021
Research and development	$ 2,261	$ 2,840
Compensation and related benefits	1,874	1,246
Professional fees	481	227
Short-term operating lease liability and other liabilities	293	317
Deferred research obligations	22	2,021
	$ 4,931	$ 6,651

7. Long-term debt

On April 30, 2020, the Company entered into a loan agreement with Silicon Valley Bank as the lender, or Lender, for a loan in an aggregate principal amount of $0.5 million pursuant to the Paycheck Protection Program under the CARES Act and implemented by the U.S. Small Business Administration. The Company used the proceeds of the PPP Loan for payroll and other qualifying expenses. The entire PPP Loan was forgiven on May 21, 2021 and recognized as other income in the statement of operations for the year ended December 31, 2021.

8. Commitments and contingencies

Employment agreements

The Company entered into employment agreements, or the Employment Agreements, with certain key personnel providing for compensation and severance in certain circumstances, as defined in the respective Employment Agreements. The Employment Agreements may be terminated by either the Company or the employees in accordance with the respective Employment Agreements (subject to the payment of severance upon certain terminations) and provide for annual pay adjustments and bonuses at the discretion of the Board of Directors.

Employee benefit plan

The Company maintains a defined-contribution plan under Section 401(k) of the Internal Revenue Code, or the 401(k) Plan. The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company assumes all administrative costs of the 401(k) Plan and makes matching contributions as defined in the 401(k) Plan document. The Company made matching contributions of $0.2 million and $0.1 million to the 401(k) Plan for the years ended December 31, 2022 and 2021, respectively.

Legal proceedings

The Company is not a party to any material litigation and does not have contingency reserves established for any litigation liabilities. At each reporting date, the Company evaluates whether a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies.

9. Licensing arrangements

The Company has entered into various license agreements to further discover, develop and commercialize certain technologies and treatments. The Company may need to pay developmental and regulatory milestone payments of up to approximately $2.6 million. In addition, the Company may need to pay royalty rates on net product sales, a portion of certain sublicense and collaboration payments, and certain commercial milestone payments of up to approximately $1.5 million, if any.

The Company recorded $0.1 million in development and regulatory milestone payments during the year ended December 31, 2022 in research and development expenses in the statements of operations. There were no development and regulatory milestone payments during the year ended December 31, 2021.

2022 Amendment to Exclusive License Agreement

In December 2022, the Company and Arrayjet Limited, or Arrayjet, amended the Exclusive License Agreement, effective as of June 28, 2019 and amended July 10, 2020. The agreement was amended, among other things, to increase the recurring exclusivity annual fee and make certain adjustments to the termination rights.

2021 Patent License Agreement

In June 2021, the Company entered into an exclusive worldwide patent license agreement with several Philadelphia based universities and hospitals (the Licensors) to further discover, develop and commercialize human antibodies, identified using Immunome's human hybridoma technology, for the treatment of diseases associated with the formation of bacterial biofilms. The Licensors are eligible to receive up to $2.2 million in the aggregate for certain regulatory, developmental, and commercial milestone payments. In addition, the Licensors are eligible to receive low single digit royalty rates for net product sales, which are subject to adjustment in the event the Company sublicenses the approved technology.

The Company recorded $0.1 million in initiation and minimum annual payments related to this agreement for each of the years ended December 31, 2022 and 2021, respectively, in research and development expenses in the statement of operations.

10. Leases

In May 2017, the Company entered into a 62-month office and laboratory space lease commencing on July 1, 2017 for approximately 11,000 square feet of space in Exton, Pennsylvania. The Company has an option to extend the lease for up to two additional five-year terms. In December 2021, the Company extended the lease for an additional eighteen-month term ending in March 2024. Beginning July 2021, the Company leased laboratory equipment on a month-to-

month basis. In April 2022, the Company terminated the agreement through exercising the option to purchase the leased laboratory equipment under the lease agreement.

Supplemental balance sheet information related to leases as of December 31, 2022 was as follows (in thousands):

Operating leases:		
Operating lease right-of-use assets	$	284
Operating lease liability	$	229
Operating lease liability, net of current portion		62
Total operating lease liability	$	291

Operating lease liability and operating lease liability, net of current portion is included in accrued expenses and other current liabilities and other long-term liabilities, respectively, in the accompanying balance sheets.

Operating lease expense recorded as research and development and general and administrative expenses in the statements of operations is as follows (in thousands):

Operating lease cost (in thousands)		Year Ended December 31, 2022
General and administrative	$	78
Research and development		163
Total lease expense	$	241

Short term lease expense recorded as research and development expense in the statements of operations was $0.1 million for year ended December 31, 2022.

Under ASC 840, lease expense was $0.5 million for the year ended December 31, 2021.

Other information related to the operating lease where the Company is the lessee was as follows:

	Year Ended December 31, 2022
Weighted-average remaining lease term (in years)	1.25
Weighted-average discount rate	9.0%

Supplemental cash flow information related to the operating lease was as follows (in thousands):

		Year Ended December 31, 2022
Cash paid for operating lease liability	$	234

As of December 31, 2022, minimum rental commitments under the operating lease were as follows (in thousands):

Years ending December 31,		Amount
2023	$	246
2024		63
Total lease payments		309
Less imputed interest		(18)
Present value of lease liability	$	291

11. Common stock

Common stock

The holders of common stock are entitled to one vote for each share of common stock. Subject to the approval of the majority of shareholders, the holders of common stock shall be entitled to receive dividends out of funds legally available. In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, the holders of common stock shall be entitled to share ratably in the remaining assets of the Company available for distribution.

On October 1, 2021, the Company entered into the ATM Agreement with Jefferies Group LLC, which provides that, upon the terms and subject to the conditions and limitations in the ATM Agreement, the Company may elect, from time to time, to offer and sell shares of common stock under the registration statement having an aggregate offering price of up to $75.0 million through Jefferies Group LLC acting as sales agent. The Company filed a shelf registration statement on Form S-3, which was declared effective by the SEC on October 14, 2021, pursuant to which the Company may issue from time-to-time securities with an aggregate value of up to $200.0 million. The company has not sold any shares under the ATM Agreement or the shelf registration statement as of December 31, 2022.

On August 4, 2021, the Company sold 14,115 shares of the Company's common stock for $15.94 per share to a purchaser in accordance with the Stock Purchase Agreement, or Stock Purchase Agreement.

On April 28, 2021, the Company sold 1,000,000 units, each unit comprising one share of the Company's common stock and one Series B Warrant (each, a "Series B Warrant") to purchase one-half of a share of common stock. The units were issued in a private placement at a price of $27.00 per unit for gross proceeds of $27.0 million. The Series B Warrants are equity-classified, exercisable at any time, have an exercise price of $45.00 per share and will terminate three years from the date of issuance. The fair value of the warrants on the date of issuance was $6.0 million. The fair value of the warrants was estimated using a Black-Scholes Option Pricing Model. The significant assumptions used in preparing the option pricing model for valuing the Company's warrants to purchase shares of common stock as of April 28, 2021 included (i) volatility of 82.7%, (ii) risk free interest rate of 0.35%, (iii) strike price of $45.00 per share, (iv) fair value of common stock of $28.70 per share, and (v) expected life of three years. As described below, in September 2022, the Series B Warrants were modified to reduce the strike price to $10.00 per share and to remove the Company's call right.

Warrants to acquire shares of common stock

On September 2, 2022, the Company notified holders of the Company's Series B Warrants, or the Holders, of the Company's agreement to permit Holders to exercise the Series B Warrants at an exercise price of $10.00 per share (reduced from the previous exercise price of $45.00 per share) at any time prior to the expiration date of the Series B Warrants. The Company recognized a deemed dividend of $0.6 million, which represents the incremental fair value of the outstanding warrants as a result of the modification. This deemed dividend is recorded in the Company's statement of operations as an increase to the net loss attributable to common stockholders for purposes of computing net loss per share, basic and diluted. The net impact to the statements of changes in stockholders' equity was zero because the warrants were equity classified before and after the modification.

At December 31, 2022 common stock warrants outstanding were as follows:

Warrants	Warrants Outstanding	Exercise Price per Share	Expiration Date
Series A	803,112	$ 9.00	June 2, 2023
Series B	500,000	$ 10.00	April 28, 2024

For the year ended December 31, 2022, no warrants were exercised. For the year ended December 31, 2021, 148,653 warrants exercisable for $9.00 per share were exercised, and the Company received proceeds of $1.3 million

and 148,653 shares of the Company's common stock were issued. Additionally, 83,431 warrants exercisable for $9.00 per share were exercised in cashless transactions during the year ended December 31, 2021 and 52,326 shares of the Company's common stock were issued.

12. Share-based compensation

On September 18, 2020, the Company adopted the Equity Incentive Plan, or the 2020 Plan, which supersedes all prior equity incentive plans. Under the 2020 Plan, the number of shares of common stock reserved for issuance under the 2020 Plan will automatically increase on January 1 of each year, beginning on January 1, 2021 and continuing through and including January 1, 2030, by 4% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's Board of Directors. As of December 31, 2022, there were 1,325,192 shares available for future issuance under the 2020 Plan. On January 1, 2023, the number of shares available for future issuance under the 2020 Plan increased by 485,153 shares.

The Company also adopted the 2020 Employee Stock Purchase Plan, or the ESPP, on September 18, 2020 which provides for the grant of purchase rights to purchase shares of the Company's common stock to eligible employees, as defined by the ESPP. The maximum number of shares of common stock that may be issued under the ESPP will not exceed 125,000 shares of common stock, plus the number of shares of common stock that are automatically added on January 1 of each calendar year for a period of up to ten years, commencing on the first January 1 following the year in which an IPO occurs and ending on, and including, January 1, 2030, in an amount equal to the lesser of (i) 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, and (ii) 1,000,000 shares of common stock. As of December 31, 2022, there were 352,445 shares available under the ESPP. No shares of common stock have been issued under the ESPP as of December 31, 2022. On January 1, 2023, the number of shares available for future issuance under the ESPP increased by 121,288 shares.

The 2020 Plan and the ESPP are administered by the Board of Directors subject to the Board's right to delegate to a committee. The exercise prices, vesting and other restrictions are determined at the discretion of the Board of Directors. Stock options awarded under the 2020 Plan generally expire 10 years after the grant date unless the Board of Directors sets a shorter term. Vesting periods for awards under the 2020 Plan are determined at the discretion of the Board of Directors. Stock options granted to employees, officers, members of the Board of Directors and consultants of the Company typically vest over one to four years. Certain options provide for accelerated vesting if there is a change in control, as defined in the 2020 Plan.

Share-based compensation expense recorded as research and development and general and administrative expenses in the statements of operations is as follows (in thousands):

	Year Ended December 31,	
In thousands)	2022	2021
General and administrative	$ 3,471	$ 2,071
Research and development	1,861	1,377
	$ 5,332	$ 3,448

Unrecognized compensation cost related to unvested options was $9.2 million as of December 31, 2022 and will be recognized over an estimated weighted average period of 2.6 years.

Stock options

The weighted average assumptions used in the Black-Scholes option-pricing model for stock options granted were:

	Year ended December 31,	
	2022	2021
Expected volatility	85.6 %	83.0 %
Risk-free interest rate	2.7 %	1.0 %
Expected term (in years)	6.0	6.0
Expected dividend yield	—	—
Fair value of common stock	$ 3.63	$ 23.04

A summary of option activity under the 2020 Plan and prior Plans during the year ended December 31, 2022 is as follows:

	Number of shares	Weighted average exercise price per share	Weighted average remaining contractual term (years)
Outstanding at January 1, 2022	2,005,756	$ 11.26	8.50
Granted	563,900	3.63	9.19
Forfeited	(24,990)	11.97	—
Expired	(6,791)	17.54	—
Exercised	(18,470)	1.76	6.62
Outstanding at December 31, 2022	2,519,405	9.60	7.90
Exercisable at December 31, 2022	1,239,114	8.86	7.30

The weighted-average grant date fair value per share of stock options granted during the years ended December 31, 2022 and 2021 was $2.65 and $16.49, respectively. The aggregate intrinsic value of stock options exercised during the year ended December 31, 2022 was $0.2 million. The aggregate intrinsic value for options exercisable at December 31, 2022 was $0.8 million. The aggregate intrinsic value of stock options outstanding at December 31, 2022 was $0.9 million.

Restricted Stock Awards

During August 2021, the Company granted 13,500 fully vested restricted stock awards. The Company recorded share-based compensation expense of $0.2 million for the year ended December 31, 2021 related to the restricted stock awards granted. No such transaction occurred for the year ended December 31, 2022.

13. Income taxes

A reconciliation of the federal income tax rate to the Company's effective tax rate is as follows:

	Year ended December 31,	
	2022	2021
Federal tax benefit at statutory rate	21.0 %	21.0 %
State tax, net of federal benefit	4.3	8.0
Effects of state tax legislation, net of federal benefit	(7.1)	—
Research and development credits	1.9	2.4
Permanent differences	(0.2)	0.3
Change in valuation allowance	(19.9)	(31.7)
	— %	— %

The components of the Company's deferred taxes are as follows (in thousands):

	December 31,	
(in thousands)	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 20,523	$ 19,925
Research and development intangibles	4,839	—
Research and development credits	2,878	2,157
Share-based compensation	2,016	886
Accrued bonus	383	331
Other	1	1
Gross deferred tax assets	30,640	23,300
Less: valuation allowance	(30,609)	(23,255)
Net deferred tax asset	31	45
Deferred tax liability		
Depreciation	(31)	(45)
Total deferred tax liabilities	$ —	$ —

The Company had no income tax expense due to the operating losses incurred for the years ended December 31, 2022 and 2021. Management has evaluated the positive and negative evidence bearing upon the realizability of the Company's net deferred tax assets and has determined that it is more likely than not that the Company will not recognize the benefits of the net deferred tax assets. As a result, the Company has recorded a full valuation allowance at December 31, 2022 and 2021. The valuation allowance increased by $7.4 million and $7.8 million in 2022 and 2021, respectively, due to the increase in deferred tax assets, primarily due to net operating loss carryforwards, and research and development tax credits, and deductible accrued expenses.

Realization of the future tax benefits is dependent on many factors, including the Company's ability to generate taxable income within the net operating loss carryforward period. Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership, including a sale of the Company or significant changes in ownership due to sales of equity, may have limited, or may limit in the future, the amount of net operating loss and other attributes including research and development credit carry forwards which could be used annually to offset future taxable income. Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has not currently completed an evaluation of ownership changes through December 31, 2022 to assess whether utilization of the Company's net operating loss or research and development credit carryforwards would be subject to an annual limitation under

Sections 382 and 383. To the extent an ownership change occurs in the future, the net operating loss and credit carryforwards may be subject to limitation. Further, until a study is completed and any limitation is known, no amounts are presented as an uncertain tax position. As a result, the Company is not able to estimate the effect of the change in control, if any, on the Company's ability to utilize net operating loss and research and development credit carryforwards in the future. The Company has not yet conducted a study of its research and development credit carryforwards. This study may result in an increase or decrease to the Company's credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are presented as an uncertain tax position. A full valuation allowance has been provided against the Company's credits, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. As a result, there would be no impact to the Company's financial statements.

As of December 31, 2022, the Company had $81.0 million of federal and $81.4 million of state net operating loss carryforwards. If not utilized, the federal and state net operating loss carryforwards expire starting in 2027. Included in the federal net operating loss carryforwards are $64.0 million of net operating loss generated from 2018 to 2022 that will not expire and are limited to offset 80% of the Company's taxable income for years beginning after December 31, 2020. Certain federal and state net operating loss carryforwards expire at various dates through 2042. As of December 31, 2022, the Company had cumulative federal R&D tax credits of $2.7 million. These tax credit carryforwards will expire at various dates through 2042.

As of December 31, 2022 and 2021, the Company had no uncertain tax positions. The Company recognizes both interest and penalties associated with unrecognized tax benefits as a component of income tax expense. The Company has not recorded any interest or penalties for unrecognized tax benefits since its inception.

The Company filed income tax returns in the United States and Pennsylvania in all tax years since inception. The tax years 2006 and beyond remain open to examination by these jurisdictions. Carryforward attributes generated in all years since inception remain subject to adjustment. The Company is not currently under examination by the Internal Revenue Service or any other jurisdiction for these years.

14. Related party transactions

Broadband services agreement

In November 2015, the Company entered into a management services agreement, or MSA, with BCM Advisory Partners LLC and Broadband Capital Partners LLC, or Broadband Capital. Certain directors of the Company are principals of Broadband Capital. Under the Broadband MSA, the Company engages Broadband Capital as a consultant for advice in connection with senior management matters related to the Company's business, administration and policies in exchange for a cash fee to Broadband Capital of $20,000 per month. The Broadband MSA was amended and/or restated in July 2016, January 2017, June 2018, March 2020 and August 2020. In June 2021, the Company extended the Broadband MSA to continue through June 2022. The Broadband MSA expired in June 2022. The Company recorded $0.1 million and $0.2 million during the years ended December 31, 2022 and 2021, respectively, related to the Broadband MSA, which is included in general and administrative expenses in the statements of operations. Amounts due to Broadband Capital were $0.1 million and $0.0 as of December 31, 2022 and December 31, 2021, respectively.

15. Subsequent events

Collaboration Agreement with AbbVie

On January 4, 2023, the Company entered into the Collaboration Agreement with AbbVie, pursuant to which the Company will use its proprietary discovery engine to discover and validate targets derived from patients with three specified tumor types, and antibodies that bind to such targets, which may be the subject of further development and commercialization by AbbVie. The research term is at least 66 months, subject to extension in certain circumstances by specified extension periods. Pursuant to the terms of the Collaboration Agreement, with respect to each novel target-antibody pair that the Company generates that meets certain mutually agreed criteria (each, a Validated Target Pair or VTP), the Company granted to AbbVie an exclusive option (up to a maximum of 10 in total) to purchase all rights in and to such Validated Target Pair, for all human and non-human diagnostic, prophylactic and therapeutic uses throughout the

world, including without limitation the development and commercialization of certain products derived from the assigned Validated Target Pair and directed to the target comprising such VTP (Products). No rights are granted by the Company to AbbVie under any of Company's platform technology covering the Company's discovery engine. Until the expiration of the research term, the Company is not permitted to conduct any activities in connection with targets or antibodies derived from patients with the specified tumor types, whether independently or with other third parties, except in limited circumstances with respect to certain target-antibody pairs that are no longer subject to the collaboration with AbbVie. In addition, during the term of the Collaboration Agreement, the Company is not permitted to develop products directed to targets that are included in VTPs purchased by AbbVie, or to which AbbVie still has rights under the Collaboration Agreement, whether independently or with other third parties.

Under the Collaboration Agreement, AbbVie will pay the Company an upfront payment of $30.0 million, plus certain additional platform access payments in the aggregate amount of up to $70.0 million based on the Company's use of its discovery engine in connection with activities under each stage of the research plan, and delivery of VTPs to AbbVie. AbbVie will also pay an option exercise fee in the low single digit millions for each of the up to 10 VTPs for which it exercises an option. If AbbVie progresses development and commercialization of a Product, AbbVie will pay the Company development and first commercial sale milestones of up to $120.0 million per target, and sales milestones based on achievement of specified levels of net sales of Products of up to $150.0 million in the aggregate per target, in each case, subject to specified deductions in certain circumstances. On a Product-by-Product basis, AbbVie will pay the Company tiered royalties on net sales of Products at a percentage in the low single digits, subject to specified reductions and offsets in certain circumstances. AbbVie's royalty payment obligation will commence, on a Product-by-Product and country-by-country basis, on the first commercial sale of such Product in such country and will expire on the earlier of (a) (i) the ten (10)-year anniversary of such first commercial sale for such Product in such country, or (ii) solely with respect to a Product that incorporates an antibody comprising a VTP (or certain other antibodies derived from such delivered antibody), the expiration of all valid claims of patent rights covering the composition of matter of any such antibody (whichever out of (i) or (ii) is later), and (b) the expiration of regulatory exclusivity for such Product in such country. The Company is potentially eligible to receive up to $2.8 billion from AbbVie under the Collaboration Agreement from the sources described above.

The Collaboration Agreement will expire upon the expiration of the last to expire royalty payment obligation with respect to all Products in all countries, subject to earlier expiration if all option exercise periods for all Validated Target Pairs expire without AbbVie exercising any option. In addition, the research term will terminate if AbbVie does not elect to make certain platform access payments at specified points during the research term, in order for the Company to continue the target discovery activities under the collaboration. The Collaboration Agreement may be terminated by (a) either party upon the other party's uncured material breach, or upon any insolvency event of the other party, (b) AbbVie for convenience upon a specified period prior written notice, or (c) AbbVie for the Company's breach of representations and warranties with respect to debarment or compliance with anti-bribery and anti-corruption laws. If AbbVie has the right to terminate the Collaboration Agreement for the Company's uncured material breach or a breach of representations and warranties with respect to debarment or compliance with anti-bribery and anti-corruption laws, AbbVie may elect to continue the Collaboration Agreement, subject to certain specified reductions applicable to certain of AbbVie's payment obligations (with a specified floor on such reductions).

Whitehead Letter Agreement

On November 17, 2022, the Company entered into a Letter Agreement, or the Letter Agreement, with the Whitehead Institute of Biomedical Research, or Whitehead, which became effective on January 4, 2023 upon the satisfaction of the conditions described therein. The Letter Agreement supplements the Exclusive Patent License Agreement entered into between the Company and Whitehead on June 25, 2009 (as amended on December 17, 2009, March 21, 2013, August 21, 2017 and July 21, 2020, the License Agreement). Pursuant to the Letter Agreement, Whitehead and the Company agreed that certain payments received by the Company from the Collaborator (as defined in the Letter Agreement) (i.e., a corporate partner, as defined in the License Agreement) would be excluded from the Company's payment obligations to Whitehead. The Company and Whitehead further agreed, among other things, that the Company will make certain payments to Whitehead (i) as Net Sales (as defined in the License Agreement) as long as the Company receives those payments from the Collaborator on a specified number of products purchased by the Collaborator and (ii) upon the achievement of certain milestones whether by the Company or the Collaborator.

EXHIBIT INDEX

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Immunome, Inc. (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed October 6, 2020).
3.2	Amended and Restated Bylaws of Immunome, Inc. (incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K filed October 6, 2020).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.2 to Amendment No. 1 to our Registration Statement on Form S-1/A filed on September 24, 2020).
4.2	Amended and Restated Investors' Rights Agreement by and among the registrant and certain of its stockholders, dated as of June 2, 2020 (incorporated by reference to Exhibit 4.1 to our Registration Statement on Form S-1 filed on September 9, 2020).
4.3	Form of 2020 Series A Preferred Stock Warrant (incorporated by reference to Exhibit 4.3 to our Registration Statement on Form S-1 filed on September 9, 2020).
4.4	Form of Amendment to 2020 Series A Preferred Stock Warrants (incorporated by reference to Exhibit 4.4 to Amendment No. 1 to our Registration Statement on Form S-1/A filed on September 24, 2020).
4.5	Form of Series B Warrant (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on April 26, 2021).
4.6*	Description of Securities.
10.1	Form of Indemnification Agreement between the registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to our Registration Statement on Form S-1 filed on September 9, 2020).
10.2#	Amended and Restated 2008 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 to our Registration Statement on Form S-1 filed on September 9, 2020).
10.3#	Form of Incentive Stock Option and Option Agreement for the Amended and Restated 2008 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.3 to our Registration Statement on Form S-1 filed on September 9, 2020).
10.4#	Amended and Restated 2018 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.4 to our Registration Statement on Form S-1 filed on September 9, 2020).
10.5#	Form of Incentive Stock Option and Option Agreement for the Amended and Restated 2018 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.5 to our Registration Statement on Form S-1 filed on September 9, 2020).
10.6#	2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to Amendment No. 1 to our Registration Statement on Form S-1/A filed on September 24, 2020).
10.7#	Forms of Stock Option Grant Notice, Option Agreement, RSU Award Grant Notice and Notice of Exercise for the 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to Amendment No. 1 to our Registration Statement on Form S-1/A filed on September 24, 2020).

10.8#	2020 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.8 to Amendment No. 1 to our Registration Statement on Form S-1/A filed on September 24, 2020).
10.9†	License Agreement by and between the registrant and Arrayjet Limited, dated June 28, 2019, as amended by the Amendment to the License Agreement dated July 10, 2020 (incorporated by reference to Exhibit 10.14 to our Registration Statement on Form S-1 filed on September 9, 2020).
10.10*†	Amendment #2 to the License Agreement by and between the registrant and Arrayjet Limited, dated December 30, 2022.
10.11†	Exclusive Patent License Agreement by and between the registrant and the Massachusetts Institute of Technology as licensing agent for Whitehead Institute for Biomedical Research, dated June 25, 2009, as amended by the First Amendment to the Exclusive Patent License Agreement dated December 17, 2009, by the Second Amendment to the Exclusive Patent License Agreement Dated March 21, 2013, by the Third Amendment to the Exclusive Patent License Agreement dated August 21, 2017 and by the Fourth Amendment to the Exclusive Patent License Agreement dated July 21, 2020 (incorporated by reference to Exhibit 10.15 to our Registration Statement on Form S-1 filed on September 9, 2020).
10.12*†	Letter Agreement by and between the registrant and the Whitehead Institute for Biomedical Research, dated November 17, 2022.
10.13†	Exclusive License Agreement by and between the registrant and Thomas Jefferson University, dated June 1, 2012, as amended by the First Amendment to License Agreement dated October 19, 2017 (incorporated by reference to Exhibit 10.16 to our Registration Statement on Form S-1 filed on September 9, 2020).
10.14†	Second Amendment to License Agreement by and between the registrant and Thomas Jefferson University, dated July 28, 2020 (incorporated by reference to Exhibit 10.17 to our Form 10-Q for the quarterly period ended September 30, 2020 filed on November 16, 2020).
10.15†	Other Transaction Authority for Prototype Agreement by and between the registrant and the Department of Defense, United States of America, dated July 3, 2020 (incorporated by reference to Exhibit 10.18 to our Registration Statement on Form S-1 filed on September 9, 2020).
10.16	Second Amended and Restated Management Services Agreement, by and among the registrant, BCM Advisory Partners LLC and Broadband Capital Partners LLC, dated as of January 17, 2017, as amended by the Amendment to Second Amended and Restated Management Services Agreement dated June 12, 2018, the Second Amendment to Second Amended and Restated Management Services Agreement dated March 3, 2020 and the Third Amendment to Second Amended and Restated Management Services Agreement dated August 4, 2020 (incorporated by reference to Exhibit 10.19 to our Registration Statement on Form S-1 filed on September 9, 2020).
10.17#	Amended and Restated Employment Agreement by and between the registrant and Purnanand D. Sarma, dated September 23, 2020 (incorporated by reference to Exhibit 10.23 to Amendment No. 1 to our Registration Statement on Form S-1/A filed on September 24, 2020)
10.18#	Employment Agreement between the Company and Sandra G. Stoneman effective October 19, 2020. (incorporated by reference to Exhibit 10.26 to our Annual Report on Form 10-K filed on March 25, 2021).
10.19#	Employment Letter Agreement between the Company and Corleen M. Roche, effective April 19, 2021 (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on April 20, 2021).
10.20*#†	Employment Agreement between the Company and Dennis Giesing effective April 7, 2021.

10.21*#†	Amended and Restated Employment Agreement of Matthew Robinson effective June 16, 2022.
10.22	Securities Purchase Agreement by and among the Company and the Purchasers signatory thereto, dated April 26, 2021 (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on April 26, 2021).
10.23†	Modification of Contract between the Company and the Department of Defense, United States of America, dated May 19, 2021 (portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv)) (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on May 20, 2021).
10.24*†	Modification of Contract between the Company and the Department of Defense, United States of America, dated January 4, 2023.
10.25	Fourth Amendment to Second Amended and Restated Management Services Agreement, dated June 1, 2021, by and between the Company and Broadband Capital Partners LLC (incorporated by reference to Exhibit 10.5 to our Quarterly Report on Form 10-Q filed on August 16, 2021).
10.26#	Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q filed on November 15, 2021).
10.27	Open Market Sale Agreement, dated October 1, 2021, by and between Immunome, Inc. and Jefferies LLC (incorporated by reference to Exhibit 1.2 to our Registration Statement on Form S-3 filed on October 1, 2021).
10.28	Letter to Holders of Series B Warrants to Purchase Shares of Common Stock (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on September 2, 2022).
10.29*†	Collaboration and Option Agreement by and between the Registrant and AbbVie Global Enterprises Ltd., dated January 4, 2023.
10.30*†	Master Services Agreement by and between the registrant and Arrayjet Limited, dated November 8, 2016.
10.31*†	Revision to Master Services Agreement by and between the registrant and Arrayjet Limited, dated February 15, 2021.
10.32*†	Amendment #2 to Master Services Agreement by and between the registrant and Arrayjet Limited, dated January 1, 2022.
10.33*†	Amendment #3 to Master Services Agreement by and between the registrant and Arrayjet Limited, dated December 30, 2022.
10.34*†	Quotation and Contract of Sale by and between the registrant and Arrayjet Limited, dated December 30, 2022.
10.35#	Immunome, Inc. Annual Employee Bonus Plan (incorporated by reference to Exhibit 10.28 to our Annual Report on Form 10-K filed on March 28, 2022).
16.1	Letter from Deloitte & Touche LLP to the Securities and Exchange Commission, dated October 6, 2022 (incorporated by reference to Exhibit 16.1 to our Current Report on Form 8-K filed on October 6, 2022).
23.1*	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.
23.2*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.

31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief 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 Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following financial information from the Annual Report on Form 10 K of IMMUNOME, INC. for the year ended December 31, 2022, formatted in Inline XBRL (eXtensible Business Reporting Language): (1) Balance Sheets as of December 31, 2022 and 2021; (2) Statements of Operations for the years ended December 31, 2022 and 2021; (3) Statements of Changes in Stockholders' Equity for the years ended December 31, 2022 and 2021; (4) Statements of Cash Flows for the years ended December 31, 2022 and 2021; and (5) Notes to Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL).

* Filed or furnished herewith.

\# Management contracts or compensatory plans or arrangements

† Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and would likely cause competitive harm to Immunome, Inc. if publicly disclosed.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 16, 2023.

IMMUNOME, INC.

By: /s/ Purnanand D. Sarma
Name: Purnanand D. Sarma, Ph.D.
Title: President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Purnanand D. Sarma, Ph.D. and Corleen M. Roche, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him in his name, place and stead, in any and all capacities, to sign this report, and file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them 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 in the capacities and on the dates indicated on behalf of the Registrant.

Signature	Title	Date
/s/ Purnanand D. Sarma Purnanand D. Sarma, Ph.D.	President, Chief Executive Officer and Director (*Principal Executive Officer*)	March 16, 2023
/s/ Corleen M. Roche Corleen M. Roche	Chief Financial Officer (Principal Financial Officer)	March 16, 2023
/s/ Michael Rapp Michael Rapp	Director	March 16, 2023
/s/ Richard Baron Richard Baron	Director	March 16, 2023
/s/ John LaMattina John LaMattina, Ph.D.	Director	March 16, 2023
/s/ Michael Lefenfeld Michael Lefenfeld	Director	March 16, 2023
/s/ Philip Wagenheim Philip Wagenheim	Director	March 16, 2023
/s/ Frank Prendergast Frank Prendergast	Director	March 16, 2023

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Purnanand D. Sarma, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 of Immunome, 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 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 16, 2023

By: /s/ Purnanand D. Sarma
Name: Purnanand D. Sarma, Ph.D.
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Corleen Roche, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 of Immunome, 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 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 16, 2023

By: /s/ Corleen Roche
Name: Corleen Roche
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Immunome, Inc. (the "Company") for the fiscal year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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 16, 2023

By: /s/ Purnanand D. Sarma
Name: Purnanand D. Sarma, Ph.D.
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
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 on Form 10-K of Immunome, Inc. (the "Company") for the fiscal year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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 16, 2023

By: /s/ Corleen Roche
Name: Corleen Roche
Title: Chief Financial Officer
(Principal Financial Officer)

Corporate Information
Immunome, Inc.

Directors
Michael Rapp
Managing Member,
Broadband Capital Investments, LLC

Richard A. Baron
Founder,
RA Baron Associates, LLC

John L. LaMattina, Ph.D.
Former President of Pfizer Global Research and Development,
Pfizer Inc.

Michael Lefenfeld
President and Chief Executive Officer,
Hexion, Inc.

Philip Wagenheim
Managing Partner,
Broadband Capital Partners, LLC

Franklyn G. Prendergast, M.D., Ph.D.
Emeritus Professor of Biochemistry, Molecular Biology and Pharmacology,
Mayo Clinic College of Medicine and Science

Purnanand D. Sarma, Ph.D.
President and Chief Executive Officer,
Immunome, Inc.

Executive Officers
Purnanand D. Sarma, Ph.D.
President and Chief Executive Officer

Corleen M. Roche
Chief Financial Officer

Sandra G. Stoneman
Chief Legal Officer and General Counsel

Dennis H. Giesing, Ph.D.
Chief Development Officer

Matthew K. Robinson, Ph.D.
Chief Technology Officer

Corporate Headquarters
Immunome, Inc.
665 Stockton Drive, Suite 300
Exton, Pennsylvania 19341
(610) 321-3700
www.immunome.com

Annual Meeting
The Annual Meeting of Immunome, Inc. will be held virtually, via the internet, at 1:00 P.M., Eastern Time, on Wednesday, June 7, 2023.

The meeting will take place via live webcast on the internet at www.virtualshareholdermeeting.com/IMNM2023. Online check-in will begin at approximately 12:45 P.M., Eastern Time. You can attend the Annual Meeting, vote your shares and submit your questions during the live webcast. You will need your 16-digit control number included in your Notice of Internet Availability of Proxy Materials, the proxy card, or in the instructions that accompany your proxy materials. Additional details regarding how to participate in the Annual Meeting can be accessed at www.proxyvote.com.

Transfer Agent and Registrar
American Stock Transfer & Trust Company
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Brooklyn, New York 11219
(718) 921-8200
www.amstock.com

Legal Counsel
Mintz Levin, Cohn, Ferris, Glovisky & Popeo, P.C.
New York, New York

Auditors
Ernst & Young, LLP
Philadelphia, Pennsylvania