

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

or

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

For the transition period from _____ to _____

Commission File Number: 001-40675

Immuneering Corporation

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

245 Main St.
Second Floor
Cambridge, MA
(Address of Principal Executive Offices)

26-1976972
(I.R.S. Employer Identification Number)

02142
(Zip Code)

(617) 500-8080
(Registrant's telephone number)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

| <u>Title of Each Class</u> | <u>Trading symbol</u> | <u>Name of Exchange on which registered</u> |
|---|-----------------------|---|
| Class A common Stock, par value \$0.001 per share | IMRX | The Nasdaq Global Market |

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of June 30, 2022, the aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant was approximately \$112.1 million (based upon the closing sale price of the Class A common stock on that date on the Nasdaq Global Market).

As of February 27, 2023, the registrant had 26,436,109 shares of Class A common stock, \$0.001 par value per share, issued and outstanding and 0 shares of Class B common stock, \$0.001 par value per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement relating to the registrant's 2023 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the end of the registrant's fiscal year ended December 31, 2022 are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, (“the Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. All statements other than statements of historical fact contained in this Annual Report on Form 10-K, including without limitation statements regarding our plans to develop, manufacture and commercialize our product candidates, the timing or outcome of our ongoing or planned clinical trials for IMM-1-104, IMM-6-415, any of our other pipeline product candidates and any future product candidates, the clinical utility of our product candidates, the filing with, and approval by, regulatory authorities of our product candidates, the sufficiency of funds to operate the business of the Company, the ongoing impact of the pandemic related to COVID-19 and its variants on our business and operations, including manufacturing, research and development, clinical trials and employees, our cash needs and availability including our revenue streams, our anticipated financial performance and the plans and objectives of management for future operations, are forward-looking statements.

The forward-looking statements in this Annual Report on Form 10-K are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of known and unknown risks, uncertainties and other important factors that could cause actual results to differ materially from those projected in the forward-looking statements, including, but not limited to, those described in the sections of this Annual Report on Form 10-K entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These risks and uncertainties include, but are not limited to:

- our limited operating history;
- our history of operating losses;
- our ability to raise the substantial additional capital that will be required to finance our operations;
- the difficulty of obtaining regulatory approval for any of our current or future product candidates;
- our ability to submit an Investigational New Drug application (“IND”), or IND amendments or comparable documents in foreign jurisdictions in order to commence clinical trials on the timelines we expect;
- our limited experience in designing and conducting clinical trials;
- the risk of substantial delays in completing, if at all, the development and commercialization of our current or future product candidates;
- risks related to adverse events, toxicities or other undesirable side effects caused by our current or future product candidates;
- the risk of delays or difficulties in the enrollment and/or maintenance of patients in clinical trials;
- our substantial reliance on the successful development of our current and future product candidates, as well as our platform, including our proprietary technologies such as DCT and Fluency;
- risks related to competition in our industry;

- the market opportunity for our product candidates, if approved;
- risks related to manufacturing;
- risks related to our reliance on third parties;
- risks related to our intellectual property;
- risks related to the pandemic related to COVID-19, its variants and future pandemics; and
- other important risk factors that could affect the outcome of the events set forth in these statements and that could affect our operating results and financial condition are described in Part II, Item 1A. “Risk Factors” section of this Annual Report on Form 10-K.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Unless otherwise stated or the context requires otherwise, references to “Immuneering,” the “Company,” “we,” “us,” and “our,” refer to Immuneering Corporation and its subsidiaries.

Risk Factors Summary

We are subject to numerous risks and uncertainties, including those further described below in Part I Item IA. “Risk Factors” in this Annual Report on Form 10-K, that represent challenges that we face in connection with the successful implementation of our strategy and the growth of our business. In particular, the following are principal factors that may offset our competitive strengths or have a negative effect on our business strategy, which could materially adversely affect our business, financial conditions, results of operations, future growth prospects, or cause a decline in the price of our common stock:

- We are a clinical-stage oncology company with a limited operating history in developing pharmaceutical products, have not completed any clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- We have incurred significant net losses for the past several years and we expect to continue to incur significant net losses for the foreseeable future and may never obtain profitability.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.
- The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, or to obtain regulatory approval to treat the indications we seek to treat with our product candidates, we will be unable to generate product revenue or the level of planned product revenue and our business will be substantially harmed.
- We may encounter substantial delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities.
- Our current or future product candidates may cause adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.
- We are early in our development efforts. Our business is substantially dependent on the successful development of our current and future product candidates. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval to treat the indications we seek to treat with our product candidates, and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.
- We are substantially dependent on our platform, including our proprietary technologies such as DCT and Fluency, which are supported by our information technology systems. Any failure of these or other elements of our platform will materially harm our business.
- Our long-term prospects depend in part upon discovering, developing and commercializing product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.
- Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to use and expand our DCT platform to build a pipeline of product candidates with commercial value.
- We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.
- The COVID-19 pandemic and potential future pandemics could continue to adversely impact our business, including our current and future clinical trials, supply chain and business development activities.
- We substantially rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our preclinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
- We contract with third parties for the manufacture of our product candidates for preclinical studies and clinical trials, and expect to continue to do so for commercialization of any approved product candidate. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.
- If we are unable to obtain and maintain patent and other intellectual property protection for our product candidates and technologies or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our products and technology may be impaired, and we may not be able to compete effectively in our market.

PART I

Item 1. Business

We are a clinical-stage oncology company developing medicines for broad populations of cancer patients. Our initial aim is to develop a universal-RAS therapy, an approach designed to include patients with solid tumors driven by any mutation in KRAS, NRAS, or HRAS. Our inclusive approach differentiates us from narrowly targeted precision therapies, which are limited to patients with tumors harboring select mutations.

We are currently evaluating our lead product candidate, IMM-1-104, in a Phase 1/2a clinical trial in patients with advanced solid tumors harboring RAS mutations. IMM-1-104 is being developed as a once-daily oral monotherapy that aims to achieve universal-RAS activity through deep cyclic inhibition of the MAPK pathway. Deep cyclic inhibition is a novel mechanism that aims to deprive tumor cells of the sustained proliferative signaling required for rapid growth, while sparing healthy cells through a cadenced, normalized level of signaling. This mechanism was engineered using our proprietary informatics-based discovery platform. The development of our pipeline is translationally guided by our proprietary, human-aligned 3D tumor modeling platform that we combine with bioinformatics-driven patient profiling, which we believe has the potential to increase the probability of success in clinical development versus traditional drug development approaches. Our second product candidate, IMM-6-415, aims to achieve universal-MAPK activity with an accelerated twice-daily oral dosing cadence, also through deep cyclic inhibition of the MAPK pathway. IMM-6-415 is currently in Investigational New Drug application, or IND, enabling studies. Our pipeline also includes Trifecta MEK, RAS modulators, and other small molecule drug discovery programs.

In November 2022, we commenced dosing in our Phase 1/2a clinical trial of IMM-1-104 for the treatment of advanced RAS mutant solid tumors. The Phase 1/2a clinical trial is designed to assess the safety, tolerability, pharmacokinetics, or PK, pharmacodynamics, or PD, and preliminary anti-tumor activity of IMM-1-104. The Phase 1 portion of the clinical trial includes a dose escalation and expansion portion and will evaluate IMM-1-104 using a Bayesian modified toxicity probability interval, or mTPI-2, statistical design to establish an optimized recommended Phase 2 dose in solid tumor patients with evidence of any RAS mutation. The planned Phase 2a portion will evaluate IMM-1-104 at the recommended Phase 2 dose in an expanded cohort of solid tumor patients with certain RAS mutated cancers, including potentially pancreatic, melanoma, colorectal and lung. IMM-1-104 is currently in the dose escalation portion of the trial. We anticipate reporting initial PK and safety data from the Phase 1 portion of the clinical trial in mid-2023, and initial PD modeling and additional PK and safety data in the second half of 2023. Subject to the results from the Phase 1 portion of the trial, including safety and tolerability data, we anticipate initiating the Phase 2a portion of the trial in mid-2024.

Overview

Our platform is enabled by two key elements:

- **Bioinformatics:** our ability to efficiently analyze high-throughput molecular-level biochemical assays, including transcriptomics, genomics and/or proteomics, collectively referred to as Omics data; and
- **3D Tumor Modeling:** our ability to conduct *in vitro* studies in our own labs using proprietary humanized 3D tumor growth assays that we believe predict *in vivo* activity more accurately than traditional 2D cell culture models.

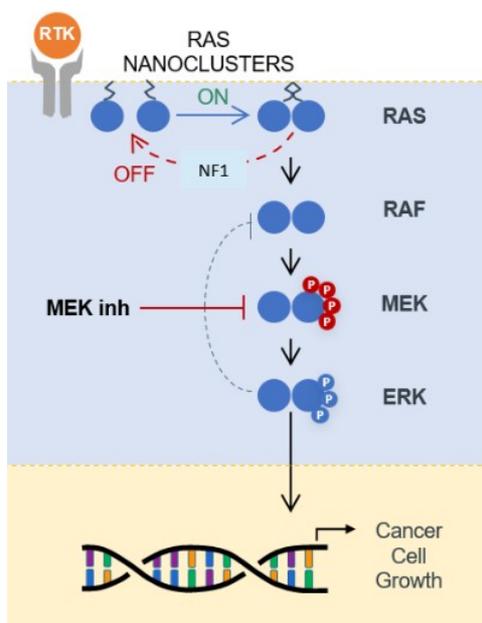
These different types of biochemical and 3D tumor growth assays each provide us with unique information about the molecular mechanisms of disease biology and drug response and help to guide our translational planning and development. Since our inception, we have partnered with industry-leading pharmaceutical and biotechnology companies to perform a variety of analyses that utilize our expertise in translational bioinformatics. Examples publicly disclosed by our partners include our analyses of ibrutinib, ipilimumab, daratumumab, glatiramer acetate and pridopidine.

In early 2018, we began applying our proprietary platform and approach to internally develop our wholly owned pipeline of orally administered small molecule drug programs. Our approach played a critical role in determining the most important characteristics for and creation of IMM-1-104. Specifically, our platform enables us to:

- leverage insights from human data to identify disease transcriptional profiles we aim to counteract;
- identify novel biology, specifically evaluating potential new ways to drug an existing target by utilizing our proprietary Disease Cancelling Technology, or DCT, and analyze mechanisms of existing drugs;
- generate novel chemistry that is designed to overcome MAPK-feedback loops and other adaptive resistance mechanisms to achieve optimal signaling dynamics; and
- profile IMM-1-104 and any other product candidates in a large number of proprietary humanized 3D tumor growth assays using our own translational planning to identify the types of cancer we believe most likely to be sensitive to the product candidate.

Our current oncology programs are focused on tumors driven by mutations of the RAS/RAF/MEK/ERK, or MAPK pathway, and other relevant signaling pathways. Existing drugs targeting the MAPK pathway are limited by toxicity, resistance and/or are narrowly focused on subpopulations with specific mutations. The MAPK pathway functions to drive cell proliferation, differentiation, survival and a variety of other cellular functions that are critical for the formation and progression of tumors.

Fundamental Cancer Signaling Cellular Pathways



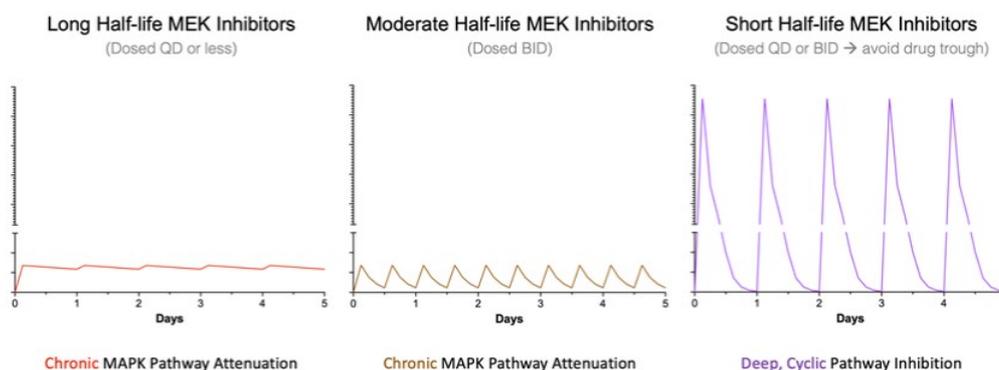
Deep Cyclic Inhibition of Cancer Signaling Pathways Challenges the Prevailing Chronic Ablation Approach

Each of the programs in our oncology pipeline is designed to drive cyclical disruption of abnormal activation of the MAPK signaling pathway or other relevant signaling pathways, with the goal of maximizing antitumor therapeutic effects while limiting drug-related toxicity and adaptive resistance.

Traditional targeted oncology drug development generally seeks to chronically sustain pathway inhibition, by prioritizing drugs with long to moderate half-lives and dosing them at intervals that maintain a sufficient level of drug, even at trough, to maintain target occupancy. This prevailing chronic ablation approach can cause on-target drug-related toxicity and limit clinical durability as a result of drug holidays, treatment discontinuation, and/or adaptive resistance. By contrast, our differentiated approach, based on counterintuitive insights derived from our translational bioinformatics platform, is to design novel drugs with at least three key aims: 1) achieve a manyfold higher C_{Max} , 2) display a short plasma drug half-

life, and 3) endow drugs with the ability to block feedback loops that would otherwise be susceptible to pathway reactivation. This design aims to provide enhanced mechanistic control of the target of interest and break tumor addiction, to prevent tumors from indefinitely self-replicating, metastasizing and evading the host's immune system, among other capabilities. By cyclically disrupting these core oncogenic signaling pathways in cancer cells (i.e., imposing normalized signaling dynamics), we believe we can create novel therapeutics that maximize therapeutic activity in broad patient populations while providing an improved tolerability profile and improved durability through reduced pressure stemming from adaptive resistance. We believe we are pioneers in this unique approach of therapeutically leveraging signaling dynamics against tumor addiction.

Pharmacokinetic Conceptual Visualization: Traditional Sustained Pathway Attenuation Versus Deep, Cyclic Inhibition



Our Wholly Owned Pipeline

Our oncology programs target clinically validated pathways, while seeking to improve patient outcomes across a wide range of solid tumor types through our differentiated programs. Our current pipeline of product candidates and discovery programs is depicted below.



Universal-RAS Program (IMM-1-104)

Our lead product candidate, IMM-1-104, is being developed as a once-daily oral monotherapy in RAS mutant tumors. IMM-1-104 is designed to achieve a unique pharmacokinetic, or PK, profile: it aims for a manyfold higher C_{Max} to provide

stronger inhibition of the MAPK pathway than has been observed with first and second generation MEK inhibitors, followed by a complete release of the MAPK pathway through a near-zero drug trough. We believe this deep cyclic inhibition may enable broad universal-RAS activity with improved tolerability and limit the development of adaptive resistance.

IMM-1-104 was observed to bind to mitogen-activated protein kinase kinase, or MEK, and acts as a highly selective inhibitor of mitogen-activated protein kinase kinase kinase, or ERK, activation (i.e., phosphorylation), with a “Dual MEK” function that is designed to block the CRAF-bypass feedback to prevent MAPK pathway reactivation. IMM-1-104 is designed with a short plasma half-life that reduces sustained pathway inhibition (as depicted below). IMM-1-104 is also designed to prevent RAF-mediated activation of MEK, such as CRAF-bypass, by engagement of the RAF activation loop on MEK, and at elevated levels further disrupt the kinase suppressor of RAS 1 and 2, or KSR. We believe this innovative method of pathway inhibition has the ability to normalize cancer cell signaling dynamics and limits unnecessary harm to normal healthy cells. Collectively, we believe these qualities differentiate IMM-1-104 from other treatment options for RAS mutant and other MAPK-addicted tumors, as well as from known MEK inhibitors, by potentially enabling IMM-1-104 to reduce drug resistance while improving tolerability.

In preclinical studies, we observed that IMM-1-104 inhibited MEK and ERK across a wide range of human and murine solid tumor models, including those with activating mutations in KRAS, NRAS, HRAS and BRAF. In addition, in head-to-head preclinical studies, we evaluated IMM-1-104 in murine-based KRAS, NRAS, and BRAF mutant solid tumor models representing lung, colon, pancreas and skin cancer, and observed tumor stasis or regression with insignificant body weight loss, or BWL, when compared to certain FDA-approved MEK inhibitors at reported human dose equivalent dose and schedules. Given the data observed in these preclinical studies, we believe that IMM-1-104 has the potential to deliver clinical benefit as monotherapy and, in the future, if approved, may potentially be administered in select drug combinations for patients with RAS mutant solid tumors who currently have limited treatment options.

In September 2022, the FDA cleared our IND for IMM-1-104 and in November 2022 we commenced dosing in a Phase 1/2a clinical trial for IMM-1-104. IMM-1-104 is currently in the dose escalation portion of the trial. We anticipate reporting initial PK and safety data from the Phase 1 portion of the clinical trial in mid-2023, and initial PD modeling and additional PK and safety data in the second half of 2023. Subject to the results from the Phase 1 portion of the trial, including safety and tolerability data, we anticipate initiating the Phase 2a portion of the trial in mid-2024.

Universal-MAPK Program (IMM-6-415)

Our second program, which we refer to as our Universal-MAPK program, is focused on developing innovative allosteric MEK inhibitors that drive deep cyclic inhibition of the MAPK pathway with an even shorter plasma half-life and accelerated pharmacokinetic cadence relative to IMM-1-104. Our product candidate for this program is designated as IMM-6-415. In a scientific poster presented at the Society for Immunotherapy of Cancer Annual Meeting in November 2022, we presented preclinical data demonstrating that IMM-6-415 inhibited the growth of RAF and RAS mutant tumors as a monotherapy across multiple human and murine solid tumor models and could be administered in combination with select immune modulators (e.g., checkpoint inhibitors) for the treatment of certain solid tumors, which are often poorly immunologically accessible. IMM-6-415 is designed to target MEK in a way that disrupts the MAPK pathway at ERK through reduction of MEK activation. We designed IMM-6-415 to have a unique PK and pharmacodynamic, or PD, profile that may be optimized for distinct solid tumors, potentially including a broad range of MAPK-driven tumors as a monotherapy, as well as for normalizing the patient’s immune response and promoting maximal antitumor responses when administered in combination with select immune modulators. IMM-6-415 is currently in IND-enabling studies and we plan to submit an IND for IMM-6-415 to the FDA in the fourth quarter of 2023.

Additional Oncology Discovery Research Programs

We are leveraging our platform to continue expanding our oncology pipeline by targeting the MAPK pathway and other relevant signaling pathways representing critical tumor-addicted pathways in novel ways. We also continue to evaluate and prioritize our pipeline, including our earlier stage discovery pipeline. We currently have three additional programs at various stages of drug discovery focused on targeting these pathways through novel pharmacological approaches. We recently streamlined the number of our early discovery programs to three in order to focus our efforts and resources on

what we believe represent the most promising near-term areas of development and enable the greatest pipeline synergies. To that end, we have deprioritized and paused our covalent MEK and PI3K programs and combined our RAS inducer and RAS inhibitor program into a RAS modulators program. We have also suspended our neuroscience programs to sharpen our focus on our core oncology programs.

Our Team

We were founded in 2008 by our Chief Executive Officer and President, Benjamin J. Zeskind, Ph.D., and the Chairman of our board of directors, Robert J. Carpenter, with the goal of leveraging translational bioinformatics to generate insights into the mechanisms that cause certain patients to respond to specific medicines across multiple therapeutic areas and then seeking to make responses happen in a much broader population of patients. Our multi-disciplinary R&D team is led by our Chief Scientific Officer, Dr. Brett Hall, who was the translational lead for Sylvant® (siltuximab) and Imbruvica® (ibrutinib) throughout clinical development, and our Chief Medical Officer, Dr. Scott Barrett, an accomplished medical oncologist and R&D expert with more than 30 years of clinical and research experience. Under their leadership, our R&D team brings together expertise across translational bioinformatics, preclinical and clinical development in oncology and includes individuals with extensive experience at some of the leading pharmaceutical companies, including Johnson & Johnson, AstraZeneca, Merck and Incyte.

Our History

Our company is built on more than a decade of experience in translational bioinformatics. Since our founding in 2008, we have utilized this experience to generate insights into the mechanisms that cause certain patients to respond to specific medicines across therapeutic areas, and then sought to apply these insights to create medicines aimed at larger groups of patients. Our computational biology services business helped us to better understand how translational bioinformatics can contribute to each stage of drug development, from early drug discovery to clinical development and through commercialization. However, we recognized the limitations of applying translational bioinformatics in isolation to specific stages of the drug development process and realized that bioinformatics could be even more helpful if applied continuously throughout the drug development process. Over time, we have developed a proprietary technology platform to facilitate that process and, in early 2018, we began applying the extensive counterintuitive insights from and capabilities of our platform and approach to create a wholly owned pipeline of novel small molecule drug programs, initially focusing on oncology.

Our Strategy

We are a clinical-stage oncology company developing medicines for broad populations of cancer patients. Our initial aim is to develop a universal-RAS therapy, an approach designed to include patients with solid tumors driven by any mutation in KRAS, NRAS, or HRAS. Our platform allows us to leverage human biological data to generate insights that are not constrained by the inherent limitations of conventional approaches or prevailing scientific views. We are developing novel product candidates that aim to optimize safety, efficacy, and durability of response for diseases with suboptimal treatment options. To achieve our mission, we are executing a near-term strategy with the following key elements:

- ***Advance our Universal-RAS Program, IMM-1-104, through Clinical Development.*** We believe that IMM-1-104 has the potential to treat broad populations of solid tumor patients, specifically those with inappropriate activation of the MAPK pathway. IMM-1-104 has been specifically designed to provide deep cyclic inhibition of the MAPK pathway with a once-daily oral dosing cadence. IMM-1-104 was designed to overcome MAPK-feedback loops and to have an intentionally short plasma half-life, which we believe could enable it to provide deep cyclic inhibition. Collectively, we believe IMM-1-104 has the potential to provide broader therapeutic activity and an improved tolerability profile relative to known MEK inhibitors and that IMM-1-104 has the potential to target patients with solid tumors driven by any mutation in KRAS, NRAS, or HRAS. IMM-1-104 is currently being evaluated as a monotherapy in a Phase 1/2a clinical trial.

- **Advance our Universal-MAPK Program, IMM-6-415, into Clinical Development.** IMM-6-415 has been specifically designed to provide deep cyclic inhibition of the MAPK pathway with an accelerated cadence relative to IMM-1-104, and we predict that its characteristics will be optimal for twice-daily (BID) administration in humans. We believe that this accelerated cadence will be differentiated from IMM-1-104 for monotherapy activity in a variety of tumors including those with RAF or RAS mutations, as well as enhanced activity in combination with checkpoint inhibitors. IMM-6-415 is currently in IND-enabling studies and we plan to submit an IND to the FDA in the fourth quarter of 2023.
- **Progress Our Pipeline of Additional MAPK and other Pathway Programs to IND-Enabling Studies.** Other key programs in our pipeline leverage our deep understanding of the MAPK and other relevant signaling pathways, and are grounded in translational bioinformatics and signaling dynamics. For example, we are advancing programs designed to directly modulate RAS activity through novel mechanisms with the aim of killing RAS-driven tumors while sparing healthy cells. We also actively apply our platform to other relevant pathways as new opportunities arise that may strengthen our pipeline.
- **Continue to Grow and Advance Our Platform.** We have built a clinical-stage oncology company that fully integrates bioinformatics and translational planning across all aspects of drug discovery and development. We currently utilize our bioinformatics platform for our drug discovery efforts in oncology, which efforts are translationally guided by our proprietary, human-aligned 3D tumor models, and as we advance our product candidates into and through the clinic, we plan to utilize data and insights from our bioinformatics platform and proprietary humanized 3D tumor models to not only guide future clinical development but to also provide key learnings back to our earlier stage programs. Lastly, we continue to iterate on our existing technology and processes, and develop new technologies for our platform, all aimed at creating the most efficient process for the development of product candidates that we believe have the potential to optimize both safety and efficacy in broad patient populations of cancer patients with high unmet medical needs.

Our Bioinformatics Approach

Leveraging our history in translational bioinformatics, we have built a clinical-stage oncology company that incorporates our expertise into every step of our process to discover and develop novel product candidates. Our goal is to meaningfully improve patient outcomes as compared to drugs developed through traditional drug discovery approaches. Our integrated approach has already yielded programs that have exhibited preclinical tumor growth inhibition against a broad range of clinically challenging solid tumors, which are in or advancing towards the clinic. Our lead product candidate IMM-1-104 is currently being evaluated in a phase 1/2a clinical trial and our IMM-6-415 product candidate is currently in IND-enabling studies, while the rest of our programs are in earlier stages of discovery. We have expanded our team of experts, including drug discovery and clinical development experts, to develop a pipeline of product candidates by leveraging our translational bioinformatics expertise.

Cancer Overview

Cancer is the second most common cause of death worldwide with approximately 10 million deaths annually and an incidence of approximately 19.3 million new cases in 2020. Cancer is defined as a collection of diseases in which abnormal cells divide uncontrollably and can invade nearby and distant tissues. The uncontrollable division of abnormal cells typically results in a malignant tumor (i.e., cancerous) or benign tumor (i.e., non-cancerous). There are two main categories of cancer: hematologic (i.e., blood) cancers and solid tumor cancers. Hematologic cancers are cancers of the blood cells, and include leukemia, lymphoma and multiple myeloma. Solid tumor cancers are cancers of any of the body's other organs or tissue, including the pancreas, skin, lung and colon. Core tumor capabilities seen in cancer patients include the ability to indefinitely self-replicate, develop new blood vessels (i.e., angiogenesis), evade cell death (i.e., apoptosis), sustain self-sufficient growth, invade other tissues (i.e., metastasis), alter signaling pathways, evade immune system responses and modify metabolism. Tumor survival is dependent on certain of these capabilities (i.e., tumor addiction).

MAPK Pathway and Beyond

In all cells, signaling pathways govern how cells regulate themselves as well as direct activities in relation to other cells in the body. One of the most commonly altered signaling pathways in cancer is the MAPK pathway. RAS is a family of related oncogenes found upstream in the MAPK pathway that codes for four highly related protein isoforms, HRAS, NRAS, KRAS4A and KRAS4B. In many solid tumors, the MAPK pathway is inappropriately activated, often through mutations in the key members of the pathway, including RAS. When RAS is switched “on” through the activation of the membrane-bound receptor tyrosine kinase, or RTK, the MAPK pathway functions to drive cell proliferation, differentiation, survival and a variety of other cellular functions that are critical for the formation of tumors.

Through widespread adaptation of molecular profiling, we now recognize that up to one in two cancer patients harbor tumors which are inappropriately activated through the MAPK pathway. Many of these patients display tumors with activation mutations in RAS or RAF, which lie upstream of MEK and ERK. Because inappropriate activation of the MAPK pathway supports many of the core tumor capabilities described above, efforts to create new therapeutics to target this pathway have been a high priority in cancer drug research. However, to date nearly all therapeutics that target the MAPK pathway have been limited to narrow patient subpopulations and have struggled to balance tolerability, durability of response, and efficacy. Nearly all targeted therapeutics against the MAPK pathway have been designed for sustained pathway suppression, which has resulted in on-target drug-related toxicities that limit clinical durability and potential drug-drug combinations. Furthermore, sustained irreversible covalent inhibition of these pathways may lead to treatment resistance, as highlighted in a recent study in the *New England Journal of Medicine* (N Engl J Med 2021; 384:2382-2393). The study focused on patients treated with adagrasib, an irreversible covalent inhibitor of KRAS^{G12C}, and reported that 45% of patients (17 patients out of 38) in the study receiving adagrasib monotherapy developed resistance. Of these patients, many resistance mechanisms were observed involving non-G12C variations in KRAS, variations in NRAS or BRAF, or other resistance mechanisms related to the MAPK pathway. A second recent study published in *Nature* (November 10, 2021) evaluated 43 patients treated with sotorasib, an irreversible covalent inhibitor of KRAS^{G12C}, and reported 27 patients with multiple treatment-emergent resistance alterations. Of these, 70% (19 out of 27) patients reported resistance mechanisms involving RAS/RAF mutations (Nature 2021; 599:679-683).

Developing novel therapeutics to effectively, broadly and safely target this pathway may provide clinical benefit in large patient populations with significant unmet needs. In addition, although this pathway represents one of the most active areas in cancer drug discovery and development, targeted therapeutics that more effectively and safely normalize, but not chronically ablate, ERK signaling may uncouple drug activity and tolerability, while optimizing both. Our pipeline is designed to disrupt molecular pathways in a pulsatile way that undermines tumor addiction while limiting drug-related toxicity of normal healthy cells that are less reliant on a sustained high level of signaling along these pathways

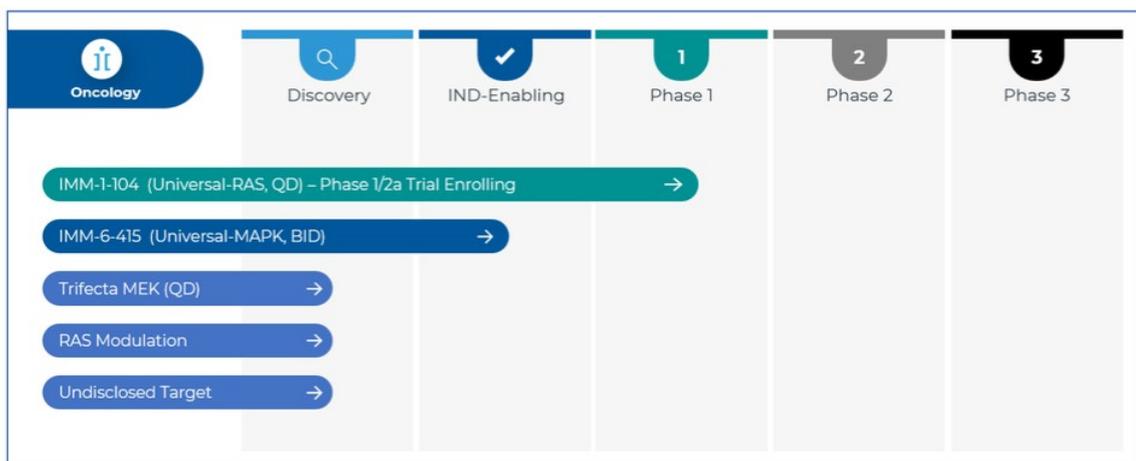
Our Differentiated Approach to Tackling Some of the Most Challenging Cancers

We are leveraging our platform to target tumors driven by the MAPK pathway and other relevant signaling pathways. Our differentiated approach is to design drugs that can achieve high C_{max} levels through short half-lives and provide enhanced mechanistic control of the target of interest and break tumor addiction through deep, cyclic disruption of these pathways (i.e., regulate signaling dynamics and reduce adaptive resistance). We believe we are pioneers in therapeutically leveraging signaling dynamics against tumor addiction, and our insights derived from our translational bioinformatics platform supports our belief that this approach may result in novel therapies targeting this pathway and potentially other pathways. Traditional drug approaches have been designed to sustain pathway inhibition, which leads to on-target drug-related toxicity and becomes limiting for clinical durability as a result of drug holidays, treatment discontinuation, or the development of adaptive resistance. Mutational activation and/or overexpression of key signaling components that activate the MAPK pathway are well-known, and MEK has been previously validated as a therapeutic target. We believe our programs, as compared to FDA-approved treatments targeting the MAPK pathway, have the potential to be differentiated by their unique potential combination of target engagement, PK and PD profile. For example, our lead product candidate, IMM-1-104, is designed to inhibit ERK and MEK, prevent MAPK pathway reactivation and have a short plasma half-life, which would reduce sustained pathway inhibition compared to other drugs targeting the same mechanistic pathway. By cyclically disrupting these core oncogenic signaling pathways in cancer cells, we believe we can create novel therapeutics in oncology that maximize therapeutic activity in broad patient populations while providing improved tolerability as

compared to other FDA-approved treatments and treatments currently being developed for cancers caused by MAPK pathway activation.

Our Pipeline

Our current development programs in oncology are focused on providing treatments for patients with solid tumors caused by mutations of the MAPK pathway or other relevant signaling pathways. Our Universal-RAS product candidate, IMM-1-104, is currently being evaluated in a Phase 1/2a clinical trial, and our Universal-MAPK product candidate, IMM-6-415 is currently being evaluated in IND-enabling studies. IMM-1-104 and IMM-6-415 are complemented by multiple earlier stage programs that are designed to uniquely target the MAPK pathway or other relevant signaling pathways. The following table summarizes our oncology pipeline:

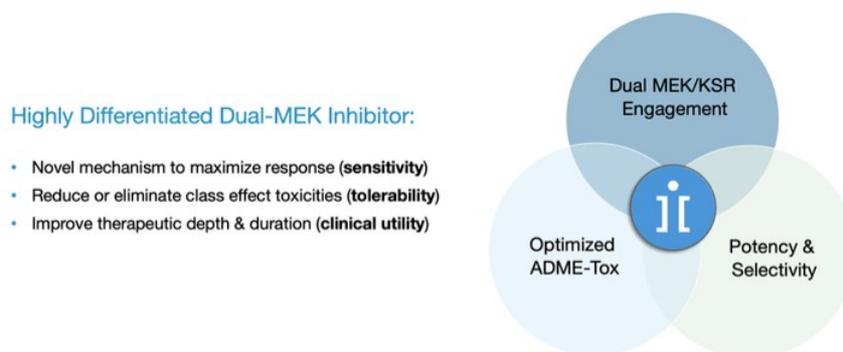


Overview of Our Lead Program: Universal-RAS, IMM-1-104

Background of MEK Inhibitors

Activating mutations of RAS and/or RAF in the MAPK pathway are observed in approximately 30% of all cancer patients, and inappropriate activation of this pathway is observed in up to 50% of all tumors and represents one of the most highly utilized signaling pathways in oncology. In aggressive solid tumors of the pancreas, skin, lungs and colon, mutations in RAS and/or RAF are even more common. For example, approximately 40% of lung cancers and approximately 90% of pancreatic cancers are due to RAS and/or RAF mutations. To date, FDA-approved MEK inhibitors have been ineffective at treating RAS mutant tumors when compared to BRAF mutant tumors because of a well-known mechanism of resistance, CRAF-mediated MEK reactivation, also known as CRAF-bypass. In addition, a well-known limitation of current FDA approved MEK inhibitors are high rates of serious drug-related adverse events, or SAE's, most often observed in over 50% of treated patients, which leads to drug intolerability. The longer half-life of these drugs (e.g., up to 2 to 4 days) with once per day or less frequent dosing, or moderate half-life (e.g., 3 to 6 hours) with increased dosing frequency, contributes to high rates of adverse events because these drugs systemically circulate for an extended period of time harming healthy normal cells, which also rely on the pathway for survival. Our goal in developing IMM-1-104 is to address these shortcomings and potentially provide patients with better outcomes, improved tolerability, durability and expand drug-drug combination opportunities (as depicted below).

IMM-1-104: Designed for Universal-RAS Activity as a once-daily oral monotherapy



Our Solution: IMM-1-104

We have leveraged our platform to develop our lead product candidate in our Universal-RAS program, IMM-1-104, which is designed to be a highly selective dual-MEK inhibitor, to inhibit ERK and MEK, and to promote additional scaffold-related disruption of KSR at elevated drug levels. We are developing IMM-1-104 to treat patients with cancer, including pancreatic, melanoma, colorectal and non-small cell lung cancer, or NSCLC, caused by mutations of RAS. In order to overcome MAPK-feedback and CRAF-mediated MEK activation, a well-known limitation of current FDA-approved MEK inhibitors, we developed IMM-1-104 to allosterically inhibit MEK by targeting the site lying adjacent to the binding pocket of adenosine triphosphate, or ATP, which would result in downstream inhibition of ERK. In addition, unlike FDA-approved MEK inhibitors, IMM-1-104 is designed to prevent MEK activation through a unique target engagement to prevent RAF or KSR-mediated activation of MEK. We believe that bypassing pathway reactivating drug resistance mechanisms would provide for better patient outcomes by enhancing therapeutic activity throughout the course of treatment. By reducing or eliminating steady state drug trough levels, we also designed IMM-1-104 to limit or reduce high rates of serious drug-related adverse events that have been observed in current FDA-approved MEK inhibitors (e.g., which can range from 45% to 69%), most often given in combination with a RAF inhibitor, which contributes to discontinuation rates of up to 10% to 15%.

With a goal of improving tolerability, we designed IMM-1-104 to have a short plasma half-life, to result in a near-zero steady state drug trough concentration to enable deep, cyclic inhibition of the MAPK pathway. We believe this method of drug cadence-driven pathway inhibition has the potential to normalize cancer cell signaling dynamics and prevent further damage to normal healthy cells. Collectively, we believe these dosing attributes may differentiate IMM-1-104 from known MEK inhibitors by potentially allowing IMM-1-104 to reduce drug resistance while improving tolerability due to its design to allosterically inhibit MEK, be uniquely resistant to MAPK pathway reactivation and to enable deep, cyclic inhibition stemming from a short plasma half-life.

Preclinical Studies Overview: IMM-1-104

In multiple preclinical studies, we observed that IMM-1-104 inhibited activation of MEK (i.e., pMEK) as well as activation of ERK (i.e., pERK) across a wide range of murine and humanized 3D solid tumor models, including those with MAPK pathway activating mutations in KRAS, NRAS, HRAS and BRAF. In addition, in head-to-head preclinical studies, we evaluated IMM-1-104 in murine-based KRAS, NRAS, and BRAF mutant solid tumor models representing lung (i.e., A549), colon (i.e., Colon-26), pancreas (i.e., MIA PaCa-2, CAPAN-2) and skin cancer (i.e., A375 and SK-MEL-2), and observed superior antitumor activity with insignificant body weight loss, or BWL, when compared to certain FDA-approved MEK inhibitors and superior to non-inferior antitumor activity when compared to certain FDA-approved KRAS-G12C and BRAF inhibitors at reported human dose equivalent dose and schedules. Given the data observed in our previously conducted preclinical studies, we believe that IMM-1-104 has the potential to deliver clinical benefit as monotherapy and, in the future, may potentially be administered in select drug combinations for patients with RAS mutant solid tumors who currently have limited treatment options.

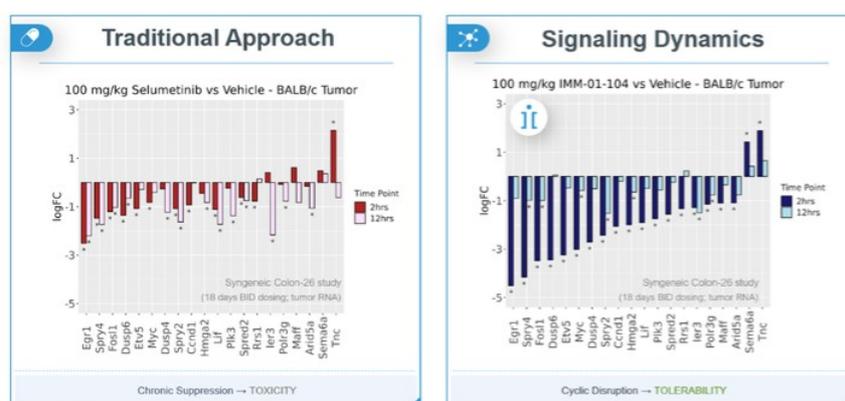
Preclinical Studies: Maximum Tolerated Dose and Therapeutic Effect Data

In our early maximum tolerated dose, or MTD, studies, we observed that oral administration of IMM-1-104 twice a day of up to 150 mg/kg/dose was well-tolerated in mice. In other preclinical studies, we observed that the maximum therapeutic effect of IMM-1-104 was reached when administered orally twice a day between 100 and 150 mg/kg/dose. These dosing studies provided the basis of IMM-1-104's dosing schedule in subsequent preclinical studies.

Preclinical Studies: Pharmacogenomics Data

In a pharmacogenomics study utilizing a colorectal KRAS^{G12D} tumor model in BALB/c mice, we evaluated downstream ERK inhibition of the MAPK pathway after IMM-1-104 treatment. We orally administered vehicle, selumetinib and IMM-1-104 twice a day at 100 mg/kg/dose, then harvested the tumors after 18 days of chronic treatment at 2 and 12 hours following the last drug dose to evaluate RNAseq changes. The tumors were collected across distinct BALB/c mice and RNAseq changes were evaluated using statistical analysis software. Consistent with IMM-1-104's designed short plasma half-life, we observed deep, cyclic inhibition of most of the top genes in the ERK transcriptome, as noted by the differences of the dark and light blue bars, which we believe suggests the potential for improved tolerability by allowing healthy normal cells to regenerate before the next dose is administered. For example, *Erg1* and *Spry4* were both downregulated over 16-fold at 2 hours after receiving the first dose on day 18 of the study, and at 12 hours after the first dose, which was prior to the second dose, both genes were approaching their baseline state when compared to vehicle treated tumors (as depicted below). In contrast to IMM-1-104, we did not observe deep cyclic inhibition by selumetinib, but rather observed sustained MAPK pathway suppression versus vehicle groups between the two timepoints on day 18 (as depicted below). The top 20 genes were a subset of a 52-gene signature for ERK signaling.

Head-to-Head Comparison of IMM-1-104 Against Selumetinib Using a Colon-26 Syngeneic Tumor Model: Deep Cyclic Inhibition of the ERK Transcriptome Observed

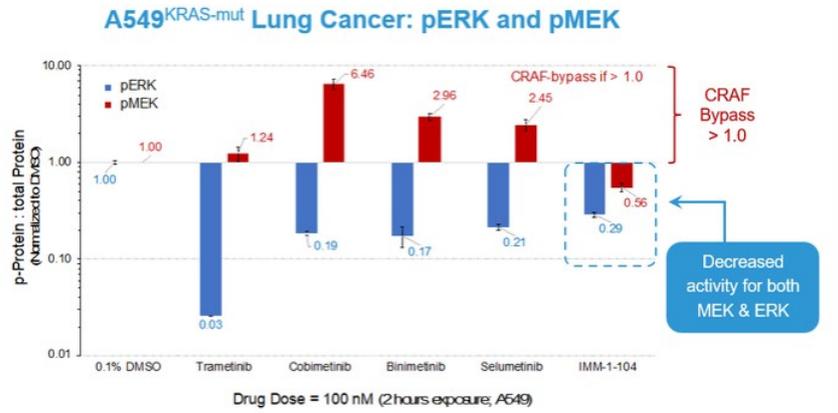


* Adjusted p-value < 0.05, for each treatment versus vehicle (n = 3-4 independent tumors per group)

Preclinical Studies: Resistance to CRAF-bypass Observed

We evaluated IMM-1-104 head-to-head against four FDA-approved MEK inhibitors for CRAF-bypass resistance in a KRAS mutant NSCLC tumor model. We exposed the tumor cells with 100 nM of each drug for 2 hours and evaluated MEK and ERK activation levels. We observed that IMM-1-104 reduced overall activity of the MAPK pathway at ERK and pathway reactivation at MEK through a decrease in MEK and ERK activation, resulting in CRAF-bypass resistance. In contrast, we observed that all four FDA-approved MEK inhibitors displayed an increase in activated MEK, resulting in CRAF-bypass (as depicted below).

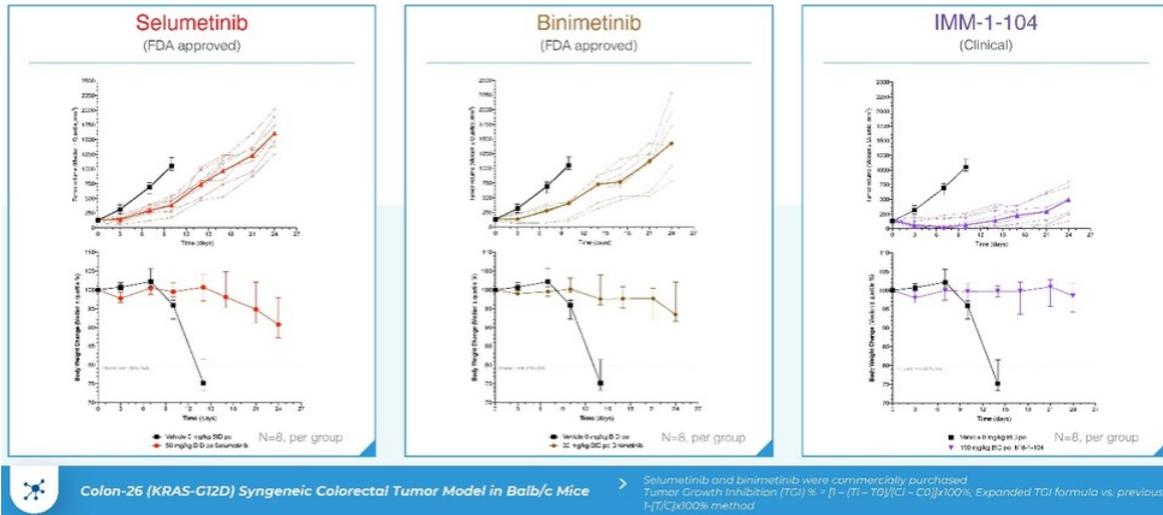
Head-to-Head Comparison of IMM-1-104 against Four FDA-Approved MEK Inhibitors Using a A549 Xenograft Tumor Model: Prevented Downstream Activation of ERK (↓ pERK) and Inhibited Activation of MEK (↓ pMEK)



Preclinical Studies: Tumor Regression and Body Weight Loss Observed

We evaluated IMM-1-104 head-to-head against binimetinib and selumetinib in an aggressive murine colorectal tumor model (i.e., Colon-26), which expresses mutant KRAS^{G12D}. We observed that IMM-1-104 demonstrated greater tumor growth inhibition, where notably 5 of 8 mice experienced tumor regression during the first 10 days of dosing, as well as greater tolerability, evidenced by changes in BWL. In addition, we observed that IMM-1-104 had overall better durability of antitumor response as compared to the two FDA-approved MEK inhibitors, as demonstrated by significantly lower tumor volume, or TV, progression. This study demonstrated that IMM-1-104 as compared to binimetinib and selumetinib provided greater tumor inhibition, lower BWL and lower TV progression (as depicted below).

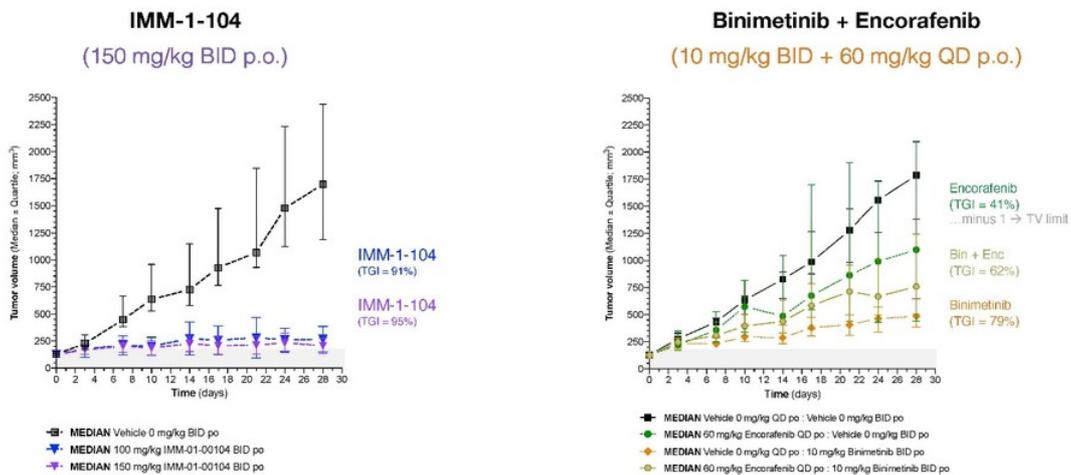
Head-to-Head Comparison of IMM-1-104 Against Binimetinib and Selumetinib Using a Colon-26 Syngeneic Tumor Model: Body Weight Loss and Tumor Volume Observed



After observing the results of the Colon-26 tumor study, we completed two follow-up *in vivo* studies, where we evaluated IMM-1-104 head-to-head against binimetinib or encorafenib, a BRAF inhibitor, as monotherapy plus the combination of binimetinib with encorafenib in BALB/c mice tumor models with RAS and RAF mutations. It should be noted that when encorafenib is used to treat KRAS mutant tumors that are wild type for BRAF, it can paradoxically activate the MAPK pathway and antagonize the effects of binimetinib. In addition, the drug doses and schedules used for binimetinib and encorafenib in these studies were consistent with or exceeded what was provided in their NDAs to the FDA for human-relevant exposures in rodent models.

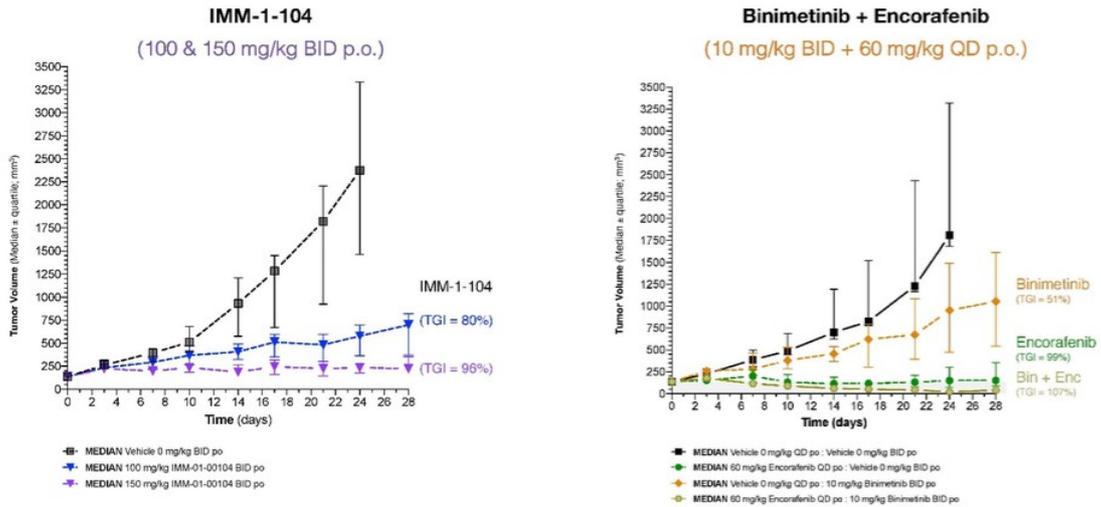
We evaluated IMM-1-104 head-to-head against binimetinib monotherapy and in combination with encorafenib in the KRAS^{G12S} human NSCLC xenograft tumor model (i.e., A549). When comparing IMM-1-104 to binimetinib monotherapy, we observed that IMM-1-104 had greater tumor growth inhibition (as depicted below). The observations of IMM-1-104 head-to-head against binimetinib alone and in combination with encorafenib, which was not considered relevant for a KRAS mutant, RAF wild-type tumor model, has been included in the figure below for comparison purposes.

Head-to-Head Comparison of IMM-1-104 Against Binimetinib +/- Encorafenib Using a A549 Xenograft Tumor Model: Tumor Volume



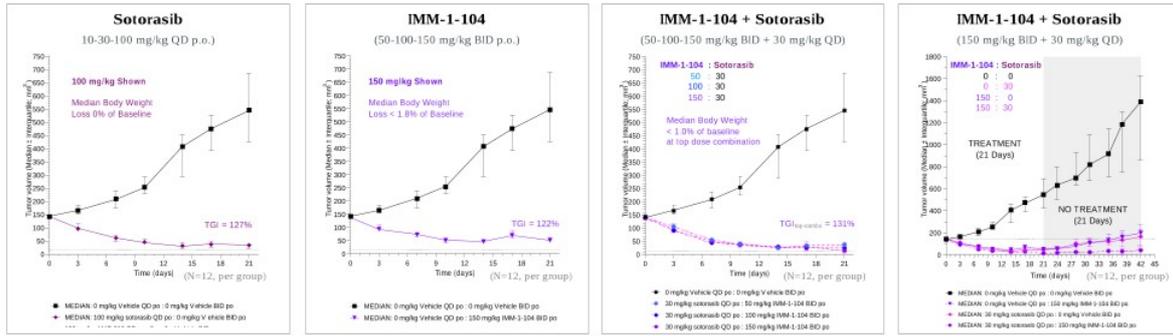
We also evaluated IMM-1-104 head-to-head against binimetinib and encorafenib monotherapy and the combination of binimetinib with encorafenib in a BRAF^{V600E} human melanoma xenograft model. It should be noted that the administered combination of binimetinib and encorafenib for BRAF mutant melanoma, such as BRAF^{V600E}/K, is an FDA-approved combination. As expected, when comparing IMM-1-104 alone to binimetinib in combination with encorafenib, we observed that the combination therapy had greater tumor growth inhibition (as depicted below). However, when we compared IMM-1-104 to binimetinib monotherapy, we observed that IMM-1-104 had greater tumor growth inhibition (as depicted below). While our initial focus is on monotherapy of RAS mutant disease, we believe the greater single agent MEK inhibitor activity observed with our deep cyclic inhibition approach demonstrates the potential of IMM-1-104 (and/or IMM-6-415, which has an accelerated cadence of deep cyclic inhibition) in drug-drug combinations with other MAPK pathway inhibitors, such as encorafenib, to treat RAF mutant cancers, such as BRAFV600E/K, among other MAPK pathway mutations.

Head-to-Head Comparison of IMM-1-104 Against Binimetinib +/- Encorafenib Using a A375 Xenograft Tumor Model: Tumor Volume



In a further *in vivo* study based on humanized 3D tumor model data, we evaluated IMM-1-104 head-to-head against sotorasib (AMG-510) and gemcitabine alone, and IMM-1-104 in combination with sotorasib, for 21 days in the KRAS^{G12C} xenograft model (i.e., MIA PaCa-2). In a previous study conducted by a third-party, sotorasib demonstrated sensitivity to this pancreatic tumor model. Comparing IMM-1-104 alone, against sotorasib and in combination with sotorasib, we observed tumor regressions with insignificant median BWL (i.e., within 3% of baseline), which we believe indicates activity, durability and tolerability of IMM-1-104 against a KRAS^{G12C} mutant pancreatic cancer model (as depicted below).

Head-to-Head Comparison of IMM-1-104 +/- sotorasib (AMG-510) Using a MIA PaCa-2 Xenograft Tumor Model: Tumor Volume

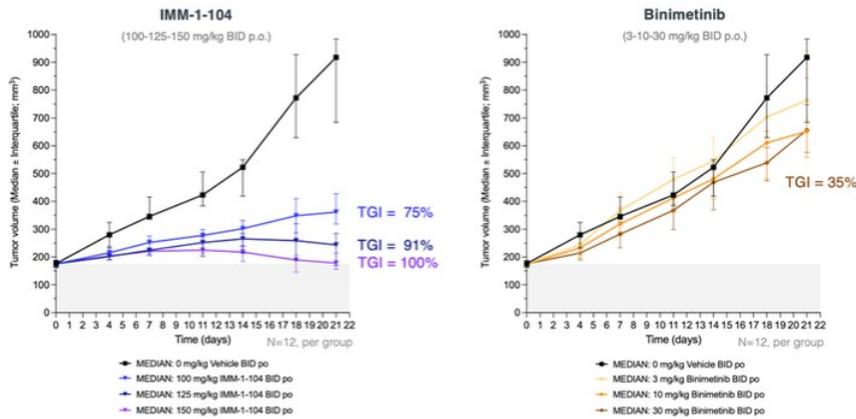


MIA PaCa-2 (KRAS^{G12C}) Pancreatic Xenograft Tumor Model in Athymic Nude Mice

Sotorasib (AMG-510) was commercially purchased
 Tumor Growth Inhibition (TGI) % = $[1 - (T_1/C_1 - C_2)] \times 100\%$; Expanded TGI formula vs. previous $1-[T/C] \times 100\%$ method

In an *in vivo* study based on humanized 3D tumor model data, we evaluated IMM-1-104 monotherapy as compared to binimetinib for 21 days in the NRAS^{Q61R} mutant tumor model (i.e., SK-MEL-2). We observed superior tumor growth inhibition relative to binimetinib (as depicted below).

Head-to-Head Comparison of IMM-1-104 Against Binimetinib Using a SK-MEL-2 Xenograft Tumor Model: Tumor Volume

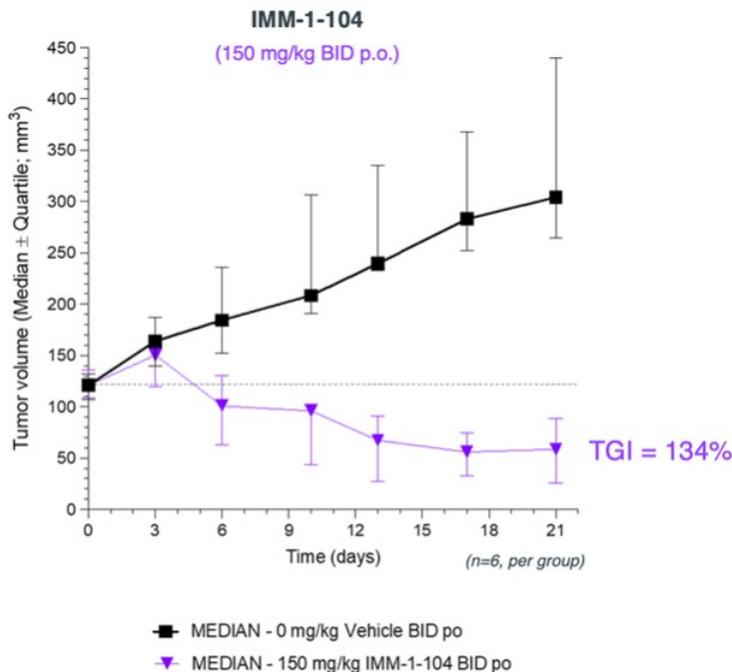


SK-MEL-2 (NRAS^{Q61R}) Melanoma Xenograft Tumor Model in Athymic Nude Mice

Binimetinib was commercially purchased
 Tumor Growth Inhibition (TGI) % = $[1 - (T_1/C_1 - C_2)] \times 100\%$; Expanded TGI formula vs. previous $1-[T/C] \times 100\%$ method

In a further *in vivo* study based on humanized 3D tumor model data, we evaluated IMM-1-104 monotherapy as compared to vehicle for 21 days in the NRAS^{Q61R} mutant tumor model (i.e., SK-MEL-2). We observed midcycle tumor regressions in mice treated with IMM-1-104, which demonstrated activity and durability of IMM-1-104 against an NRAS^{Q61R} mutant melanoma cancer model (as depicted below).

Evaluation of IMM-1-104 as Compared to Vehicle Using a SK-MEL-2 Xenograft Tumor Model: Tumor Volume



SK-MEL-2 (NRAS^{Q61R}) Melanoma Xenograft Tumor Model in Athymic Nude Mice

Tumor Growth Inhibition (TGI) % = $[1 - (T_t - T_0)/(C_t - C_0)] \times 100\%$; Expanded TGI formula vs. previous $1 - [T/C] \times 100\%$ method

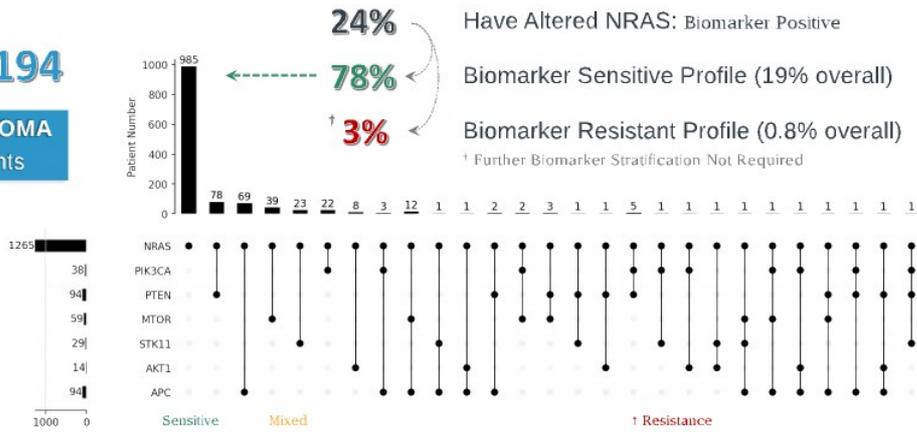
In a study described in our June 2022 ASCO abstract, we utilized a Capan-2 PDAC xenograft animal model to evaluate single agent activity of IMM-1-104 (100, 150 mg/kg BID p.o.) vs. sotorasib and adagrasib (30 and 100 mg/kg QD p.o. each) for 21 days treatment after tumors had reached volumes of 150 to 200 mm³. A head-to-head comparison *in vivo* demonstrated no Tumor Growth Inhibition (TGI) by sotorasib or adagrasib in KRAS-G12V mutant Capan-2 PDAC tumors, while IMM-1-104 prompted TGIs up to 84% at 150 mg/kg BID po.

Preclinical Studies: 3D Tumor Growth Models

3D tumor growth models mimic the tumor microenvironment, or TME, more closely than 2D culture models, and we believe humanized 3D models more accurately reflect human tumor biology and complexity when translating pharmacological data of MAPK pathway inhibition *in vivo*. We have established and evaluated over 130 humanized 3D tumor models, a majority of which display activating mutations in the RAS isoforms, amongst other altered MAPK pathway targets, including BRAF, CRAF, NF1 and ERK, to evaluate their sensitivities to IMM-1-104. In general, we observed that tumor models with KRAS or NRAS mutations and certain molecular profiles were sensitive to IMM-1-104, including tumor models displaying BRAF mutations. For example, IMM-1-104 IC₅₀ dose-response values in 3D assays as low as 23.7 nM were observed in tumor models that expressed NRAS mutants such as Q61L, Q61R, G12D, Q61K, among others. Similarly, KRAS mutant tumor models were sensitive to IMM-1-104 treatment, with IC₅₀ dose responses as low as 66.7 nM when displaying mutations including Q61H, G12C, G12V, G13D, G12D, G12R, among others. Certain tumor models with BRAF mutations were also found to be sensitive to IMM-1-104 with IC₅₀ dose responses in 3D assays as low as 54.2 nM for V600E (class 1) and G464E (class 2) mutations. A clear driver mutation in RAS or RAF was generally predictive of IMM-1-104 response, but a smaller number of RAS or RAF mutant models displaying certain oncogenic mutation profiles were found to be insensitive to IMM-1-104 and displayed IC₅₀ dose response values of over 10,000 nM.

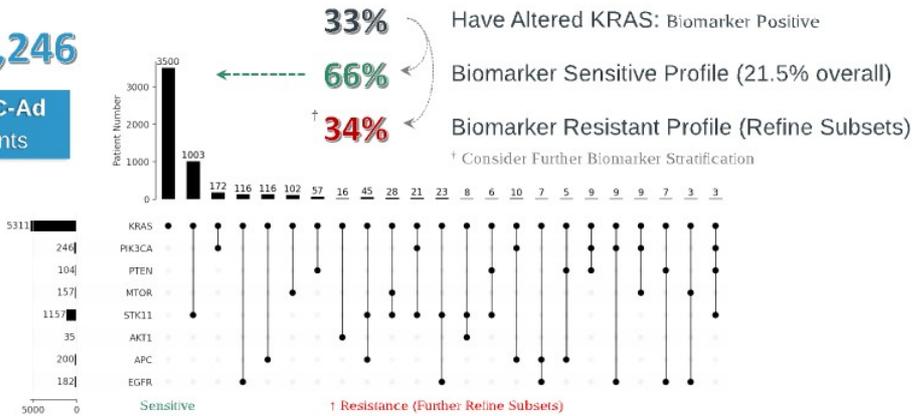
of 5,194

MELANOMA Patients



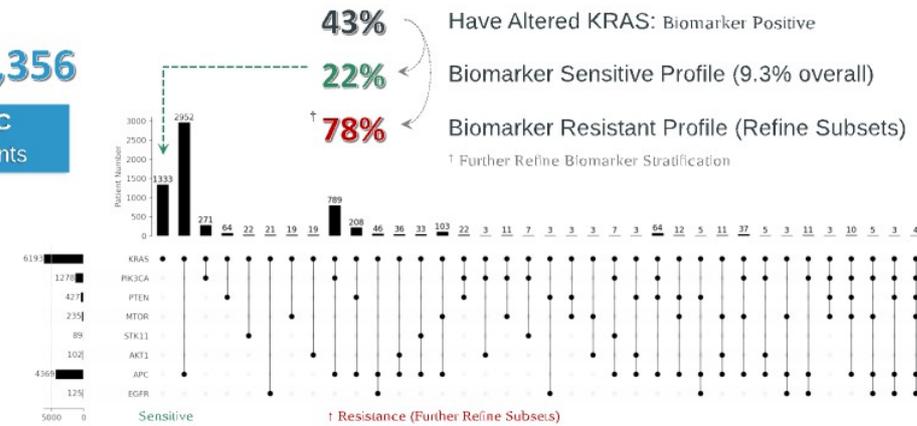
of 16,246

NSCLC-Ad Patients



of 14,356

CRC Patients



Clinical Development Overview: IMM-1-104

In September 2022 the FDA cleared our IND for IMM-1-104, and in November 2022, we commenced dosing in a *first-in-human*, phase 1/2a clinical trial of IMM-1-104.

The Phase 1/2a clinical trial is an open-label study designed to evaluate the safety, tolerability, clinical pharmacology, and preliminary efficacy of IMM-1-104 when dosed as monotherapy, once daily, in participants with advanced RAS mutant solid tumors, following at least one line of systemic, standard-of-care therapy.

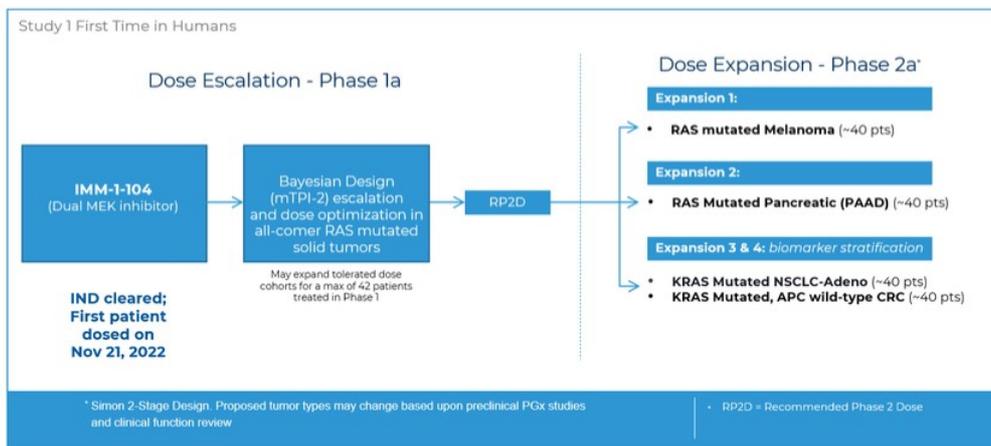
The Phase 1 (*dose exploration*) study consists of both dose escalation and dose expansion portions and may enroll up to 42 patients across five clinical sites within the United States.

- Dose Escalation follows a Bayesian (mTPI-2) statistical design. This streamlined design is designed to allow for the most efficient approach to optimize dose escalation.
- Dose Expansion will further evaluate and refine selected dose-level candidates for recommended phase 2 dose, or RP2D, in accordance with guidance provided by FDA under its Project Optimus initiative. The final RP2D selection will be based upon composite review of data related to safety, tolerability, pharmacokinetics, pharmacodynamics, and anti-tumor activity accumulated during Phase 1.

Once a final RP2D has been determined, the Phase 2a portion of the trial may commence, evaluating the monotherapy activity and safety of IMM-1-104 within selected tumor-specific indications, which we currently plan to expand in parallel. Based upon our internally developed and proprietary bioinformatics platform and translational modeling, we have initially identified four potential indications for phase 2a expansion: RAS mutant pancreatic cancer, RAS mutant melanoma, KRAS mutant non-small cell lung cancer, and KRAS mutant (*APC wild type*) colorectal cancer. Each of these will be evaluated using a Simon 2-stage statistical design and independently considered for further indication-specific development. The final indication selection and design of the Phase 2a portion of the study is subject to change based on information learned in the Phase 1 portion. IMM-1-104 is currently in the dose escalation portion of the trial. We anticipate reporting initial PK and safety data from the Phase 1 portion of the clinical trial in mid-2023, and additional safety and PK and initial PD modeling data in the second half of 2023. Based on results from the Phase 1 portion of the trial, including safety and tolerability data, we anticipate initiating the Phase 2a portion of the trial in mid-2024

In addition to the above, we also may engage in appropriate IMM-1-104 anchored combination studies dosed at the RP2D. Specific combination partners and indications will be selected based-upon pooled discovery and clinical proof of concept data accumulated by that time.

Phase 1/2 Clinical Trial Plan



Universal-MAPK, IMM-6-415 Program

Our second program, which we refer to as our Universal-MAPK program, is focused on developing innovative allosteric MEK inhibitors that drive deep cyclic inhibition of the MAPK pathway with a shorter plasma half-life and accelerated cadence relative to IMM-1-104. Our product candidate for this program is designated as IMM-6-415. As described, in a poster presentation of results from preclinical studies at the SITC 2022 Annual Meeting in November 2022, IMM-6-415 inhibited the growth of RAF and RAS mutant tumors as a monotherapy in human and murine solid tumor models, and was administered in combination with select immune modulators (e.g., checkpoint inhibitors) for the treatment of “cold” solid tumors, which are immunologically inaccessible. IMM-6-415 was designed to target MEK in a way that disrupts the MAPK pathway at ERK and to also reduce baseline MEK activation. We designed IMM-6-415 to have a unique PK and PD profile that may be optimized for distinct tumors, potentially including a broad range of MAPK-driven tumors as monotherapy and to optimize the patient’s immune response and promote maximal antitumor responses when administered in combination with select immune modulators. We plan to submit an IND for IMM-6-415 to the FDA in the fourth quarter of 2023.

Preclinical Studies: Resistance to CRAF-bypass

We evaluated IMM-6-415 head-to-head against two FDA-approved MEK inhibitors to assess their control of pMEK, pERK and CRAF-bypass in a NRAS, HRAS, NF1 and BRAF mutant melanoma tumor models. We exposed the tumor cells with 100 nM of each drug for 2 hours and evaluated MEK and ERK activation levels. We observed that IMM-6-415 reduced overall activity of the MAPK pathway at ERK and pathway reactivation at MEK through a decrease in MEK and ERK activation, resulting in CRAF-bypass resistance. In contrast, we observed that both FDA-approved MEK inhibitors displayed an increase in activated MEK, resulting in CRAF-bypass in RAS and NF1 mutant tumors (as depicted below).

Head-to-Head Comparison of IMM-6-415 against Two FDA-Approved MEK Inhibitors Using a Panel of Nine Melanoma Tumor Models: Observed Activity in RAS and RAF Mutant Tumors and Prevented Downstream Activation of ERK (↓ pERK) and Inhibited Activation of MEK (↓ pMEK)

| Key Mutations & 3D-TGA Response [Melanoma Tumor Models] | | | | | pERK to Total-ERK Ratio [100nM Drug] | | | | pMEK to Total-MEK Ratio [100nM Drug] | | | | | | |
|--|--------|--------|---------|-----|---|----------|-----------|-------------|---|-----------|----------|-----------|-------------|-------------|-----------|
| Model | HRAS | NRAS | BRAF | NF1 | 3D-TGA | pERK/ERK | 0.1% DMSO | Binimetinib | Selumetinib | IMM-6-415 | pMEK/MEK | 0.1% DMSO | Binimetinib | Selumetinib | IMM-6-415 |
| SK-MEL-2 | | p.Q61R | | | | 1.00 | 1.00 | 0.13 | 0.19 | 0.44 | 1.00 | 2.59 | 2.06 | 0.52 | |
| MM127 | | p.G19R | p.G464E | | | 1.00 | 1.00 | 0.20 | 0.26 | 0.53 | 1.00 | 3.01 | 2.34 | 0.77 | |
| MM415 | | p.Q61L | | | n.t. | 1.00 | 1.00 | 0.06 | 0.11 | 0.42 | 1.00 | 3.06 | 2.39 | 0.58 | |
| MEL-JUSO | p.G13D | p.Q61L | | | | 1.00 | 1.00 | 0.14 | 0.18 | 0.63 | 1.00 | 3.29 | 2.99 | 0.55 | |
| SK-MEL-30 | | p.Q81K | | | | 1.00 | 1.00 | 0.08 | 0.16 | 0.52 | 1.00 | 2.65 | 2.18 | 0.61 | |
| Hs852T | | p.G12V | | | n.t. | 1.00 | 1.00 | 0.20 | 0.29 | 0.73 | 1.00 | 6.49 | 4.95 | 0.67 | |
| MeWo | | | | LoF | n.t. | 1.00 | 1.00 | 0.16 | 0.20 | 0.52 | 1.00 | 7.42 | 5.48 | 0.90 | |
| A375 | | | p.V600E | | | 1.00 | 1.00 | 0.14 | 0.20 | 0.48 | 1.00 | 1.06 | 0.96 | 0.59 | |
| SK-MEL-28 | | | p.V600E | | | 1.00 | 1.00 | 0.08 | 0.15 | 0.75 | 1.00 | 1.06 | 0.98 | 0.76 | |

Tumor cell lines were acquired from ATCC, ECACC and DSMZ. 3D-Tumor Growth Assay (3D-TGA) sensitivity (green fill) defined as $IC_{50} < 10\mu M$ in 72-hour ECM-based assay with %EdU readout, and $IC_{50} \geq 10\mu M$ considered resistant. Cell-based 2D in vitro molecular assays were performed to assess cellular levels of phosphorylated and total ERK and MEK across 9 melanoma models (100 nM drug for 2-hours followed by quantitative Western blot analysis for pERK, total ERK, pMEK and total MEK); Binimetinib & selumetinib were commercially purchased (MAPK pathway reactivation observed, pMEK); n.t. = not yet tested

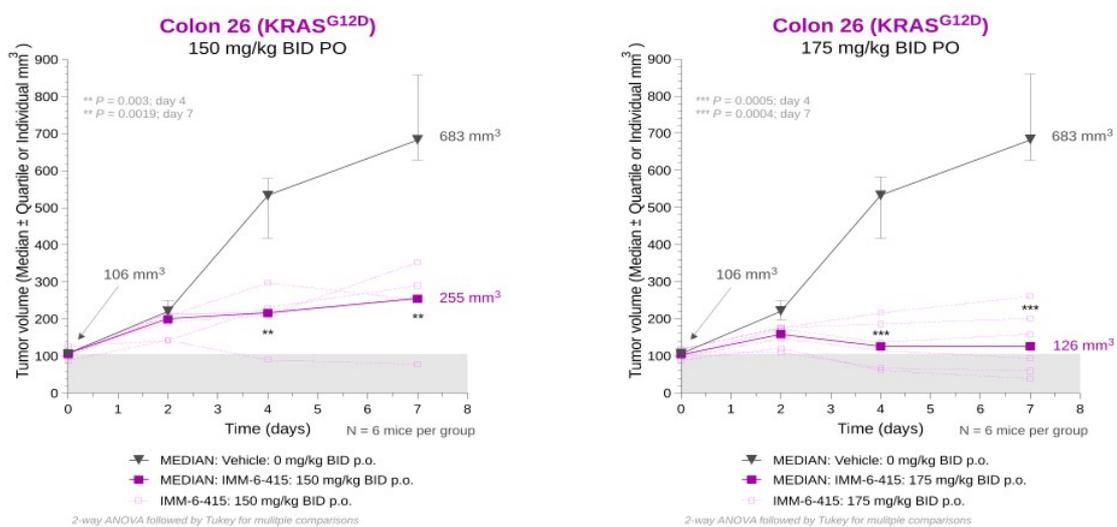
Preclinical Studies: Maximum Tolerated Dose and Therapeutic Effect Data

In our early maximum tolerated dose, or MTD, studies, we observed that oral administration of IMM-6-415 twice a day of up to 175 to 180 mg/kg/dose was well-tolerated in mice. In other preclinical studies, we observed that the maximum therapeutic effect of IMM-6-415 was reached when administered orally twice a day between 150 and 180 mg/kg/dose. These dosing studies provided the basis of IMM-6-415’s dosing schedule in subsequent preclinical studies.

Preclinical Studies: Tumor Regression and Body Weight Loss Data

We evaluated IMM-6-415 against vehicle and historic responses from IMM-1-104 in an aggressive murine colorectal tumor model (i.e., Colon-26), which expresses mutant KRAS^{G12D}. We observed that IMM-6-415 demonstrated robust tumor growth inhibition at top effective doses of 150 and 175 mg/kg BID p.o., with multiple mice experiencing tumor regression during the first 7 days of dosing (as depicted below), with good tolerability, and evidenced limited (-8.61% to +3.34% vs. vehicle group) changes in median BWL at doses in the range of 25 to 175 mg/kg BID p.o. While IMM-6-415 displayed a plasma half-life in mice of only a 0.3 to 0.4 hours (0.5 to 0.7 in non-human primates), IMM-6-415 led to comparable tumor growth inhibition of that observed with IMM-1-104, a molecule that has been observed to have a 1.3 hour half-life in mice (i.e., 3 to 4 times longer than IMM-6-415 in the same species), which was previously observed to be superior in a head-to-head comparison against binimetinib and selumetinib in the same model (as described previously).

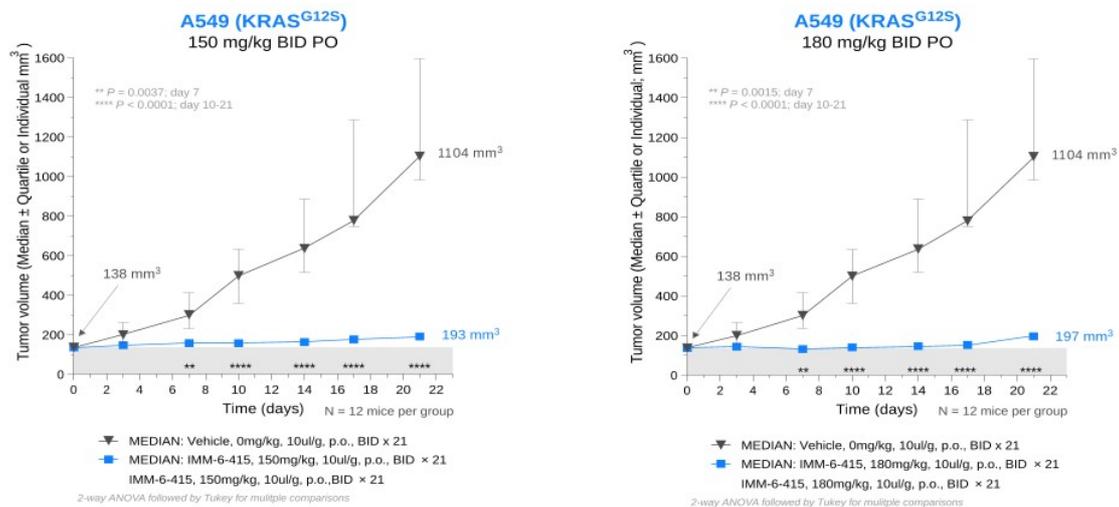
Evaluation of IMM-6-415 as Compared to Vehicle Using a Colon 26 Syngeneic Rodent Tumor Model: Tumor Volume



Colon 26 (KRAS^{G12D}) syngeneic colorectal tumor model in immune competent BALB/c mice. Tumor Growth Inhibition (TGI) % = $[1 - (T_i - T_0)/(C_i - C_0)] \times 100\%$; Maximum Antitumor Effective Dose Range for IMM-6-415 in mice is 150 mg/kg to 175-180 mg/kg BID p.o.

We evaluated IMM-6-415 against vehicle treatment as well as historic IMM-1-104 responses in the KRAS^{G12S} human NSCLC xenograft tumor model (i.e., A549). When comparing IMM-6-415 to previous studies with IMM-1-104 (shown previously), we observed similar and sustained tumor growth inhibition with IMM-6-415 treatment at top effective doses of 150 to 175 mg/kg BID p.o. (as depicted below), and an IMM-6-415 dose range of 60 to 180 mg/kg BID p.o. was well-tolerated with each group gaining 4.77% to 10.75% body weight (similar to vehicle) over the 21 day study. Unlike IMM-1-104, which is being developed as a once-daily monotherapy, we project a shorter human plasma half-life for IMM-6-415. We believe that this would enable twice per day (BID) dosing schedules while still achieving deep, cyclic inhibition for IMM-6-415.

Evaluation of IMM-6-415 as Compared to Vehicle Using a A549 Xenograft Tumor Model: Tumor Volume



A549 (KRAS^{G12S}) human NSCLC xenograft tumor model in athymic nude BALB/c mice. Tumor Growth Inhibition (TGI) % = $[1 - (T_i - T_0)/(C_i - C_0)] \times 100\%$; Maximum Antitumor Effective Dose Range for IMM-6-415 in mice is 150 mg/kg to 175-180 mg/kg BID p.o.

In a further *in vivo* study based on the positive and negative impact of MAPK pathway activation in antitumor responses, we evaluated IMM-6-415 head-to-head against PD1 and CTLA4 checkpoint inhibitors alone, and IMM-6-415 in combination with each, for 28 days in the KRAS^{G12D} mutant syngeneic tumor model (i.e., CT-26). Historically, this KRAS mutant colorectal tumor mouse model has demonstrated greater sensitivity to CTLA4 over PD1/PDL1 checkpoint inhibition. Comparing IMM-6-415 alone at moderated doses below the maximum cytoreductive levels described above, against anti-PD-1 or anti-CTLA4 treatments and in each combination with IMM-6-415 (e.g., QD, BID at multiple dose levels), we observed superior survival through 28 days with insignificant median BWL (i.e., median body weight gain observed in all groups), which we believe indicates the potential for activity, durability and tolerability of IMM-6-415 against a KRAS^{G12D} mutant colorectal cancer model in immune competent rodents (as depicted below).

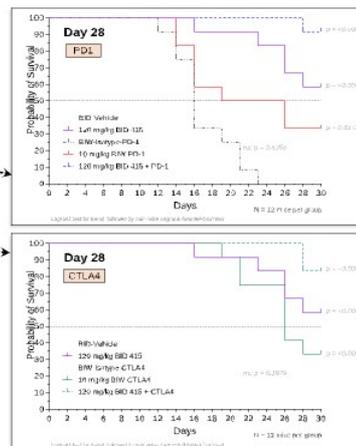
Head-to-Head Comparison of IMM-6-415 +/- anti-PD-1 and anti-CTLA4 Using a CT-26 Syngeneic Tumor Model: Probability of Survival Based on Tumor Volume Limits

IMM-6-415 +/- Checkpoint Inhibitor in KRAS^{G12D} CT-26

| Schedule | Dose (mg/kg) | Veh | PD-1 (BIW) | CTLA-4 (BIW) | IMM-6-415 | IMM-6-415 + PD-1 | IMM-6-415 + CTLA-4 |
|----------|--------------|------|------------|--------------|-----------|------------------|--------------------|
| BID | 120 | 0/12 | | | 7/12 | 11/12 | 10/12 |
| BID | 60 | 0/12 | | | 0/12 | 8/12 | 8/12 |
| BID | 30 | 0/12 | | | 0/12 | 5/12 | 5/12 |
| QD | 120 | 0/12 | | | 0/12 | 7/12 | 7/12 |
| QD | 60 | 0/12 | | | 1/12 | 4/12 | 8/12 |
| QD | 30 | 0/12 | | | 0/12 | 6/12 | 7/12 |
| BIW | 10 | 0/12 | 4/12 | | | | |
| BIW | 10 | 0/12 | | 4/12 | | | |

• Number of BALB/c mice (out of 12) with tumors through Day 28 with volumes lower than 2,000 mm³

 Monotherapy Treated Alive at Day 28
 Combination ≥ 3 Advantage



CT-26 (KRAS^{G12D}) syngeneic colorectal tumor model in immune competent BALB/c mice (note: monotherapy and combinations were inactive in athymic nude CT-26 model – data not shown).

Translational Preclinical Studies: Humanized 3D Tumor Assays

IMM-6-415 has been evaluated for response/non-response profiles in over 60 humanized 3D tumor models that display a wide range of mutations in the MAPK and other pathways. These include and are enriched for activation mutations in KRAS, NRAS, HRAS and BRAF. While IMM-1-104 generally demonstrates more potent head-to-head responses in RAS mutant models, IMM-6-415 displayed more comparable potency, based on IC₅₀ values, to IMM-1-104 in BRAF mutant models. Given the increased cadence of IMM-6-415 BID (versus QD for IMM-1-104) as projected for the clinic, we believe that IMM-6-415 has the potential to afford differentiated treatment options for certain cancer patients with RAS or RAF mutant disease as monotherapy and in potential future drug-drug combinations. Deep, cyclic MEK inhibition can potentially help optimize antitumor immune responses, prevent adaptive resistance to enhance durability and reshape signaling dynamics that focus drug activity against the tumor compartment.

Trifecta-MEK Program

We are developing novel product candidates that are designed to uniquely engage MEK and inhibit the upstream activation events of MEK and the downstream activation events of ERK in MEK itself, for the treatment of solid tumors. We believe the inhibition of upstream and downstream activation events of MEK and ERK bypass MAPK pathway reactivation events (i.e., contributing to drug resistance). Our investigational Trifecta-MEK program inhibitors are designed to be differentiated from IMM-1-104 and IMM-6-415 due to their potential mechanism of target engagement, novel potential to allosterically inhibit MEK and KSR disruption, along with a unique PK design approach. The potential dosing intervals, potency and mechanisms of target engagement of our investigational Trifecta-MEK program inhibitors may broaden the application of these inhibitors to metabolically diverse RAS and RAF mutant tumors. We are designing our investigational Trifecta-MEK program inhibitors to be administered as monotherapy to provide potentially better alternatives to combination therapies inhibiting MEK and RAF in BRAF mutant tumors.

We have evaluated one of our investigational Trifecta-MEK program inhibitors head-to-head against binimetinib and encorafenib in a cell-based potency study to observe comparisons in the reduction of activated MEK and ERK in KRAS^{G12S} and BRAF^{V600E} mutant tumor models. In the KRAS mutant tumor model, our investigational Trifecta-MEK program inhibitor provided greater inhibition of activated MEK and ERK as compared to binimetinib and encorafenib (as depicted below). In the BRAF mutant tumor model, our investigational Trifecta-MEK program inhibitor displayed greater inhibition of activated MEK and ERK as compared to binimetinib, and greater activated ERK inhibition as compared to encorafenib (as depicted below). Our Trifecta-MEK program is currently in the drug discovery stage of development.

Head-to-Head Comparison of One of Our Investigational Trifecta-MEK Program Inhibitors Against Encorafenib and Binimetinib Using A549 and A375 Xenograft Tumor Models

A549 Tumor Model: KRAS^{G12S} mutant NSCLC

| Compound | pERK: tERK 100 nM A549 % of control, 4h | pMEK: tMEK 100 nM A549 % of control, 4h | Notes |
|----------------------|---|---|------------------------------|
| 0.1% DMSO | 1.000 | 1.000 | Vehicle Control |
| Encorafenib | 2.693 | 3.431 | Paradoxical MAPK Activation |
| Binimetinib | 0.173 | 4.031 | CRAF-bypass Evident |
| Trifecta-MEK* | 0.011 | 0.345 | pERK and pMEK control |

A375 Tumor Model: BRAF^{V600E} mutant Melanoma

| Compound | pERK: tERK 100 nM A375 % of control, 4h | pMEK: tMEK 100 nM A375 % of control, 4h | Notes |
|----------------------|---|---|-----------------------------------|
| 0.1% DMSO | 1.000 | 1.000 | Vehicle Control |
| Encorafenib | 0.023 | 0.039 | Prevents pMEK (BRAF inhibitor) |
| Binimetinib | 0.057 | 1.094 | BRAF activity stable (pMEK) |
| Trifecta-MEK* | 0.002 | 0.095 | pERK and pMEK control |

* Binimetinib and encorafenib were commercially purchased.

*One of our investigational Trifecta-MEK program inhibitors.

RAS Modulators Program

We are developing investigational mutation agnostic RAS modulators that are designed to bind to a unique, undisclosed site on RAS for the treatment of solid tumors. We believe our investigational RAS modulators have the potential to disrupt RAS biology and therapeutically disrupt MAPK signaling in patients with various RAS mutant tumors, which represent approximately 20% of all cancer patients. Although drugs in this class have begun targeting RAS mutations, such as KRAS^{G12C} and KRAS^{G12D}, we believe a majority of KRAS mutations, which we are designing our RAS modulators to target, will remain unaddressed.

In the humanized 3D-TGA tumor model, we observed a half maximal tumor inhibitor concentration, or IC₅₀, of less than 0.1 μM for twelve of our investigational RAS modulators. A low IC₅₀ value means that a drug may be effective at low concentrations and may provide lower systemic toxicity when administered to the patient because of the low concentration required to generate therapeutic activity. Based on these tumor models, we believe our investigational RAS modulators may achieve RAS signaling disruption when administered at low concentrations, providing the potential for improved tolerability as compared to other FDA-approved MAPK pathway drugs. Our RAS program is currently in the drug discovery stage of development.

Additional Early Discovery Drug Programs

In addition to the discovery programs described above, we are also pursuing drug discovery efforts towards an undisclosed but validated oncology target. We continue to periodically evaluate our drug discovery efforts and are focused on developing and advancing our early pipeline by addressing validated oncology targets in new ways that may

better address unmet clinical needs. Our proprietary and we believe, innovative, platforms are central to our discovery and translational efforts, and we continue to prioritize and de-prioritize early discovery drug programs that demonstrate (or fail to demonstrate) clear, targetable patterns of oncogenic addiction that are therapeutically responsive to deep, cyclic target inhibition. This approach ensures that we advance drug programs with potential for broad activity and improved overall tolerability.

To that end, we have deprioritized and paused our covalent MEK and PI3K programs. We also suspended our neuroscience programs to sharpen our focus on our core oncology programs.

Our Platform

Consistent with our approach of weaving bioinformatics and computational biology into every stage of the drug development process, we have developed a proprietary disease-agnostic platform that allows us to leverage human biological data to generate insights that are not constrained by the inherent limitations of conventional approaches or prevailing scientific views. We are developing novel product candidates that aim to optimize both safety and efficacy for diseases with high unmet medical needs and suboptimal treatment options. Key elements of our platform include:

- **Insights from Human Data.** Compare distinct groups of individuals who differ in a certain aspect of disease or response to a particular therapy, or identify new patient subsets.
- **Novel Biology.** Identify potential novel targets and new ways to drug existing targets using DCT and/or our insights into mechanisms of response.
- **Novel Chemistry.** Identify small molecules that selectively bind to a target of interest using our proprietary Fluency technology, and/or engineer PK to achieve optimal signaling dynamics.
- **Proprietary Translational Planning.** Use proprietary, humanized 3D preclinical models and bioinformatics to prioritize indications and identify sensitive subpopulations.

Underlying each of these elements is our rigorous quality control and ability to analyze complex biological datasets. We are one of the few biopharmaceutical companies that has been involved in defining best practices for robustly analyzing bioinformatics data, as evidenced by co-authorship on journal articles together with regulators as well as writing invited reviews to educate the scientific community on this topic. This attention to rigorous quality control pervades all of our analyses, and we believe this enables us to extract meaningful information from a variety of databases of human data, including GENIE and The Cancer Genome Atlas Program, or TCGA.

Our platform is not limited to a single aspect or pathology; rather, it is disease-agnostic, which we believe enables us to identify, develop and evaluate product candidates across multiple disease areas simultaneously, with our current focus in oncology. While we currently have an emphasis on transcriptomic data, our platform is not limited to a single data type and thus we believe it will be able to evolve as new datasets emerge. Our platform enabled the initiation, discovery and development of our lead product candidate, IMM-1-104, and has led us to identify additional product candidates with novel compositions of matter by leveraging our platform and drug discovery process. Moreover, our platform has been applied extensively in successful partnerships with large pharmaceutical and biotechnology companies, and through our internal drug discovery and development.

Insights from Human Data

Our analyses often begin by comparing existing transcriptomic data from two groups of patients (e.g., from those whose tumors have metastasized versus those whose tumors have not) to help elucidate the biological mechanisms underlying a particular aspect of disease which we seek to counteract. As another example, we may analyze existing data from patients with differences in response to an existing therapy, in order to better understand what is happening in responders versus non-responders. We may also analyze existing data from patients with a disease to identify novel subsets of patients. Our platform has enabled us to conduct multiple projects that involve stratifying patients into novel subsets. We associate transcriptomic profiles with each subset, which can then be directly inputted into DCT to identify novel targets specific to a given patient subset.

Novel Biology

Disease Cancelling Technology

We have developed DCT to identify targets that reverse a disease signal across multiple relevant genes with the potential to yield product candidates with differentiated mechanisms that are less likely to be discovered by traditional drug discovery methods. Additional biologic context is derived from quantifying the extent to which different time points, concentrations and perturbations (e.g., inhibition and overexpression) may cancel a disease signal more effectively than existing drug targets. DCT ranks target perturbations by the extent to which they generate signals that counteract disease-associated gene expression changes observed in patient data. Thus, we believe DCT enables hypothesis-free, data-driven identification of novel targets and new ways to drug existing targets.

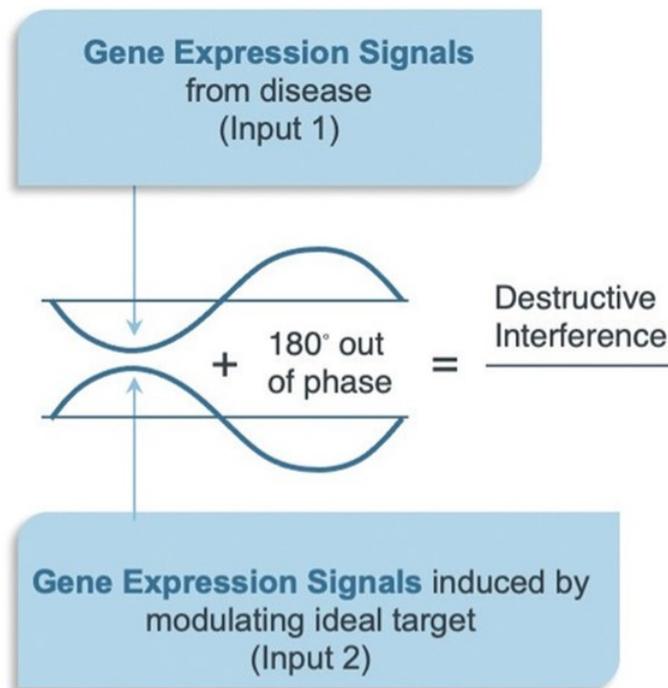
DCT leverages gene expression data derived from human patient samples to identify targets that may rescue abnormal gene expression and restore pathway homeostasis. In addition, DCT identifies biology relevant to attenuating a disease by quantifying the similarity of genome-wide signatures of specific aspects of the disease to signatures of target induced gene expression changes using a mathematical similarity metric. Uniquely, DCT quantifies the per-gene contribution to overall disease amplification or cancellation. An example of a typical analysis begins by running DCT to identify an unwanted, disease-specific gene expression pattern. The ideal input to DCT is focused on a specific aspect of a disease, such as tumors that have metastasized versus those that have not, rather than comparing diseased versus healthy states. DCT identifies target candidates by screening a disease differential expression signature and comparing it to thousands of target gene expression signatures.

DCT is able to rapidly compare disease state signatures against vast numbers of target signatures. DCT ranks signatures resulting from the modulation of specific targets by the extent to which they oppose disease signatures (as depicted below). Unlike some algorithms or artificial intelligence, or AI, approaches, the results originating from DCT are designed to be interpretable from a computational and biological perspective. This platform uses gene expression from patient datasets and does not rely on literature. Together with the target, DCT provides a specific list of testable genes associated with the target of interest, relevant drug concentrations and temporal dynamic information driving the result. Thus, we believe DCT can identify new targets and readily detect dynamic relevant biology relating to modulating a target in a better way.

A summary workflow for DCT's novel target identification can be described as follows:

- Carefully curated and quality-controlled human transcriptomic data representing a specific aspect of disease, or Input 1, is input and vectorized for processing (as depicted below).
- A carefully curated and quality-controlled library of gene expression signals associated with perturbing specific targets at specific time points and concentrations, or Input 2, is input and vectorized for processing (as depicted below). This library can potentially include clustered regularly interspaced short palindromic repeats, or CRISPR, RNA interference, tool compounds, screening library compounds and existing drugs.
- The strength of disease signal cancellation is measured between Input 1 and every target signature in Input 2.

Disease Cancelling Technology Summary Workflow for Target Identification



A second filtration step selects target candidates for which multiple biological pathways are restored in the proper direction compared to the disease signal. DCT includes a method to compute a per pathway contribution to disease canceling in terms of percent contribution to overall disease reversal for cases when a specific pathway is particularly relevant. DCT is designed to have many capabilities in addition to identifying novel targets or novel ways to drug existing targets. To enable rapid translation to experimental validation, DCT can suggest ideal concentrations, temporal dynamics and marker genes to monitor. DCT is also capable of predicting target combinations for a given disease or an ideal target for combination with an existing therapy. For expanded utility, DCT has a graphical user interface that enables our biologists to interact with, sort, modify, query and run results along with producing visualizations of results.

We believe DCT has several advantages over other target identification technologies. The platform uses patient data as a starting point, rather than artificial 2D *in vitro* models. We have presented data at American Association for Cancer Research and other conferences demonstrating how cell lines fail to capture the heterogeneity of patient tumors, and our discovery team's experience in the 3D tumor modeling field has also highlighted the limitations of 2D *in vitro* data. Moreover, working closely with several FDA-approved drugs, we have found that transcriptomic data was most frequently and dynamically linked to drug activity. Thus, our core insights are derived from transcriptomic data (RNA), while some of our competitor's platforms may focus on sequencing data (DNA), imaging data from phenotypic screens and/or literature. DCT is focused on identifying novel targets or novel ways to modulate existing targets, with the goal of generating novel therapeutics with improved clinical activity. We have not in-licensed external drugs and we do not focus on "drug repurposing" activities. Our pipeline is composed of programs with potentially novel pharmacological effects.

Biological Mechanisms of Response

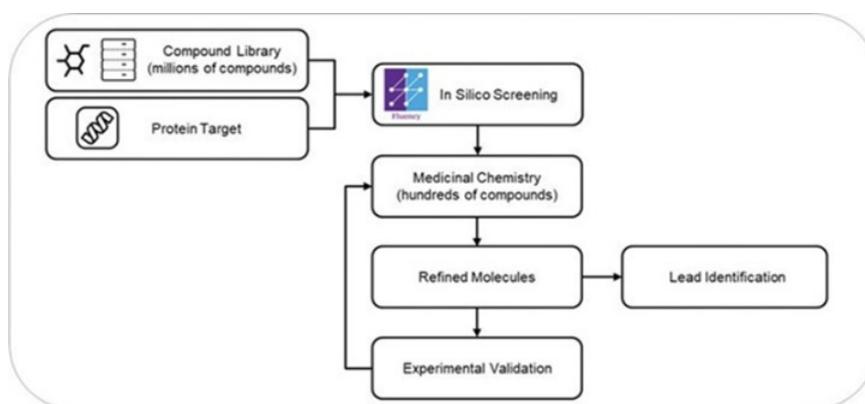
We also identify novel biology by applying translational bioinformatics to analyze the biological mechanisms of response of existing therapies. This may include comparing the transcriptional profiles induced by a drug at different timepoints in order to highlight biological feedback loops that we then seek to counteract.

Novel Chemistry

Fluency

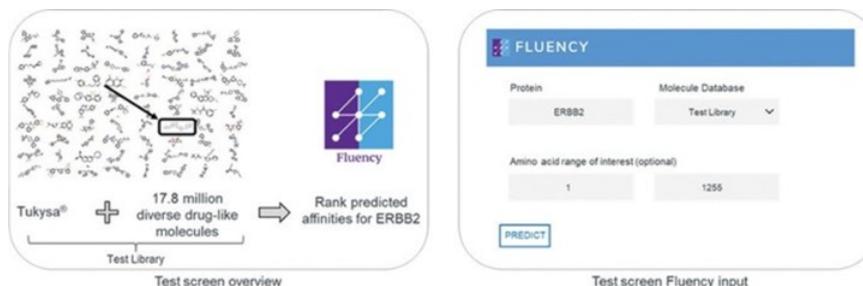
We developed Fluency, an easy-to-use AI-based tool, to allow for the rapid screening of large compound libraries for potential binders to a protein target of interest. Fluency can be run with any compound library, including libraries containing millions of compounds. It identifies the most attractive drug candidates within a library by making ranked predictions of binding affinity for all compounds. It also makes predictions about the target binding location for all compounds, which allows us to filter the library for drug candidates that are the most likely to affect a specific region of interest on the desired target. Fluency accelerates our drug development process by allowing us to go from millions of potential compounds down to what Fluency selects as the best hundred drug candidates within a single workday. This allows us to quickly advance only those select candidates to medicinal chemistry and experimental validation (as depicted below), increasing our capital efficiency. Knowledge of the 3D structure of the protein target of interest is not required, which expands the applicability of Fluency to include targets with poorly defined or non-existent 3D structures.

Fluency Accelerates Our Drug Discovery



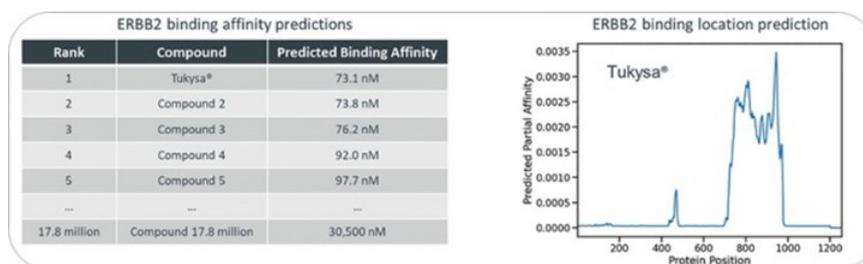
To illustrate both the ease of use, as well as the power of Fluency to identify promising drug candidates, we constructed a test screen of Tukysa® (tucatinib), a recently FDA-approved drug for the treatment of advanced breast cancer in combination with trastuzumab and capecitabine. Tukysa® is a tyrosine kinase inhibitor of human epidermal growth factor receptor 2, or HER2 (also referred to as ERBB2). We created a test compound library by placing Tukysa® in a diverse chemical library of 17.8 million drug-like molecules and evaluated whether or not Fluency could identify it as a promising drug candidate against ERBB2 (depicted in the first panel below). The binding models within Fluency were trained against millions of carefully quality controlled, publicly available binding affinity measurements for compounds against thousands of proteins. However, because Fluency did not see Tukysa® or other molecules highly similar to Tukysa® during training, it did not know whether or not it was a promising candidate before the test screen was run. In our test screens, we input the protein of interest into Fluency, then select a library to screen, and optionally enter the region of interest within the protein (depicted in the second panel below). In the test screen for Tukysa®, we screened the test library against all amino acids within ERBB2.

Fluency Test Screen Input Example



Fluency rapidly screened approximately 17.8 million compounds in less than 7 hours and identified Tukysa® as the best binder to ERBB2 along with a number of other potential candidates (as depicted below). Fluency’s location prediction for this compound points towards the kinase domain of ERBB2 which contains the binding site. Referring back to our drug discovery flow chart depicted above, Tukysa® would have been amongst the hundreds of compounds to go on to medicinal chemistry and experimental validation if we were searching for general ERBB2 binders or if we were searching for potential binders specific to the kinase domain.

Fluency Test Screen Output Example



Fluency has been used to screen for potential drug candidates within our early-stage oncology programs. Our team includes AI specialists with expertise in Fluency who are embedded in our end-to-end preclinical drug development processes. We continue to seek new ways to apply our AI expertise to develop novel product candidates and potentially improve the lives of patients.

Signaling Dynamics (PK-Driven)

Transcriptomic data has proven critical to these analyses because it provides an understanding of the extent to which specific genes are expressed at any given time, capturing temporal changes in pathway activation. Signaling networks differ between cell types, and we leverage this to modulate targets in such a way that certain cell types will be more impacted than others. Our platform enables us to assess the signaling dynamics of product candidates, which we believe allows us to optimize the chemistry of our product candidate programs to achieve broad therapeutic activity against diseased cells while sparing healthy normal cells. Modulation of these signaling networks impacts cell fate decisions in many cell types, including cancerous cells. Our computational biology expertise enables us to analyze transcriptomic data that closely reflects spatiotemporal dynamics of biological signaling networks.

Proprietary Translational Planning

Humanized 3D Tumor Models.

In oncology, we are deeply experienced in advanced, humanized 3D-based tumor growth models, which based on peer reviewed research by members of our team and others, more accurately predict drug response in animal models, and we believe in patients, compared to standard models. Unlike *in vitro* approaches, the 3D tumor growth models reflect the complexity of tumor biology given their alignment with the TME. Thus, we believe our deep expertise in 3D tumor models enables us to more accurately stratify patients likely to benefit from our potential product candidates.

3D-TGA Background and Utility

Although two-dimensional, or 2D, tissue culture has dominated cell-based preclinical oncology research for over 70 years, successful translation and regulatory approval of new oncology drugs are amongst the lowest of all therapeutic areas. Innovations in cell-based platform technologies, such as matrix-based humanized 3D Tumor Growth Assay, or 3D-TGA, tumor models, offer the promise to enrich preclinical drug discovery and improve overall clinical translational success. Our company and leadership have a strong history in research and translation of drug response using patient-derived tumor models (e.g., patient-derived xenografts and 3D ex vivo models) and translational bioinformatics using public and internal patient data. Our team has built on previous ex vivo tumor modeling experience and patient-alignment model selection approaches to identify models that better reflect molecular profiles of target patient populations. We believe this effort will help improve translational success of our pipeline and help ensure that established 3D-TGA models perform well as a core platform for innovative oncology drug R&D. By leveraging over two decades of humanized modeling expertise, our translational and discovery teams have built, characterized, and interrogated a large set of 3D-TGA tumor models from commonly used human tumor cell lines (i.e., currently at over 130 tumor models). The cohort of 3D-TGA tumor models span at least 12 major tumor types, including: breast, colorectal, lung, pancreas, melanoma, ovary, liver, stomach, prostate, neuroblastoma, rhabdomyosarcoma, and thyroid. Over time, additional 3D-TGA models may be developed to add new indications or expand existing indications to better test emerging discovery or translational hypotheses. A large, proprietary 3D-TGA collection ensures that new drug candidates, identified as active in one cohort, could be quickly tested for broader tumor activity in additional tumor types. The established collection of 3D-TGA tumor models can also be used to perform novel drug screens and develop novel chemical entities (NCE's) that demonstrate drug activity.

Prioritize Indications and Identify Sensitive Subpopulations

We are able to leverage bioinformatics to analyze genomic data from large patient databases to identify specific indications where the majority of patients have characteristics that align with our more reflective humanized models and identify biological mechanisms and biomarkers that enable us to identify subpopulations that are more likely to be sensitive based on their similarity to our translational approaches.

Our Platform and its Role in the IMM-1-104 Program

Our platform played a key role in creating the most important characteristics of our lead product candidate, IMM-1-104. In the early stages of the program, insights from human data were used to identify transcriptional profiles we aimed to counteract. DCT and our analysis of mechanisms of existing drugs led us to identify what we believe to be novel biology, specifically new ways to drug an existing target, to highlight the goal of counteracting a biologic feedback loop. Novel chemistry was generated to counteract the feedback loop, and the PK was tuned to generate optimal signaling dynamics (deep but cyclic interruptions of the pathway) as confirmed for translational profiling. Our proprietary translational planning has involved profiling IMM-1-104 in a large number of 3D models to identify the types of cancer (and biomarkers of subsets when needed) that we believe will have the highest probability of success in the clinic. Together, these insights enabled us to demonstrate in an *in vitro* model that a drug with feedback loop resistance combined with a short half-life was able to move toward *in vivo* improvements in key efficacy metrics and tolerability through modulation of tumor cell signaling dynamics.

Early in the program, we utilized human data to generate translational profiles specific to cancer patients experiencing cachexia, which causes extreme weight loss and muscle wasting. DCT was then utilized to identify targets and intervention time points, otherwise known as biological perturbations, that could counteract cachexia. Among the highest ranked perturbations were multiple MEK, inhibitors, but only the gene expression profiles induced by these MEK inhibitors at early time points (i.e., at 3 and 6 hours) were ranked highly for cancelling the disease-associated signals according to our

technology. In contrast, the gene expression signals induced by MEK inhibitors at a later time point (i.e., at 24 hours) amplified or mimicked the transcriptomic signatures associated with diseases. These findings pointed to the importance of a feedback loop in the MAPK pathway called the CRAF-bypass, which may lead to resistance of MEK inhibition, and highlighted the critical importance of designing IMM-1-104 to potentially counteract the CRAF-bypass.

We next applied our platform's ability to characterize mechanisms of response by generating transcriptomic (RNA sequencing) data evaluating the impact of a recently approved MEK inhibitor, selumetinib, relative to vehicle in KRAS^{G12D} tumor-bearing BALB/c mice, which are inbred, albino and immunodeficient mice ordinarily used in research models for cancer therapy. The BALB/c mice were orally administered 100 mg/kg of selumetinib twice a day for 18 days. Notably, when we examined a set of genes known to be downstream of ERK and activated by the MAPK pathway, we saw reduced downregulation of the pathway following selumetinib treatment. There was very little difference between the degree of MAPK pathway downregulation at the 2 hour time point and the 12 hour time point, demonstrating that the inhibition achieved by a typical MEK inhibitor with a non-zero drug trough was both static and limiting in a chronic setting. This focused us on the need to develop IMM-1-104 with novel chemistry, specifically a short half-life to achieve deep cyclic inhibition. Through the medicinal chemistry process, we were able to conduct similar analyses to assess the impact of varying PK profiles on signaling dynamics, and when we conducted the same analysis with IMM-1-104 in the model referenced above, we observed much stronger downregulation at the 2 hour time point followed by a return to baseline at the 12 hour time point. These observed results confirm that we achieved the desired signaling dynamics of cycles of deep inhibition and release of the MAPK pathway.

We are utilizing our platform's proprietary translational planning capabilities by evaluating IMM-1-104 in a large panel of 3D tumor models, and then applying our ability to robustly analyze challenging datasets to assess genomic data from publicly available cancer patient databases to prioritize indications for IMM-1-104 and identify biomarkers of response, when needed. We believe this analysis will enable us to identify substantial translational opportunities for additional indications.

Our Platform and Our Early-Stage Oncology Pipeline

We utilize Fluency, the novel chemistry element of our platform, to rapidly identify small molecule hits for a targeted region of a protein for many of the earlier stage programs in our oncology pipeline. For example, Fluency is being utilized to accelerate the advancement of our RAS modulator program. In addition, these earlier stage programs also utilize our platform's ability to generate novel biology by characterizing mechanisms of response to address these targets in new ways. In the case of our RAS modulators, this includes targeting the process of RAS dimerization. Finally, we are also leveraging novel chemistry in the form of PK changes with the goal of achieving optimal signaling dynamics and deep cyclic inhibition to maximize therapeutic activity in broad populations while improving tolerability. We plan to evaluate each of our programs in humanized 3D models and leverage bioinformatics to prioritize indications and identify sensitive patient subgroups.

Competition

The pharmaceutical and biotechnology industries are characterized by rapid advancement of novel technologies, significant competition and a strong defense of intellectual property rights. While we believe that our proprietary platform and scientific expertise provides us with competitive advantages, we face competition from multiple sources, including larger and better-funded pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future. Key factors that would affect our ability to effectively compete with other therapeutics include safety, efficacy, ease of administration, pricing, brand recognition and availability of reimbursement and coverage by third party payors.

Our Oncology Programs

The current FDA-approved treatment options that target MAPK pathway cancers are either MEK inhibitors limited by their high rates of serious drug-related adverse events that result in drug intolerability and drug resistance through MAPK-feedback loops, or KRAS inhibitors limited to patients with specific KRAS mutations. We expect that our oncology

programs targeting the MAPK pathway may compete with current FDA-approved therapies or clinical programs targeting KRAS mutant tumors that are being advanced by certain pharmaceutical and biotechnology companies.

Intellectual Property

Our ability to obtain and maintain intellectual property protection for our products and technology is fundamental to the long-term success of our business. We rely on a combination of intellectual property protection strategies, including patents, trademarks, copyrights, trade secrets, license agreements, confidentiality policies and procedures, non-disclosure agreements, invention assignment agreements and technical measures designed to protect the intellectual property and confidential information and data used in our business.

As of February 27, 2023, we have: one issued U.S. patent; five pending U.S. patent applications; 20 pending patent applications outside the U.S.; three U.S. provisional applications; and one Patent Cooperation Treaty, or PCT, application that has not entered national stage. These patents and patent applications relate to subject matter, including: our lead product candidate, IMM-1-104, our Universal-MAPK candidate, IMM-6-415, our DCT, and Fluency. Excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable; our owned issued U.S. patent and any patents that may issue from our owned pending U.S. patent applications are expected to expire in February, 2039 or January 2041; any patents that may issue from our owned pending foreign patent applications are expected to expire in January, 2041, and any patents that may issue from national phase filings from our PCT application are expected to expire in January, 2043.

With respect to IMM-1-104, as of February 27, 2023, we have one pending U.S. patent application and 20 pending patent applications outside the U.S. This U.S. patent application, and these pending patent applications outside the U.S., include pending claims directed to compounds, pharmaceutical compositions, and methods of use. Any patent that may issue, based upon these pending applications related to IMM-1-104, is expected to expire in January, 2041, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable.

With respect to IMM-6-415, as of February 27, 2023, we have one pending provisional U.S. application and one pending PCT application. Any patent that may issue, based upon this provisional U.S. application related to IMM-6-415, is expected to expire in November, 2043 and any patent that may issue based upon the pending PCT application is expected to expire in January, 2043, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable.

With respect to our DCT, as of February 27, 2023, we have one issued U.S. patent and one pending U.S. patent application. The issued claims of this U.S. patent and the pending claims of this U.S. patent application are directed to methods (processes) and systems. Our issued U.S. patent related to our DCT and any patent that may issue from our pending patent application related to our DCT are expected to expire in February, 2039, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable.

With respect to Fluency, as of February 27, 2023, we have three pending U.S. patent applications. The pending claims of these U.S. patent applications are directed to methods (processes) and systems. Any patent that may issue from our pending patent application related to Fluency is expected to expire in February, 2039, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. We cannot be sure that our pending patent applications that we have filed or may file in the future will result in issued patents, and we can give no assurance that any patents that have

issued or might issue in the future will protect our current or future products, will provide us with any competitive advantage, and will not be challenged, invalidated, or circumvented.

In the United States, the patent term of a patent that claims an FDA-approved drug or biologic may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during 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 that the drug or biologic 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 and only one patent applicable to an approved drug or biologic may be extended. Similar provisions are available in the EU and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug or biologic. In the future, if any drug candidates that we may develop receive FDA approval, we expect to apply for patent term extensions where applicable on patents covering those drugs. We plan to seek patent term extensions to any of our future 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 these extensions should be granted, and if granted, the length of these extensions.

We intend to pursue additional intellectual property protection to the extent we believe it would be beneficial and cost-effective. Our ability to stop third parties from making, using or commercializing any of our patented inventions will depend in part on our success in obtaining, defending and enforcing patent claims that cover our technology, inventions, and improvements. With respect to our intellectual property, we cannot provide any assurance that any of our current or future patent applications will result in the issuance of patents in any particular jurisdiction, or that any of our current or future issued patents will effectively protect any of our products or technology from infringement or prevent others from commercializing infringing products or technology.

In addition to our reliance on patent protection for our inventions, products, and technologies, we also seek to protect our brand through the procurement of trademark rights. As of February 27, 2023, we own certain trademark registrations and pending applications for trademark registration, for the marks FLUENCY, DISEASE CANCELLING and IMMUNEERING in the United States and/or certain foreign jurisdictions. Furthermore, we rely on trade secrets, know-how, unpatented technology and other proprietary information, to strengthen our competitive position. We have determined that certain technologies, including some of our software, are better protected as trade secrets. To mitigate the possibility of trade secret misappropriation, we enter into non-disclosure and confidentiality agreements with parties who have access to our trade secrets, such as our employees, consultants, advisors and other third parties. We also enter into invention assignment agreements with our employees and consultants that obligate them to assign to us any inventions they have developed while working for us. We generally control access to our proprietary and confidential information through the use of internal and external controls that are subject to periodic review. Although we take steps to protect our proprietary information and trade secrets, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. As a result, we may not be able to meaningfully protect our trade secrets. For further discussion of the risks relating to intellectual property, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Government Regulation

Among others, the FDA, U.S. Department of Health and Human Services Office of Inspector General, the Centers for Medicare and Medicaid Services and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the preclinical and clinical development, manufacture, marketing and distribution of drugs such as those we are developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, packaging, storage, record keeping, approval, sales, commercialization, marketing, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our product candidates. Any drug candidates that we develop must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in those foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant

aspects of regulation in the European Union, or EU, are addressed in a centralized way, but country-specific regulation remains essential in many respects.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's good laboratory practice requirements and other applicable regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of a New Drug Application, or NDA, after completion of all pivotal trials;
- payment of user fees associated with an NDA;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, and of selected clinical investigation sites to assess compliance with GCPs;
- potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. Some preclinical testing may continue even after the IND is submitted. The IND also includes results of animal and in vitro studies assessing the toxicology, PK, pharmacology, and PD characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or 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. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. 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 study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting, under certain timelines, of ongoing clinical studies and clinical study results to public registries, specifically the clinicaltrials.gov website managed by the National Institutes of Health.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, dose tolerance and dosing schedule and to identify possible adverse side effects and safety risks.
- Phase 3: The product candidate 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 to provide an adequate basis for product approval.

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

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA regulatory requirements in order to use the study as support for an IND or application for marketing approval. Specifically, the FDA has promulgated regulations governing the acceptance of foreign clinical trials not conducted under an IND, establishing that such studies

will be accepted as support for an IND or application for marketing approval if the study was conducted in accordance with GCP, including review and approval by an independent ethics committee, or IEC, and use of proper procedures for obtaining informed consent from subjects, and the FDA is able to validate the data from the study through an on-site inspection if the FDA deems such inspection necessary. The GCP requirements encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies. If a marketing application is based solely on foreign clinical data, the FDA requires that the foreign data be applicable to the U.S. population and U.S. medical practice; the studies must have been performed by clinical investigators of recognized competence; and the FDA must be able to validate the data through an on-site inspection or other appropriate means, if the FDA deems such an inspection to be necessary.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points are generally prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor to obtain the FDA's feedback on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and 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 product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

U.S. Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. Data may come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, 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 effectiveness of the investigational drug product to the satisfaction of the FDA. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product application also includes a non-orphan indication.

The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision after it the application is submitted. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they

are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will 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 are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional clinical trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may contain limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine 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 also may condition approval on, among other things, changes to proposed labeling 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 also require one or more Phase 4 post-market studies 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.

The Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or the FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin.

Orphan Drug Designation and Exclusivity

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

of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity (i.e., greater safety, greater efficacy, or a major contribution to patient care) or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs

The FDA has a number of programs intended to expedite the development or review of products that meet certain criteria. Sponsors may request that FDA allow the use of one or more of these programs. For example, product candidates are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the review team during product development, and the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any product candidate submitted to the FDA for approval, including a product candidate with a fast track designation or breakthrough therapy designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. An NDA for a product candidate is eligible for priority review if it has the potential to provide significant improvement in treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, a product candidate may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug

receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. The FDA may withdraw accelerated approval if, among other things, the confirmatory study fails to verify clinical benefit; the applicant fails to perform required confirmatory studies with due diligence; postmarketing use demonstrates that postmarketing restrictions are inadequate to assure safe use; the applicant fails to adhere to agreed-upon postmarketing restrictions; promotional materials are false or misleading; or, other evidence demonstrates that the product is not shown to be safe or effective under its conditions of use. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product candidate 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.

Post-approval Requirements

Drug products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors 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, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or

- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy 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, in their independent professional medical judgment, 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. 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. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDAm or an NDA submitted under Section 505(b)(2), or (505(b)(2) NDA), submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

Other Healthcare Laws

Pharmaceutical companies like us are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such regulation may constrain the financial arrangements and relationships through which we research, develop, and ultimately, sell, market and distribute any products for which we obtain marketing approval. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, and false claims laws, such as the federal Anti-Kickback Statute and the federal Civil False Claims Act, as well as federal and state transparency laws and regulations with respect to drug pricing and payments and other transfers of value made by pharmaceutical manufacturers to physicians and other healthcare providers, such as the federal Physician Payment Sunshine Act. Violations of any of such laws or any other governmental regulations

that apply may result in significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations to resolve allegations of noncompliance, exclusion from participation in federal and state healthcare programs, such as Medicare and Medicaid, and imprisonment.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing coverage and reimbursement for medical products, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Moreover, as a condition of participating in, and having products covered under, certain federal healthcare programs, such as Medicare and Medicaid, we may become subject to federal laws and regulations that require pharmaceutical manufacturers to calculate and report certain price reporting metrics to the government, such as Medicaid Average Manufacturer Price, or AMP, and Best Price, Medicare Average Sales Price, the 340B Ceiling Price, and Non-Federal Average Manufacturer Price reported to the Department of Veteran Affairs, and with respect to Medicaid, pay statutory rebates on utilization of manufacturers' products by Medicaid beneficiaries. Compliance with such laws and regulations will require significant resources and may have a material adverse effect on our revenues.

Healthcare Reform

In the United States, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, each as amended, collectively known as the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. For example, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- expanded beneficiary eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 138% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expanded the types of entities eligible for the 340B Drug Pricing Program;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" and biologic agents apportioned among these entities according to their market share in certain federal government programs;

- established the Center for Medicare and Medicaid Innovation within the Centers for Medicare and Medicaid Services (“CMS”) to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;
- created the Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- required annual reporting of certain information regarding drug samples that manufacturers and distributors provide to licensed practitioners.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court’s decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 unless additional action is taken by Congress. In addition, the American Rescue Plan, effective January 1, 2024, would eliminate the statutory cap on rebate amounts owed by drug manufacturers under the Medicaid Drug Rebate Program, or MDRP, which is currently capped at 100% of the AMP for a covered outpatient drug.

Moreover, there has been heightened governmental scrutiny recently over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted 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 pharmaceutical products. On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. It also possible that governmental action will be taken in response to the COVID-19 pandemic.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could impact the amounts that federal and state governments and other third-party payors will pay for healthcare products and services.

Data Privacy and Security

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign

laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Human Capital

As of December 31, 2022 we had 73 full-time employees, 61 of whom are dedicated to research and development. 30 of our employees hold doctorate degrees (i.e., Ph.D. or M.D.). 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.

We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth and a robust employment package that promotes well-being across all aspects of their lives, including health care, retirement planning and paid time off.

We believe that much of our success is rooted in the diversity of our teams and our commitment to inclusion. We value diversity at all levels and focus on extending our diversity and inclusion initiatives across our entire workforce.

Our Corporate Information

We were incorporated under the laws of the state of Delaware in February 2008. Our principal executive offices are located at 245 Main Street, Second Floor, Cambridge, MA 02142 and our telephone number is (617) 500-8080.

Our corporate website address is www.immuneering.com. The information contained in, or accessible through, our website is not incorporated by reference into this Annual Report and you should not consider information on our website to be a part of this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

Where you can find more information

We are subject to the information requirements of the Securities Exchange Act of 1934, as amended. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically, such as ourselves, with the SEC at <http://www.sec.gov>.

Item 1A. Risk Factors

Our future operating results could differ materially from the results described in this Annual Report on Form 10-K due to the risks and uncertainties described below. You should consider carefully the following information about risks below in evaluating our business. If any of the following risks actually occur, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. In these circumstances, the market price of our Class A common stock would likely decline. In addition, we cannot assure investors that our assumptions and expectations will prove to be correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. See “Forward Looking Statements” for a discussion of some of the forward-looking statements that are qualified by these risk factors. Factors that could cause or contribute to such differences include those factors discussed below.

Risks Related to Our Financial Condition and Capital Requirements

We are a clinical-stage oncology company with a limited operating history in developing pharmaceutical products, have not completed any clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage oncology company with a limited operating history in developing pharmaceutical products which makes it difficult to evaluate our business and prospects in future product development. We have no products approved for commercial sale and have not generated any revenue from product sales. To date, we have devoted substantially all of our resources and efforts to providing computational biology services to pharmaceutical and biotechnology companies, organizing and staffing our company, business planning, executing partnerships, raising capital, discovering, identifying and developing potential product candidates, securing related intellectual property rights and undertaking research and preclinical and clinical studies of our product candidates, including our ongoing Phase 1/2a clinical trial of IMM-1-104 for the treatment of advanced solid tumors in patients harboring RAS mutant tumors. We have not yet demonstrated our ability to successfully complete any clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our future success or viability to develop new pharmaceutical products than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by biopharmaceutical companies developing products in rapidly evolving fields. We also may need to transition from a company with a research and development focus to a company capable of supporting commercial activities. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have incurred significant net losses for the past several years and we expect to continue to incur significant net losses for the foreseeable future and may never obtain profitability.

We have incurred net losses in each reporting period for the past several years, have not generated any revenue from product sales to date and have financed our operations principally through our computational biology services to pharmaceutical and biotechnology companies, the issuance of convertible debt and the sale of our convertible preferred stock and Class A common stock. We have incurred net losses of approximately \$50.5 million and \$33.5 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of approximately \$109.8 million. Our losses have resulted principally from expenses incurred in research and development of our product candidates, from management and administrative costs and other expenses that we have incurred while building our business infrastructure. We are currently conducting an ongoing Phase 1/2a clinical trial for our lead product candidate, IMM-1-104, for the treatment of advanced solid tumors in patients harboring RAS mutant tumors. Our other product candidates are in earlier stages of drug development. As a result, we expect that it will be several years, if ever,

before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses as we discover, develop and market additional potential product candidates.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- advance the development of our lead product candidate, IMM-1-104, and our other product candidates, including IMM-6-415, through preclinical and clinical development, and, if approved by the FDA or other comparable foreign regulatory authorities, commercialization;
- incur manufacturing costs for our product candidates;
- seek regulatory approvals for any of our product candidates that successfully complete clinical trials;
- increase our research and development activities to identify and develop new product candidates;
- hire additional personnel;
- expand our operational, financial and management systems;
- invest in measures to protect and expand our intellectual property;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize;
- expand our manufacturing and develop our commercialization efforts; and
- operate as a public company.

The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital and our ability to achieve and maintain profitability.

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

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we initiate and conduct clinical trials, and seek marketing approval for our current and any future product candidates. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA or other comparable foreign regulatory authorities to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. Because the design and outcome of our current and anticipated

clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop. We also expect to incur additional costs associated with operating as a public company. Accordingly, it is likely that we will need to obtain substantial additional funding in order to maintain our continuing operations in the future.

As of December 31, 2022, we had approximately \$105.5 million in cash and cash equivalents and marketable securities. Based on our current business plans, we believe that our existing cash and cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditures requirements into the fourth quarter of 2024. Our estimate as to how long we expect our existing cash and cash equivalents and marketable securities to be able to continue to fund our operating expenses and capital expenditures requirements is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Our future funding requirements will depend on many factors, including, but not limited to:

- the initiation, progress, timeline, cost and results of our clinical trials for our product candidates;
- the initiation, progress, timeline, cost and results of additional research and preclinical studies related to pipeline development and other research programs we initiate in the future;
- the cost and timing of manufacturing activities as we advance our product candidates through preclinical and clinical development, and commercialization;
- the potential expansion of our current development programs to seek new indications;
- the negative impact of the COVID-19 pandemic or future pandemics on our business;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights, in-licensed or otherwise;
- the effect of competing technological and market developments;
- the payment of licensing fees, potential royalty payments and potential milestone payments;
- the cost of general operating expenses;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the cost of establishing sales, marketing, and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own; and
- the cost of operating as a public company.

Advancing the development of our product candidates will require a significant amount of capital. Our existing cash and cash equivalents and marketable securities will not be sufficient to fund all of the activities that are necessary to complete the development of our product candidates.

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. For example, in 2022, due to macroeconomic conditions including inflation and higher interest rates, the stock price of biotech companies, including ours, has generally declined, which makes fundraising in our industry more difficult and on less favorable terms. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.

We may seek additional capital through a variety of means, including through public or private equity offering made pursuant to the Sales Agreement or otherwise, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our ability to use our net operating losses and other tax attributes may be limited.

As of December 31, 2022, we had approximately \$77.0 million of federal and \$76.2 million of state net operating loss carryforwards, or NOLs, available to offset future taxable income. Under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change,” generally defined as a greater than 50% change by value in its equity ownership over a three-year period is subject to limitations on its ability to utilize its pre-change NOLs and other tax attributes such as research tax credits to offset future taxable income. We have not performed an analysis to determine whether our past issuances of stock and other changes in our stock ownership may have resulted in other ownership changes. If it is determined that we have in the past experienced other ownership changes, or if we undergo one or more ownership changes as a result of future transactions in our stock, which may be outside our control, then our ability to utilize NOLs and other pre-change tax attributes could be further limited by Sections 382 and 383 of the Code, and certain of our NOLs and other pre-change tax attributes may expire unused. As a result, if or when we earn net taxable income, our ability to use our pre-change NOLs or other tax attributes to offset such taxable income or otherwise reduce any liability for income taxes may be subject to limitations, which could adversely affect our future cash flows.

Risks Related to Development, Regulatory Approval and Commercialization

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

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities impose similar requirements. The time required to obtain approval by the FDA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and

amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

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

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

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. In addition, the FDA or comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

In addition, even if we obtain approval of our product candidates, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy, or REMS. Regulatory authorities may not approve the price we intend to charge for products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims

necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could seriously harm our business.

We are a clinical-stage oncology company, and we may not be able to submit additional INDs or IND amendments or comparable documents in foreign jurisdictions to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

We may not be able to submit additional INDs or comparable documents for IMM-1-104, for which an IND was previously submitted, IMM-6-415 or our other potential product candidates on the timeline we expect. We may also experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND or comparable document will result in the FDA or other comparable foreign regulatory authorities allowing further clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

We are a clinical-stage oncology company, and our company has limited experience in designing clinical trials and may experience delays or unexpected difficulties in obtaining regulatory approval for our current and future product candidates.

We are a clinical-stage oncology company, and we have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. We cannot be certain that our ongoing or planned clinical trials or any future clinical trials will be successful. It is possible that the FDA may refuse to accept any or all of our planned NDAs for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval for any product candidates. If the FDA does not approve any of our planned NDAs, it may require that we conduct additional costly clinical trials, preclinical studies or manufacturing validation studies before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA or other application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any failure or delay in obtaining regulatory approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any NDA or other application that we submit. If any of these outcomes occur, we may be forced to abandon the development of our product candidates, which would materially adversely affect our business and could potentially cause us to cease operations. We face similar risks for our applications in foreign jurisdictions.

We may encounter substantial delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from the FDA or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials.

In addition, we are substantially dependent on preclinical, clinical and quality data generated by CROs and other third parties for regulatory submissions for our product candidates. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements

with them, our development programs may be significantly delayed, and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase, perhaps substantially.

We do not know whether our future clinical trials will begin on time or enroll patients on time, or whether our future clinical trials will be completed on schedule or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards, or IRBs;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- delays in enrollment due to travel or quarantine policies, or other factors related to COVID-19 and its variants, other pandemics or other events outside our control;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidates or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- subjects choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practice, or cGMP, regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;

- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or GCP, or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

In addition, the continuance of the pandemic related to COVID-19 and its variants could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our product candidates for use in our research and clinical trials, delay, limit or prevent our employees and CROs from continuing research and development activities, impede the ability of patients to enroll or continue in clinical trials, or impede testing, monitoring, data collection and analysis or other related activities, any of which could delay our clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination 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 comparable foreign 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, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;

- be sued; or
- experience damage to our reputation.

Our development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all. Any delay in, or termination of, our clinical trials will delay the submission of an NDA to the FDA or similar applications with comparable foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates, if approved, and generate product revenue. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our claims for differentiation or the effectiveness or safety of our product candidate. The FDA has substantial discretion in the review and approval process and may disagree that our data support the claims we propose.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for their intended uses. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical studies and early-stage clinical trials does not mean that future clinical trials will be successful. We do not know whether any of our product candidates will perform in current or future clinical trials as they have performed in preclinical studies. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA or other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidate. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

We are a clinical-stage oncology company and, outside of our clinical trial of IMM-1-104 which commenced in November 2022, we have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. We cannot be certain that our planned clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could seriously harm our business.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or comparable foreign regulatory authority approval. We cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret trial results as we do, and more trials could be required before we are able to submit applications seeking approval of our product candidates. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential. Furthermore, the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval, which may lead to the FDA or comparable foreign regulatory authorities delaying, limiting or denying approval of our product candidates.

Interim, “top-line” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Top-line and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between top-line, preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the trading price of our Class A common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the

particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, results of operations, prospects or financial condition. Moreover, such disclosure could adversely affect the trading price of our Class A common stock.

Our current or future product candidates may cause adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with the use of our product candidates. Results of our preclinical studies and clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with approved or other investigational products we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

Patients in our clinical trials may in the future suffer significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. Some of our product candidates may be used as chronic therapies or be used in pediatric populations, for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, if our product candidates are used in combination with other therapies, our product candidates may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate, but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If significant adverse events or other side effects are observed in any of our future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the

FDA could require us to adopt a REMS to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and costlier than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone or with collaborators. Other potentially significant negative consequences include that:

- we may be forced to suspend marketing of that product, or be forced to or decide to remove the product from the marketplace;
- regulatory authorities may withdraw or change their approvals of that product in one or more countries;
- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of the product for patients, or to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or to be sued and held liable for harm caused to subjects or patients; and
- the product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities.

If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA or other comparable foreign regulatory authorities. Additionally, our clinical trials will compete with other clinical trials for product candidates that focusing on the same therapeutic targets (e.g., evaluating patients harboring RAS mutant tumors) as our current and potential future product candidates, which may further limit enrollment of eligible patients or may result in slower enrollment than we anticipate. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants.

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

- size and nature of the patient population;
- severity of the disease under investigation;

- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- continued enrollment of prospective patients by clinical trial sites;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials; and
- delays or difficulties in enrollment and completion of studies due to the pandemic related to COVID-19 and its variants or any future pandemic.

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

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

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

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- restrictions on the use of our product candidates, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;

- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement, as well as pricing, by third-party payors, including government authorities;
- the availability of the approved product candidate for use as a combination therapy;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our products or product candidates or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications.

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

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

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

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

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

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

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

A key element of our strategy is to use and expand our DCT platform to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of various cancers. Although our research and development efforts to date have resulted in our discovery, preclinical and clinical development of IMM-1-104, it and other product candidates may not be safe or effective for the indications for which we study them in clinical trials, and we may not be able to develop any other product candidates. Our DCT platform is evolving and may not reach a state at which building a pipeline of product candidates is possible.

The scientific research that forms the basis of our efforts to develop product candidates with our platforms is still ongoing. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our DCT platform is both preliminary and limited. As a result, we are exposed to a number of unforeseen risks and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates. For example, we have only begun testing IMM-1-104 in humans, and our current data is limited to animal models and preclinical cell lines, the results of which may not translate into humans. As a result, it is possible that safety events or concerns could negatively affect the development of our product candidates, including adversely affecting patient enrollment among the patient populations that we intend to treat.

Given the novelty of our technologies, we intend to work closely with the FDA and comparable foreign regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates; however, due to a lack of comparable experiences, the regulatory pathway with the FDA and comparable regulatory authorities may be more complex and time-consuming relative to other more well-known therapeutics. Even if we obtain human data to support our product candidates, the FDA or comparable foreign regulatory agencies may lack experience in evaluating the safety and efficacy of our product candidates developed using our platforms, which could result in a longer than expected regulatory review process, increase our expected development costs, and delay or prevent commercialization of our product candidates. The validation process takes time and resources, may require independent third-party analyses, and may not be accepted or approved by the FDA and comparable foreign regulatory authorities. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies.

Additionally, a key element of our strategy is to use and expand our platforms to build a pipeline of product candidates and progress those product candidates through clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have been focused on identifying a pipeline of product candidates directed at various disease types, we may not be able to develop product candidates that are safe and effective. Even if we are successful in building our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be approvable or marketable products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop, get approval for and begin to commercialize any product candidates, we will face difficulty in obtaining product revenue in future periods, which could result in significant harm to our financial position and adversely affect our share price.

Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to

have unacceptable toxicity or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future, which likely would result in significant harm to our financial position and adversely affect our stock price.

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

We may also develop certain product candidates as biologic/drug combination products. Additional time may be required to obtain regulatory approval for our product candidates if they are combination products. Our product candidates that may be biologic/drug combination products will require coordination within the FDA and other comparable foreign regulatory authorities for review of their biologic and drug components. Although the FDA and other comparable foreign regulatory authorities have systems in place for the review and approval of combination products, we may experience delays in the development and commercialization of our product candidates that may be combination products due to regulatory timing constraints and uncertainties in the product development and approval process.

In addition, even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

We also may choose to evaluate our current product candidates or any other future product candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell our product candidates we develop in combination with an unapproved cancer therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved cancer therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

If the FDA or comparable foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with our product candidate we develop, we may be unable to obtain approval of or market such combination therapy.

If we successfully develop our product candidates, we may seek approval from the FDA through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we initially contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

We may in the future seek an accelerated approval for one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical

endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

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

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs, therapeutic platforms and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success than our product candidates. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms and product candidates for specific indications may not yield any commercially viable products.

Risks Related to Our Business

We are early in our development efforts. Our business is substantially dependent on the successful development of our current and future product candidates. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval to treat the indications we seek to treat with our product candidates, and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts and we have not yet completed our Phase 1/2a clinical trial for our lead product candidate, IMM-1-104. We have also not yet submitted our IND application for IMM-6-415. Our other product candidates are in earlier stages of drug development. We have invested substantially all of our efforts and financial resources in the identification of targets, preclinical and clinical development of small molecules targeting the MAPK and other pathways in cancer therapy.

The success of our business, including our ability to finance our company and generate revenue from products in the future, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of the product candidates we develop, which may never occur. Our current product candidates, and any future product candidates we develop, will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other markets,

demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenues from product sales.

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

- the successful and timely completion of additional preclinical studies;
- the successful initiation, patient enrollment and completion of our clinical trial for which we are currently recruiting and future clinical trials which we may initiate, on a timely basis, including any delays arising out of the pandemic related to COVID-19 and its variants or any future pandemic;
- maintaining and establishing relationships with CROs and clinical sites for clinical development, both in the United States and internationally;
- the frequency and severity of adverse events in the clinical trials;
- the efficacy, safety and tolerability profiles that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- the timely receipt of marketing approvals from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers for clinical development;
- the maintenance of existing, or the establishment of new, scaled production arrangements with third-party manufacturers to obtain finished products that are appropriate for commercial sale of our product candidates, if approved;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- the protection of our rights in our intellectual property portfolio;
- the successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for IMM-1-104, or any other product candidate we develop, we may not be able to continue our operations.

We are substantially dependent on our platform, including our proprietary technologies such as DCT and Fluency, which are supported by our information technology systems. Any failure of these or other elements of our platform will materially harm our business.

We are substantially dependent on our platform, including our proprietary technologies such as DCT and Fluency, which are supported by our information technology systems, for significant elements of our drug discovery process, bioinformatics and computational biology software systems, database of information relating to our product candidates and their role in the targeted disease process, amongst others. Although we invest substantially in the backup/restore, high-availability architecture, monitoring and reporting, documentation and preventive security controls of our systems and proprietary technologies, these elements of our platform are still vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious or inadvertent human acts, and natural disasters. Our information technology systems and proprietary technologies are potentially also vulnerable to physical or electronic break-ins, employee errors, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology systems and proprietary technologies, failures or significant downtime of these systems could prevent us from conducting research and development activities for our current and future product candidates, and ultimately delay our drug discovery process. Any failure of our information technology systems and proprietary technologies will materially harm our business.

Our long-term prospects depend in part upon discovering, developing and commercializing product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.

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

The success of the product candidates we have or may develop will depend on many factors, including the following:

- the success of our research methodology in identifying potential indications or product candidates;
- generating sufficient data to support the initiation or continuation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of the product candidate for use in clinical trials;
- adverse events in the clinical trials; and
- any potential interruptions or delays resulting from factors related to the pandemic related to COVID-19 and its variants or any future pandemic.

Even if we successfully advance any other product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this “Risk Factors” section. Accordingly, we cannot assure you that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from our other product candidates.

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

We have never commercialized a product candidate, and we currently have no sales force, marketing or distribution capabilities. We will have to develop our own sales, marketing and supply organization or outsource these activities to a third party to commercialize our products. If we decide to license our product candidate to others, we may need to rely on the marketing assistance and guidance of those collaborators.

Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.

We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.

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

In particular, there is intense competition in the fields of oncology we are pursuing. We have competitors both in the United States and internationally, including major multinational biopharmaceutical companies, established biotechnology companies, specialty biopharmaceutical companies, emerging and start-up companies, universities and other research institutions. For example, our product candidates and programs for oncology will compete with products or programs being advanced by certain pharmaceutical and biotechnology companies. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing new product candidates.

We have chosen to initially address well-validated biochemical targets, and therefore expect to face competition from existing products and products in development for each of our product candidates. There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. Many of these current and potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities and experience than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all of these factors, our competitors may succeed in obtaining approval from

the FDA or other comparable foreign regulatory authorities or in discovering, developing and commercializing products in our field before we do.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain marketing approval from the FDA or other comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

If the market opportunity for any product candidate that we develop is smaller than we believe, our revenue may be adversely affected and our business may suffer.

We intend to initially focus our product candidate development on treatments for various oncology indications. Our projections of addressable patient populations that may benefit from treatment with our product candidates are based on our estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we develop could be significantly diminished and have an adverse material impact on our business.

We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any product candidate.

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our product candidates or may conclude after review of our data that our applications are insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our NDAs for our product candidates, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA that we submit may be delayed or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues, and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

The COVID-19 pandemic and potential future pandemics could continue to adversely impact our business, including our current and future clinical trials, supply chain and business development activities.

In December 2019, SARS-CoV-2, a novel strain of coronavirus, was first reported in Wuhan, China and has since become a global pandemic. The President of the United States declared the COVID-19 pandemic a national emergency and many states and municipalities in the United States have announced aggressive actions to reduce the spread of the disease.

The effects of government actions and our own policies and those of third parties to reduce the spread of COVID-19 and its variants or any future pandemic may negatively impact productivity and slow down or delay our future clinical trials, preclinical studies and research and development activities, and may cause disruptions to our supply chain and impair our

ability to execute our business development strategy. We may also experience delays in receiving approval from regulatory authorities to initiate or conduct our ongoing or planned clinical trials and drug approval. We may also experience operational delays such as delays or difficulties in enrolling patients in our clinical trials; interruption of key clinical trial activities, such as clinical trial site monitoring due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data; and changes in local regulations as part of a response to the pandemic related to COVID-19 and its variants which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether.

While the potential economic impact brought by, and the duration of, the pandemic related to COVID-19 and its variants may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position. In addition, the trading prices for other biopharmaceutical companies have been highly volatile as a result of the pandemic related to COVID-19 and its variants.

These and other disruptions in our operations and the global economy could negatively impact our business, results of operations and financial condition.

Risks Relating to Our Dependence on Third Parties

We substantially rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our preclinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We substantially rely, and expect to continue to rely, on third parties, including independent clinical investigators and third-party CROs, to conduct certain aspects of our preclinical and clinical studies and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We, our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Further, there is no guarantee that any such CROs, investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. These risks are heightened as a result of the efforts of government agencies and the CROs themselves to limit the spread of COVID-19 and its variants or future pandemics, including quarantines and shelter-in-place orders. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or

for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or precluded entirely.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on, and in the future may rely on, third-party datasets and collaborations with third parties to inform patient selection, drug target identification and other bioinformatic and computational biology analyses for our existing product candidates and any future product candidates and for the supply of biomarker companion diagnostics.

We are using bioinformatics, including data analytics, biostatistics and computational biology, throughout our drug discovery and development process, including to identify new target and biomarker opportunities. As part of this approach, we interrogate public and proprietary datasets, including, but not limited to, human tumor genetic information and specific cancer-target dependency networks. We rely on these datasets and data analytics for multiple analyses, including identifying or validating some of our biomarker-target relationships and access to these databases may not continue to be available publicly or through a proprietary subscription on acceptable terms. Our past, present and future use of such datasets could also create potential liabilities for us if the data provided to us contains inherent errors, inaccuracies or artifacts, or if we improperly analyze, handle, store or utilize the data.

Many of our product candidates also rely on the availability and use of commercially available tumor diagnostics panels or data on the prevalence of our target patient population to inform the patient selection and drug target identification for our product candidates. In cases where such biomarker diagnostic is not already commercially available, we expect to establish strategic collaborations for the clinical supply and development of companion diagnostics. If these diagnostics are not able to be developed, or if commercial tumor profiling panels are not able to be updated to include additional tumor-associated genes, or if clinical oncologists do not incorporate molecular or genetic sequencing into their clinical practice, we may not be successful in developing our existing product candidates or any future product candidates.

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

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

We may face significant competition in seeking appropriate collaborators and the related negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of

clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

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

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

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

We may seek third-party collaborators in the future for the development and commercialization of one or more of our product candidates. Our likely collaborators for any future collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates could pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

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

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse and compliance laws and regulations, accurately report financial information or data 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, submission of false claims, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting/rebating, marketing and promotion, consulting, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

Risks Related to Manufacturing

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

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and potency.

Manufacturing drugs requires facilities specifically designed for and validated for this purpose, as well as sophisticated quality assurance and quality control procedures. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

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

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. We do not have long-term supply agreements. Furthermore, the raw materials for our product candidates may be sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

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

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and

- the misappropriation of our proprietary information, including our trade secrets and know-how.

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

In the event that any of our 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, including due to the impact of the pandemic related to COVID-19 and its variants or future pandemics, 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 commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates 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. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third-party manufacturing arrangements for these product candidates or methods. 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 product candidates. If we are required to or voluntarily 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 and that the product produced is equivalent to that produced in a prior facility. The delays associated with the verification of a new manufacturer and equivalent product could negatively affect our ability to develop product candidates in a timely manner or within budget.

Our, or a third-party's, failure to execute on our manufacturing requirements, do so on commercially reasonable terms and timelines and comply with cGMP requirements could adversely affect our business in a number of ways, including:

- inability to meet our product specifications and quality requirements consistently;
- inability to initiate or continue clinical trials of our product candidates under development;
- delays in submitting regulatory applications, or receiving marketing approvals, for our product candidates, if at all;
- inability to commercialize any product candidates that receive marketing approval on a timely basis;
- loss of the cooperation of future collaborators;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;

- requirements to cease development or to recall batches of our product candidates;
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product or any other future product candidates; and
- our future profit margins.

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

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

Risks Related to Legal and Regulatory Compliance Matters

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The term “remuneration” has been broadly interpreted to include anything of value. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per claim penalties per false claim or statement. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Criminal Statute on False Statements Relating to Healthcare Matters, which makes it a crime to knowingly and willfully falsify, conceal, or cover up a material fact, make any materially false, fictitious, or fraudulent statements or representations, or make or use any materially false writing or document knowing the same to contain any materially false,

fictional, or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items, or services;

- the federal Civil Monetary Penalties Law, which authorizes the imposition of substantial civil monetary penalties against an entity, such as a pharmaceutical manufacturer, that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal healthcare programs to provide items or services reimbursable by a federal healthcare program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, 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;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the Centers for Medicare and Medicaid Services, or CMS, information regarding payments and other transfers of value to physicians (as defined by statute), certain non-physician providers including physician assistants and nurse practitioners, and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information reported is publicly available on a searchable website, with disclosure required annually;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and
- some state laws require biotechnology companies to report information to state agencies and/or commercial purchasers on the pricing of certain drug products that exceed a certain level as identified in the relevant statute. Some of these laws and regulations contain ambiguous requirements that government officials have not yet clarified. Given the lack of clarity in the laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that our business practices, including our arrangements with physicians, some of whom have ownership interests in us, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials in the U.S. and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operation, and financial condition.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. For instance, in the U.S., most healthcare providers, including research institutions from which we may obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and the regulations promulgated thereunder, or collectively, HIPAA. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners.

We are also or may become subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions. For example, the European Union General Data Protection Regulation, or the GDPR, governs certain collection and other processing activities involving personal data about individuals in the European Economic Area, or the EEA. The GDPR imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our annual global revenue). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. Further, since January 1, 2021, companies have to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g. fines up to the greater of €20 million (£17.5 million) or 4% of global turnover.

The GDPR and UK GDPR regulate cross-border transfers of personal data out of the EEA and the UK respectively. Recent legal developments in Europe have created complexity and uncertainty regarding such transfers, in particular in relation to transfers to the United States. On July 16, 2020, the Court of Justice of the European Union or the CJEU invalidated the EU-US Privacy Shield Framework, or Privacy Shield, under which personal information could be transferred from the EEA (and the UK) to relevant self-certified U.S. entities. The CJEU further noted that reliance on the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism and potential alternative to the Privacy Shield) alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 16, 2020 have taken a restrictive approach to international data transfers. As the enforcement landscape further

develops, and supervisory authorities issue further guidance on international data transfers, we could suffer additional costs, complaints and/or regulatory investigations or fines; we may have to stop using certain tools and vendors and make other operational changes; and/or it could otherwise affect the manner in which we provide our services, and could also adversely affect our business, operations and financial condition.

If we or third-party contract manufacturing organizations, or CMOs, CROs or other contractors or consultants fail to comply with applicable federal, state or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage.

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

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

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

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

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific

and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

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

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

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

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

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

Although we will maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the potential use of hazardous materials in the future, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials.

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

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

We may choose to conduct international clinical trials in the future. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary.

Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction. If the FDA or any other comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

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

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

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

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

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include

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

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

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 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 may have obtained, and we may not achieve or sustain profitability.

We also 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 currently have a limited set of compliance policies and personnel, and intend to develop our compliance infrastructure in the future, as our clinical development programs progress. Developing a compliance infrastructure is costly and time-consuming, and even a well-designed and

implemented compliance program cannot necessarily prevent all violations of relevant laws. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our product candidates, if approved. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

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, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA 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. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the Securities and Exchange Commission, or the 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, 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. If a prolonged government shut down or other disruption at the FDA occurs, 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, as a public company, future government shutdowns could impact our ability to further access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, in response to the global COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the pandemic related to COVID-19 and its variants. 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 or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We may face difficulties from changes to current regulations and future legislation.

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

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the ACA, was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjected biologic products to potential competition by lower-cost biosimilars; increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain “branded prescription drugs” to specified federal government programs; implemented 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; expanded eligibility criteria for Medicaid programs; expanded the types of entities eligible for the 340B Drug Pricing Program; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court’s decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included the American Rescue Plan Act of 2021, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug’s average manufacturer price, beginning January 1, 2024. Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in

reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates. Further, it is possible that additional governmental action is taken in response to the pandemic related to COVID-19 and its variants.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent and other intellectual property protection for our product candidates and technologies or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our products and technology may be impaired, and we may not be able to compete effectively in our market.

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market. Our commercial success depends in part on our ability to obtain and maintain patent, trade secret or other intellectual property protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing the proprietary rights of others. If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology or our product candidates, our competitive position could be harmed. We generally seek to protect our proprietary position by filing patent applications in the United States and, in some cases, abroad related to our product candidates, technology platforms and their uses that are important to our business.

As of February 27, 2023, we owned one issued patent and four pending patent applications, in the United States only, related to our platform technologies, as well as pending patent applications related to our product candidates in and outside the United States. We currently do not have any issued patents related to our product candidates. Further, patent prosecution with respect to our pending patent applications related to our product candidates is in the early stages and, as such, no patent examiner has yet scrutinized the merits of such pending patent applications. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology and such third parties practice the technology in countries where such patents have issued. With respect to our issued patent and patent applications related to our platform technology, we filed those applications only in the U.S., so it is possible that a competitor may practice outside the U.S. the aspects of our platform technology disclosed in those patent applications. We maintain other aspects of our platform technology as trade secrets, which were not disclosed in those patent applications. There can be no assurance that any of our current and future issued patents and patent applications, if any, owned by us or our future in-licensed patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents if issued will not be infringed, designed around, invalidated or rendered unenforceable by third parties, or would effectively prevent others from commercializing competitive products or technologies. Composition of matter patents for biological and pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents may provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications related to composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office, or USPTO, or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the existence, issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Although we may obtain licenses to issued patents in the United States and foreign countries in the future, we cannot be certain that the claims in future in-licensed U.S. pending patent applications, if any, corresponding international patent

applications and patent applications in certain foreign countries will be considered patentable by the USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in future in-licensed issued patents will not be found invalid or unenforceable if challenged.

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

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

The patent prosecution process is also expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product or technology. For example, certain jurisdictions do not allow for patent protection with respect to method of treatment. Moreover, the scope of claims in a patent application can be significantly reduced before any claims in a patent are issued, and claim scope can be reinterpreted after issuance. Even if our current or future patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner, which could materially adversely affect our business, financial condition, results of operations and prospects.

It is also possible that we may not identify patentable aspects of our research and development output before it is too late to obtain patent protection. Publications of discoveries in the 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, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In addition, the USPTO might require that the term of a patent issuing from a pending patent application to be disclaimed and limited

to the term of another patent that is commonly owned or names a common inventor. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, directed to technology that we license, including those from our licensors, if any, and from third parties. We also may require the cooperation of our potential future licensors in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our potential future licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we may in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

Even if our current or future patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or potential future in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and any future in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review, or PGR, and inter partes review, or IPR, or other similar proceedings in the USPTO or foreign patent offices challenging our patent rights. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity of our patents, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. There is also no assurance that there is no prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us. Such loss of patent rights, loss of exclusivity or our patent claims being narrowed, invalidated or held unenforceable could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

As referenced above, we have filed patent applications directed to our platform technologies that involve certain of our proprietary software modules. Moreover, while software and other of our proprietary works may be protected under copyright law, we have chosen not to register any copyrights in these works, and instead, rely on the above-referenced patent applications for protection of certain modules and trade secret protection for other of our software modules. In order to bring a copyright infringement lawsuit in the United States, the copyright must be registered. Accordingly, the remedies and damages available to us for unauthorized use of our software may be limited.

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

In the future, we may enter into license agreements under which we are granted rights to intellectual property that may be important to our business. We expect that any future license agreements where we in-license intellectual property would impose on us various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we use the licensed intellectual property in an unauthorized manner or are subject to bankruptcy-related proceedings, the licensors may have the right to materially modify the terms of the licenses, such as by rendering currently exclusive licenses non-exclusive, or terminate the licenses, in which event we would not be able to market products covered by the licenses. We may also in the future enter into license agreements with third parties under which we are a sublicensee. If our sublicensor fails to comply with its obligations under its upstream license agreement with its licensor, the licensor may have the right to terminate the upstream license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all, which may impact our ability to continue to develop and commercialize our product candidates incorporating the relevant intellectual property.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates or platform, and we cannot provide any assurances that third-party patents do not exist that might be enforced against our product candidates or platform in the absence of such a license. For example, our programs may involve additional product candidates that may require the use of additional proprietary rights held by third parties. Our product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive for commercializing our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

In addition, disputes may arise between us and any future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted and obligations imposed under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the amounts, if any, we owe to a potential licensor in respect of sublicense fees or income or in respect of backup product;

- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and its affiliates and sublicensees and by us and our partners and sublicensees.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our future licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on our business.

In addition, certain of our agreements may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor's express consent in order for an assignment or transfer to take place.

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

We or our future potential licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects as to form in the preparation or filing of our potential future in-licensed patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our future potential licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our future potential licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our future potential in-licensed patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

As a future potential licensee of third parties, we would rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our future license agreements. We would not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Future potential licensors may have the right to control enforcement of our future potential licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our future licensors. We cannot be certain that our future licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If any of our future potential licensors or future collaborators fail to appropriately prosecute and maintain patent protection for patents directed to any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

In addition, even where we have the right to control patent prosecution of patents and patent applications we have acquired or licensed from third parties in the future, we may still be adversely affected or prejudiced by actions or inactions of our potential licensors and their counsel that took place prior to us assuming control over patent prosecution.

Technology we may acquire or license from various third parties in the future may be subject to retained rights. Our future licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for use in fields other than the fields licensed to us or for use in noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of

information relating to the technology. It may be difficult to monitor whether our future licensors may limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

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

Our commercial success depends in part on avoiding infringement or misappropriation of the patents and other proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Because the intellectual property landscape in the industry in which we participate is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our ability to freely make, use, and sell our products without infringing third party rights. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/or foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates, as well as related to our platform.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates or platform may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that others have not filed patent applications for a product candidate or technology covered by our pending patent applications, or that we were the first to file a patent application related to a product candidate or technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents relating to such technologies. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe.

In addition, identification of third-party patent rights that may be relevant to our product candidates or platform is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

Further, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time-consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;

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

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

Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and results of operations.

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

Moreover, if our product candidates or platform are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our future licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of these claims. The claims may require us to initiate or defend protracted and costly litigation on behalf of such licensees and other parties regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

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

Competitors may infringe or otherwise violate our, or our future licensors', patents, trademarks or other intellectual property. To prevent infringement or other violations, we and/or our future licensors may be required to file claims, which can be expensive and time-consuming. Further, our future licensors may need to file such claims, but elect not to file them. In addition, in a patent infringement proceeding, a court may decide that a patent we own or license is not valid, is unenforceable and/or is not infringed. If we or any of our future licensors or potential future collaborators were to initiate

legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty or written description, non-patentable subject matter (laws of nature, natural phenomena, or abstract idea), obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent intentionally withheld material information from the USPTO or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor to the USPTO and in good faith. The outcome following such a challenge is unpredictable. With respect to challenges to the validity of our patents, there might be invalidating prior art, of which we and the patent examiner were unaware during prosecution.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or those of our future licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights, particularly those in a foreign jurisdiction, may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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

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

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

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

Derivation or interference proceedings provoked by third parties or brought by us or our future licensors, or declared by the USPTO or similar proceedings in foreign patent offices may be necessary to determine the priority of inventions with respect to our or our potential future licensors' patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be

harm if the prevailing party does not offer us a license on commercially reasonable terms. Our, or our licensors', defense of such proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

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

In 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in our patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

The Leahy-Smith Act also includes a number of significant changes that (i) affect the way patent applications are prosecuted, (ii) redefine prior art, and (iii) provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

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

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Further, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our or our future licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

We or our future licensors may be subject to claims challenging the inventorship or ownership of our or our future in-licensed patents and other intellectual property.

We may also be subject to claims that former employees or other third parties have an ownership interest in our patents or other intellectual property. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we or our future licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we or our future licensors are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

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

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA-approved product as compensation for

the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we or our licensors may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we or our licensors are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

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

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

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on third parties to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural,

documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. While an inadvertent lapse, including due to the effect of the pandemic related to COVID-19 and its variants, our patent maintenance vendors or law firms, can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications relating to our product candidates, our competitive position would be adversely affected.

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

In addition to seeking patent protection for some of our technology and product candidates, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position, especially with respect to our technology platform. Any disclosure, either intentional or unintentional, by our employees or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a security breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties may require us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into non-disclosure and confidentiality agreements with third parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors and outside scientific collaborators, these agreements typically include invention assignment obligations. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Further, we cannot provide any assurances that all such agreements have been duly executed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. In addition, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors.

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

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or alleged trade secrets of third parties or competitors or are in breach of non-competition or non-solicitation agreements with our competitors or their former employers.

As is common in the pharmaceutical and biotechnology industries, we employ individuals and engage the services of consultants who previously worked for other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information, trade secrets or other proprietary information of their former employers, or that our consultants have used or disclosed trade secrets or other proprietary information of their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

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

We use and will continue to use registered and/or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We use third-party open source software, which could negatively affect our ability to offer our solutions and subject us to litigation or other actions.

We use open source software licensed to us by third-party authors under “open source” licenses in our platform and solutions and expect to continue to use such open source software in the future. Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide support, warranties, indemnification or other contractual protections regarding infringement claims or the quality of the code. To the extent that our platform depends upon the successful operation of open source software, any undetected errors or defects in this open source software could prevent the deployment or impair the functionality of our platform, delay introductions of new solutions, result in a failure of our platform, and injure our reputation. For example, undetected errors or defects in open source software could render it vulnerable to breaches or security attacks, and, as a result, possibly

make our systems more vulnerable to data breaches. In addition, the public availability of such software may make it easier for others to compromise our platform.

Further, there are uncertainties regarding the proper interpretation of and compliance with open source licenses, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to use such open source software, and consequently to provide or distribute our platform and solutions. Some open source licenses contain express requirements that we make available source code for modifications or derivative works we create based upon the type of open source software we use, or grant other licenses to our intellectual property. If we combine our proprietary software with open source software in a certain manner, we could, under certain open source licenses, be required to release the source code of our proprietary software to the public. This would allow our competitors to create similar offerings with lower development effort and time and ultimately could result in a loss of our competitive advantages. Alternatively, to avoid the public release of the affected portions of our source code, we could be required to expend substantial time and resources to re-engineer some or all of our software.

Despite our efforts to monitor our use of open source software to avoid subjecting our platform to conditions we do not intend, there is a risk that open source licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to provide or distribute our platform. Additionally, we may from time to time face claims from third parties claiming ownership of, or seeking to enforce the terms of, an open source license, including by demanding release of source code for the open source software, derivative works or our proprietary source code that was developed using, or that is distributed with, such open source software. These claims could also result in litigation and could require us to make our proprietary software source code freely available, devote additional research and development resources to re-engineer our platform, seek costly licenses from third parties, pay monetary damages to the owner of the copyright in the relevant open source software or otherwise incur additional costs and expenses, any of which could result in reputational harm and would have a negative effect on our business and results of operations. In addition, if the license terms for the open source software we utilize change, we may be forced to re-engineer our platform, incur additional costs to comply with the changed license terms or replace the affected open source software. Although we have implemented policies to regulate the use and incorporation of open source software into our platform and solutions, we cannot be certain that such policies will be effective and that we have not incorporated open source software in our platform and solutions in a manner that is inconsistent with such policies.

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

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

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we may own or license;
- we or our potential future licensors might not have been the first to make the inventions covered by the issued patents or patent application that we may own or license;
- we or our potential future licensors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our, or our future licensors', pending patent applications will not lead to issued patents;
- future issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

Risks Related to Employee Matters and Managing our Growth

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

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

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

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

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our results of operations. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary, including bioinformatics and computational biologist specialists, for the future success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide a wide range of opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel,

the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2022, we had 73 full-time employees, including 61 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, including operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and other comparable foreign regulatory agencies' review process of IMM-1-104, IMM-6-415, and any other product candidate we develop, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize IMM-1-104 and any other product candidate will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of any current or future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize IMM-1-104, IMM-6-415 and any other current or future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Risks Related to Ownership of Our Class A Common Stock

We may be unable to maintain an active, liquid and orderly trading market for our Class A common stock and, as a result, it may be difficult for you to sell your shares of our Class A common stock.

The market value of our Class A common stock may decrease from time to time, and you may not be able to resell your shares of our Class A common stock at or above the price you purchased them. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our Class A common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of Class A common stock as consideration.

The price of our stock may be volatile, and you could lose all or part of your investment.

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

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

- the timing and results of preclinical studies and clinical trials of our product candidates or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or our competitors’ products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our Class A common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements; and
- general economic, industry and market conditions, including the effects of recession or slow economic growth in the U.S. and abroad, interest rates, inflation, fuel prices, international currency fluctuations, corruption, political instability, acts of war, acts of terrorism, and the ongoing COVID-19 pandemic or other public health crises.

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

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

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

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

As of December 31, 2022, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 67.8% of our voting stock and these stockholders will be able to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our Class A common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their Class A common stock, and might affect the prevailing market price for our Class A common stock.

Sales of a substantial number of shares of our Class A and/or Class B common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our Class A and/or Class B common stock, or the perception that these sales might occur, could depress the market price of our Class A common stock and could impair our ability to raise capital through the sale of additional equity securities. The shares of Class A common stock that were sold in the initial public offering and shares of Class A common stock that will be sold under the registration statement filed with the SEC on August 10, 2022 are, or will be, as applicable, freely transferable without restrictions or further registration under the Securities Act, except for any shares acquired by our affiliates, as defined in Rule 144 under the Securities Act. The remaining shares of our Class A common stock that are outstanding are either unrestricted or restricted as a result of securities laws. In addition, there are shares of Class A common stock that are either subject to outstanding options or reserved for future issuance under our existing equity incentive plans and may become eligible for future sale subject to vesting, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of Class A common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our Class A common stock could decline.

In addition, in the future, we may issue additional shares of Class A common stock, or other equity or debt securities convertible into Class A common stock, in connection with a financing, acquisition, employee arrangement or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our Class A common stock to decline.

We do not currently intend to pay dividends on our Class A common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our Class A common stock.

We have never declared or paid any cash dividends on our equity securities. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying

any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of our Class A common stock, which is not certain.

Provisions in our certificate of incorporation and bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our Class A common stock.

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

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

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

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

Our amended and restated certificate of incorporation and amended and restated bylaws provides for an exclusive forum in the Court of Chancery of the State of Delaware for certain disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for any derivative action

or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that the federal district courts of the United States of America is the exclusive forum for the resolution of any complaint asserting a cause or causes of action against any defendant arising under the Securities Act. Such provision is intended to benefit and may be enforced by us, our officers and directors, employees and agents, including the underwriters and any other professional or entity who has prepared or certified any part of this Annual Report on Form 10-K. Nothing in our amended and restated certificate of incorporation or amended and restated bylaws preclude stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims or make such lawsuits more costly for stockholders, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive-forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision that will be contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

General Risks

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

Despite the implementation of security measures, our information technology systems and those of our current and any future CROs and other contractors, consultants, collaborators and third-party service providers, are vulnerable to attack, interruption and damage from computer viruses (e.g. ransomware), cybersecurity threats, malicious code, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information.

The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased and evolved. We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely,

which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. If we or our third-party vendors were to experience a significant security breach of our or their information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counter-parties and data subjects could be material. In addition, our remediation efforts may not be successful. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information.

We, and certain of our service providers, are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to our trade secrets, health-related or other personal information or other proprietary or sensitive information, it could result in a material disruption of our drug discovery and development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions, and it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to data privacy and security laws. Notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

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

Our facilities are located in regions which experience severe weather from time to time. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major tornado, flood, fire, earthquake, power loss, terrorist activity, future pandemics or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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

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

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this Annual Report on Form 10-K;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor’s report on financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our Class A common stock less attractive because we may rely on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than \$1.235 billion in annual revenue; (2) the date we qualify as a “large accelerated filer,” with at least \$700 million of equity securities held by non-affiliates; (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

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 intend to take advantage of the extended transition period for adopting new or revised accounting standards under the JOBS Act as an emerging growth company. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

The requirements of being a public company may strain our resources, result in more litigation and divert management’s attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of Nasdaq and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and results of operations. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management’s attention may be diverted from other business concerns, which could adversely affect our business and results of operations. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are 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. We intend to invest resources to comply with

evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

These new rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in this Annual Report on Form 10-K and in future filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Class A common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

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

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

New tax legislation may impact our results of operations and financial condition.

The U.S. government may enact significant changes to the taxation of business entities including, among others, an increase in the corporate income tax rate, an increase in the tax rate applicable to the global intangible low-taxed income and elimination of certain exemptions, and the imposition of minimum taxes or surtaxes on certain types of income. For example, the recently enacted Inflation Reduction Act, among other changes, introduced a 15% corporate minimum tax on certain United States corporations and a 1% excise tax on certain stock redemptions by United States corporation. The likelihood of these further changes being enacted or implemented is unclear. We are currently unable to predict whether

such changes will occur. If such changes are enacted or implemented as well as the scope of any such changes, we are currently unable to predict the ultimate impact on our business.

Item 1B. Unresolved Staff Comments

None

Item 2. Properties.

Our principal office is located at 245 Main Street, Second Floor Cambridge, Massachusetts 02142, where we lease approximately 183 square feet of office space under a service agreement that can be terminated by either party upon 30 days written notice.

We also lease the following properties in San Diego, California: (i) approximately 3,657 square feet of office space; under a lease that terminates on October 1, 2023 and is currently being subleased to a third-party through the remainder of the term of the lease; (ii) approximately 38,613 square feet of office and laboratory space under a lease that terminates on April 30, 2032; and (iii) 4,760 square feet of office and laboratory space (“Site 3”) under a lease that terminates on March 31, 2024. In February 2023, we subleased the Site 3 space to a third-party through the remainder of the term of the lease.

Additionally, we lease approximately 190 square feet of office space in New York, New York under a service agreement that currently runs through February 28, 2024 and automatically renews unless we provide 60 days advance notice to terminate; and approximately 66 square feet of office space in San Francisco, California under an agreement that currently runs through July 31, 2023.

We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Item 3. Legal Proceedings

From time to time we may be involved in claims and proceedings arising in the course of our business. The outcome of any such claims or proceedings, regardless of the merits, is inherently uncertain. We are not currently party to any material legal proceedings.

Item 4. Mine Safety Disclosures

Not applicable

PART II — OTHER INFORMATION

Item 5. Market For The Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information for Common Stock

Our common stock trades under the symbol “IMRX” on the Nasdaq Global Market.

Holders of Our Common Stock

As of February 27, 2023, there were approximately 60 registered holders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders and includes stockholders who are

beneficial owners, but whose shares are held in “street name” by brokers or held by other “nominees”. The number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our common shares. We currently anticipate that we will retain all available funds and future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

See Item 12, Part III of this Form 10-K.

Unregistered Sales of Equity Securities

During the period covered by this Annual Report on Form 10-K, we did not issue any securities which were unregistered under the Securities Act and required to be disclosed herein.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the quarterly period ended December 31, 2022.

Item 6. [Reserved]

Item 7.

MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing in Part II, Item 8 of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in Part I, Item 1A. “Risk Factors” of this Annual Report on Form 10-K, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage oncology company developing medicines for broad populations of cancer patients. Our initial aim is to develop a universal-RAS therapy, an approach designed to include patients with solid tumors driven by any mutation in KRAS, NRAS, or HRAS. Our inclusive approach differentiates us from narrowly targeted precision therapies, which are limited to patients with tumors harboring select mutations.

We are currently evaluating our lead product candidate, IMM-1-104, in a Phase 1/2a clinical trial in patients with advanced solid tumors harboring RAS mutations. IMM-1-104 is being developed as a once-daily oral monotherapy that aims to achieve universal-RAS activity through deep cyclic inhibition of the MAPK pathway. Deep cyclic inhibition is a novel approach that aims to deprive tumor cells of the sustained proliferative signaling required for rapid growth, while sparing healthy cells through a cadenced, normalized level of signaling. This cyclic inhibition was engineered using our proprietary informatics-based discovery platform. The development of our pipeline is translationally guided by our

proprietary, human-aligned 3D tumor modeling platform that we combine with bioinformatics-driven patient profiling, which we believe has the potential to increase the probability of success in clinical development versus traditional drug development approaches. Our second product candidate, IMM-6-415, aims to achieve universal-MAPK activity with an accelerated twice-daily oral dosing cadence, also through deep cyclic inhibition of the MAPK pathway. IMM-6-415 is currently in Investigational New Drug application, or IND, enabling studies. Our pipeline also includes Trifecta MEK, RAS modulators, and other small molecule drug discovery programs.

In November 2022, we commenced dosing in our Phase 1/2a clinical trial of IMM-1-104 for the treatment of advanced RAS mutant solid tumors. The Phase 1/2a clinical trial is designed to assess the safety, tolerability, pharmacokinetics, or PK, pharmacodynamics, or PD, and preliminary anti-tumor activity of IMM-1-104. The Phase 1 portion of the clinical trial includes a dose escalation and expansion portion and will evaluate IMM-1-104 using a Bayesian modified toxicity probability interval, or mTPI-2, statistical design to establish an optimized recommended Phase 2 dose in solid tumor patients with evidence of any RAS mutation. The planned Phase 2a portion will evaluate IMM-1-104 at the recommended Phase 2 dose in an expanded cohort of solid tumor patients with certain RAS mutated cancers, including potentially pancreatic, melanoma, colorectal and lung. IMM-1-104 is currently in the dose escalation portion of the trial. We anticipate reporting initial PK and safety data from Phase 1 portion of the clinical trial in mid-2023, and additional safety and PK and initial PD modeling data in the second half of 2023. Subject to results from the Phase 1 portion of the trial, including safety and tolerability data, we anticipate initiating the Phase 2a portion of the trial in mid-2024. In addition, we plan to submit an IND, for IMM-6-415 to the U.S. Food and Drug Administration, or FDA, in the fourth quarter of 2023. In February 2023, we suspended our neuroscience programs, which was in the early stages of drug discovery, in order to focus on advancing our core oncology pipeline.

For the period from inception through 2017, we devoted substantially all of our efforts to business planning, service revenue generation, developing tools to aid in drug discovery, and recruiting management and technical staff. Since 2018, we have also focused significant effort on our own internal research and development programs. We have financed our operations through service revenues, the issuance of convertible debt and the sale of convertible preferred stock and common stock.

On December 22, 2021, we completed the acquisition of all outstanding shares of capital stock of BioArkive, Inc., a California corporation (“BioArkive”) for a market value of \$8.75 million.

BioArkive is a San Diego based contract research organization that has previously provided preclinical research services and biosample storage to us and other biotechnology companies. BioArkive was fully integrated into our operations following the acquisition and exclusively supports our internal preclinical research activities for our oncology pipeline. In connection with the acquisition, we assumed the obligations under BioArkive’s three lease agreements.

Our operations have been financed primarily by service revenues and aggregate net proceeds of approximately \$81.4 million from the issuance of convertible notes payable, convertible preferred stock (Series A and B) including gross proceeds of approximately \$24.8 million from the issuance of shares in the second tranche of Series B Preferred in April and May 2021, common stock, and exercise of stock options. On August 3, 2021, we completed our IPO pursuant to which we issued and sold 8,625,000 shares of Class A common stock, inclusive of 1,125,000 shares sold by us pursuant to the full exercise of the underwriters’ option to purchase additional shares. We received aggregate net proceeds of approximately \$120.3 million from the IPO, after deducting underwriting discounts and commissions, but before deducting offering costs payable by us, which were \$2.1 million.

Since inception, we have had significant annual operating losses. Our net loss was approximately \$50.5 million and \$33.5 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of approximately \$109.8 million and approximately \$105.5 million in cash and cash equivalents and marketable securities.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued expenses. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. In particular, we expect our expenses to increase as we continue our development of, and seek

regulatory approvals for, our internally developed product candidates as well as add operational, financial and management informational systems and personnel to support our product development. In addition, if and when we seek and obtain regulatory approval to commercialize any product candidate, we will also incur increased expenses in connection with commercialization and marketing of any such product. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

Based upon our current business plans, we believe that our existing cash and cash equivalents and marketable securities will be sufficient to fund our development activities and other operations into the fourth quarter of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured.

We have not had any internally developed products approved for sale. We do not expect to generate any product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our internally developed product candidates. If we obtain regulatory approval for any of our internally developed product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. As a result, until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including collaborations, licenses or similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

Components of Our Results of Operations

Revenue

Our revenue has historically been generated by providing computational biology professional services to pharmaceutical and biotechnology companies. We charged an agreed upon rate per hour based on the aggregate level of personnel assigned to work on the project or a fixed fee for a defined scope of work. Our contracts specified the period of time over which these professional services would be provided. We recognized revenue over time by measuring the progress toward complete satisfaction of the performance obligation using a single method of measuring progress, which depicts the performance in transferring control of the associated services to the customer. We used input methods to measure the progress toward the complete satisfaction of performance obligations and evaluate the measure of progress each reporting period and, if necessary, adjusted the measure of performance and related revenue recognition. Any such adjustments were recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment.

We have ceased accepting new services contracts in order to focus on developing our wholly-owned internal pipeline. In September 2022, we completed our last remaining services contract associated with the computational biology professional services business. At this time, we do not anticipate entering into any new service contracts or agreements.

We have also discontinued our biosample storage business, which was acquired through the BioArkive transaction, to external parties. In December 2022, we completed our last remaining contract. The revenue earned associated with the biosample storage business for the year ended December 31, 2022 is immaterial to the financial statements.

Cost of Revenue

Historically, our cost of revenue has primarily consisted of expenses related to providing professional services to our customers. These costs include salaries, bonuses, benefits, stock-based compensation expense, depreciation, facilities, and other outside services.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development

Research and development expenses account for a significant portion of our total operating expenses. Our research and development expenses consist primarily of direct and indirect costs incurred in connection with the development of our research platform, product candidates, discovery efforts and preclinical and clinical activities related to our program pipeline.

Our direct costs include:

- expenses incurred under agreements with third-party contract research organizations, or CROs, and other vendors that conduct our preclinical and clinical activities on our behalf; including clinical trial sites that conduct research and development activities on our behalf;
- laboratory expenses related to the execution of discovery programs, preclinical studies and clinical trials;
- costs related to production of clinical and preclinical materials, including fees paid to contract manufacturers; and
- consulting fees and expenses related to preparation of initiation of clinical trials.

Our indirect costs include:

- personnel-related expenses, consisting of employee salaries, bonuses, benefits and stock-based compensation expense and recruiting costs for personnel engaged in research and development activities; and
- facility and equipment related expenses, consisting of indirect and allocated expenses for rent, depreciation, maintenance of facilities, insurance, and other supplies.

We expense research and development costs in the periods in which they are incurred.

Our direct research and development expenses are tracked on a program-by-program basis once they are in Phase 1 and consist of external costs and fees paid to consultants, contractors, contract manufacturing organizations, or CMOs, and CROs in connection with our preclinical and clinical development and manufacturing activities. Such program costs also include the external costs of laboratory and consumable materials and costs of raw materials that are directly attributable to and incurred for any single program. We do not allocate employee costs, costs associated with our platform development and discovery efforts, payments made under third-party licensing agreements, costs of laboratory supplies and consumable materials that are not directly attributable to any single program, and facilities expenses, including rent, depreciation and other indirect costs, to specific product development programs because these costs are deployed across multiple programs and our platform technology and, as such, are not separately classified.

Due to the inherently unpredictable nature and numerous risks and uncertainties associated with product development and the current stage of development of our product candidates and programs, we cannot reasonably estimate or know the nature, timing and estimated costs necessary to complete the remainder of the development of our product candidates or programs. We are also unable to predict if, when, or to what extent we will obtain approval and generate revenues from the commercialization and sale of any of our product candidates.

The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, such as:

- successful completion of preclinical studies and initiation of clinical trials for future product candidates;
- successful enrollment and completion of clinical trials for our current product candidates;
- data from our clinical programs that support an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- acceptance by the FDA or other applicable regulatory agencies of IND applications, clinical trial applications and/or other regulatory filings for our product candidates;
- expansion and maintenance of a workforce of experienced scientists and others to continue to develop our product candidates;

- successful application for and receipt of marketing approvals from applicable regulatory authorities;
- obtainment and maintenance of intellectual property protection and regulatory exclusivity for our product candidates;
- making of arrangements with contract manufacturing organizations for, or establishment of, commercial manufacturing capabilities;
- establishment of sales, marketing and distribution capabilities and successful launch of commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effective competition with other therapies;
- obtainment and maintenance of coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- maintenance, enforcement, defense and protection of our rights in our intellectual property portfolio;
- avoidance of infringement, misappropriation or other violations with respect to others' intellectual property or proprietary rights; and
- maintenance of a continued acceptable safety profile of our products following receipt of any marketing approvals.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates may be affected by a variety of factors.

We may never succeed in achieving regulatory approval for any of our product candidates. Further, a number of factors, including those outside of our control, could adversely impact the timing and duration of our product candidates' development, which could increase our research and development expense. We may obtain unexpected results from our preclinical studies and clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development.

We expect that our research and development expenses will substantially increase for the foreseeable future as we continue to implement our business strategy, which includes advancing our product candidates through clinical development, expanding our research and development efforts, including hiring additional personnel to support our research and development efforts, and seeking regulatory approvals for our product candidates that successfully complete clinical trials. In addition, product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development. As of the date of this Annual Report on Form 10-K, we cannot reasonably determine or accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development.

General and Administrative

Our general and administrative expenses consist primarily of personnel-related expenses, including employee salaries, bonuses, benefits, stock-based compensation, and recruiting costs for personnel in executive, finance, and other administrative functions. Other significant general and administrative expenses include legal fees relating to intellectual

property and corporate matters, professional fees for accounting, tax and consulting services, insurance costs, travel expenses and facility related expenses not otherwise included in research and development expenses.

We expect our general and administrative expenses will substantially increase for the foreseeable future as we continue to increase our general and administrative headcount to support our continued research and development activities and, if any product candidates receive marketing approval, commercialization activities, as well as to support our operations generally. As we expand our operations, we also expect to incur increased expenses associated with operating as a public company, including costs related to accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and rules and regulations of the Securities and Exchange Commission (“SEC”), Sarbanes-Oxley Act, director and officer insurance costs, and investor and public relations costs.

Amortization of intangible asset

Amortization of intangible asset relates to the technology acquired in the BioArkive acquisition.

Other Income (Expense)

Interest income

Interest income consists of interest earned on our cash and cash equivalents balances and our marketable securities. The primary objective of our investment policy is capital preservation.

Other income (expense)

Other income (expense) consists of the amortization of premiums or accretion of discounts related to our marketable securities.

Income tax benefit

Income tax benefit in 2021 is due to a release of a valuation reserve because of the business combination.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the periods indicated:

| | Year Ended December 31, | | Change | |
|----------------------------------|------------------------------------|-------------|------------|----------|
| | 2022 | 2021 | \$ | % |
| | (in thousands, except percentages) | | | |
| Revenue | \$ 317 | \$ 2,080 | \$ (1,763) | (84.8)% |
| Cost of revenue | 158 | 1,153 | (995) | (86.3)% |
| Gross profit | 159 | 927 | (768) | (82.8)% |
| Operating expenses | | | | |
| Research and development | 36,267 | 26,541 | 9,726 | 36.6 % |
| General and administrative | 15,607 | 8,272 | 7,335 | 88.7 % |
| Amortization of intangible asset | 30 | — | 30 | N/M % |
| Total operating expenses | 51,904 | 34,813 | 17,091 | 49.1 % |
| Loss from operations | (51,745) | (33,886) | (17,859) | 52.7 % |
| Other income (expense) | | | | |
| Interest income | 1,014 | 170 | 844 | 496.5 % |
| Other income (expense) | 217 | (127) | 344 | (270.9)% |
| Loss before income taxes | (50,514) | (33,843) | (16,671) | 49.3 % |
| Income tax benefit | — | 307 | (307) | (100.0)% |
| Net loss | \$ (50,514) | \$ (33,536) | | |

N/M – Not meaningful

Revenue

The following table summarizes the revenue recognized for the periods indicated:

| | Year Ended December 31, | | Change | |
|----------------|------------------------------------|----------|------------|---------|
| | 2022 | 2021 | \$ | % |
| | (in thousands, except percentages) | | | |
| Revenue | \$ 317 | \$ 2,080 | \$ (1,763) | (84.8)% |

Revenue decreased by approximately \$1.8 million, or 84.8% to approximately \$0.3 million for the year ended December 31, 2022 compared to approximately \$2.1 million for the year ended December 31, 2021. The decrease in revenue was due to the wind down of our computational biology professional services and completion of existing customer services contracts during the year compared to the year ended December 31, 2021.

Cost of Revenue

Cost of revenue decreased by approximately \$1.0 million, or 86.3%, to approximately \$0.2 million for the year ended December 31, 2022 compared to approximately \$1.2 million for the year ended December 31, 2021. The decrease was primarily due to decreased employee-related costs of approximately \$1.0 million related to services contracts that were completed during this year.

Research and Development

The following table summarizes the components of our research and development expenses for the periods indicated:

| | Year Ended December 31, | | Change | |
|--|-------------------------|------------------|-----------------|---------|
| | 2022 | 2021 | \$ | % |
| (in thousands, except percentages) | | | | |
| Direct research and development expenses by program: | | | | |
| IMM-1-104 | \$ 1,374 | \$ — | \$ 1,374 | N/M % |
| Other Programs | 18,387 | 17,307 | 1,080 | 6.2 % |
| Unallocated research and development expenses: | | | | |
| Employee related costs | 13,957 | 8,001 | 5,956 | 74.4 % |
| Stock-based compensation expense | 1,978 | 769 | 1,209 | 157.2 % |
| Facilities and other allocated expenses | 413 | 434 | (21) | (4.8)% |
| Depreciation | 158 | 30 | 128 | 426.7 % |
| Total research and development | <u>\$ 36,267</u> | <u>\$ 26,541</u> | <u>\$ 9,726</u> | 36.6 % |

Research and development expenses increased by approximately \$9.7 million, or 36.6%, to approximately \$36.3 million for the year ended December 31, 2022 as compared to approximately \$26.5 million for the year-ended December 31, 2021. The increase of approximately \$9.7 million was primarily due to an increase of approximately \$2.5 million related to direct research and development expenses, of which \$1.4 million related to IMM-1-104 and \$1.1 million for earlier stage programs. The remaining increase was driven by unallocated research and development costs of approximately \$7.2 million, of which \$6.0 million related to additional employee-related costs and \$1.2 million related to stock-based compensation expense. Depreciation, facilities and other allocated expense also increased by approximately \$0.1 million in the aggregate.

General and Administrative

The following table summarizes the components of our general and administrative expenses for the periods indicated:

| | Year Ended December 31, | | Change | |
|---|-------------------------|-----------------|-----------------|-----------|
| | 2022 | 2021 | \$ | % |
| (in thousands, except percentages) | | | | |
| Employee related costs | \$ 8,123 | \$ 4,506 | \$ 3,617 | 80.3 % |
| Stock-based compensation expense | 2,077 | 931 | 1,146 | 123.1 % |
| Professional fees | 3,096 | 1,803 | 1,293 | 71.7 % |
| Public relations | — | 262 | (262) | (100.0)% |
| Outside consultants | 68 | 75 | (7) | (9.3)% |
| Facilities and other allocated expenses | 1,513 | 125 | 1,388 | 1,110.4 % |
| Other | 730 | 570 | 160 | 28.1 % |
| Total general and administrative | <u>\$ 15,607</u> | <u>\$ 8,272</u> | <u>\$ 7,335</u> | 88.7 % |

General and administrative expenses increased by approximately \$7.3 million, or 88.7%, to approximately \$15.6 million for the year ended December 31, 2022 compared to approximately \$8.3 million for the year ended December 31, 2021. The increase of approximately \$7.3 million was primarily due to increased employee-related costs of approximately \$3.6

million as a result of increased headcount, increased professional fees incurred for accounting, auditing, legal, public relations and tax services of approximately \$1.0 million, increased facilities expenses of approximately \$1.4 million, approximately \$1.1 million increase in stock-based compensation expense.

Amortization of Intangible Asset

Amortization of intangible asset of \$30 thousand in the year ended December 31, 2022 is related to the technology acquired for the BioArkive acquisition completed in December 2021.

Other Income (expense)

Interest income increased by approximately \$0.8 million due to the interest earned on our cash and cash equivalents and marketable securities balances due to the increased in the interest rates during 2022 as compared to 2021.

Other income (expense) increased by \$0.3 million, primarily driven by the amortization of premiums related to our marketable securities.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have financed our operations through service revenues, the issuance of convertible notes payable, convertible preferred stock, common stock, and the exercise of stock options. As of December 31, 2022, we had an accumulated deficit of \$109.8 million and \$105.5 million in cash and cash equivalents and marketable securities. Cash and cash equivalents are comprised of deposits at major financial banking institutions and highly liquid investments with an original maturity of three months or less at the date of purchase. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, reflected in the change in our outstanding accounts payable and accrued expenses.

Since our inception, we have incurred significant operating losses. We have not yet commercialized any of our product candidates, and we do not expect to generate revenue from sales of any product candidates for the next several years, if at all. To date, our operations have been financed primarily by service revenues and proceeds from sales of our debt and equity securities.

On August 10, 2022, we entered into an Equity Distribution Agreement, or the Sales Agreement, with Piper Sandler & Co, or the Sales Agent, to sell shares of our common stock with aggregate gross proceeds of up to \$50 million, from time to time, through an “at the market” equity offering program. For the year ended December 31, 2022, we did not sell any shares of common stock under the Sales Agreement.

As of December 31, 2022, we have contractual obligations related to various leases of \$0.8 million for 2023, \$0.7 million for 2024, \$0.7 million for 2025, \$0.8 million for 2026, \$0.8 million for 2027 and \$3.7 million for the periods thereafter.

We have no off-balance sheet arrangements that have a material current effect or that are reasonably likely to have a material future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

Cash Flows

The following table summarizes our sources and uses of cash for the periods indicated:

| | Year Ended December 31, | |
|--|-------------------------|------------------|
| | 2022 | 2021 |
| | (in thousands) | |
| Net cash (used in) provided by: | | |
| Operating activities | \$ (44,101) | \$ (30,851) |
| Investing activities | 41,831 | (75,616) |
| Financing activities | 19 | 144,265 |
| Net increase (decrease) in cash and cash equivalents | <u>\$ (2,251)</u> | <u>\$ 37,798</u> |

Net Cash Used in Operating Activities

During the year ended December 31, 2022, operating activities used approximately \$44.1 million of cash, primarily resulting from our net loss of approximately \$50.5 million and net amortization of premium (accretion of discount) on marketable securities of \$0.2 million, partially offset by stock-based compensation expense of approximately \$4.1 million, cash provided by changes in our operating assets and liabilities of approximately \$1.7 million, and \$0.8 million for right of use amortization and depreciation.

During the year ended December 31, 2021, operating activities used approximately \$30.9 million of cash, primarily resulting from our net loss of approximately \$33.5 million, deferred tax benefit of \$0.3 million, and cash provided by changes in our operating assets and liabilities of approximately \$0.9 million, partially offset by stock-based compensation expense of approximately \$1.8 million, net amortization of premium (accretion of discount) on marketable securities of \$0.1 million, and \$0.2 million for right of use amortization and depreciation.

Net Cash Used in Investing Activities

During the year ended December 31, 2022, cash provided from investing activities was approximately \$41.8 million, primarily related to maturities of marketable securities of \$92.7 million, offset by purchases of marketable securities of \$50.1 million and \$0.7 million for purchases of property and equipment.

During the year end December 31, 2021, cash used from investing was approximately \$75.6 million, primarily related to purchases of marketable securities of approximately \$75.6 million, \$0.1 million for the purchases of property and equipment offset by cash acquired in business combination of approximately \$0.1 million.

Net Cash Provided by Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities was approximately \$19 thousand, consisting primarily of approximately \$0.3 million in net proceeds from the exercise of stock options, offset by approximately \$0.3 million from the payment of deferred offering costs.

During the year ended December 31, 2021, net cash provided by financing activities was approximately \$144.3 million, consisting primarily of approximately \$24.8 million in net proceeds received from the issuance of Series B preferred stock, approximately \$118.2 million from the net proceeds from our initial public offering, approximately \$0.9 million in net proceeds from the exercise of warrants and approximately \$0.4 million from the exercise of stock options.

Future Funding Requirements

We expect that our expenses will increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials for our product candidates in development. The timing and amount of our operating and capital expenditures will depend largely on:

- the costs and results of our ongoing clinical trial for IMM-1-104 and potential future clinical trials for our other product candidates;
- the scope, progress, results and costs of discovery research, preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to enter into contract manufacturing arrangements for supply of active pharmaceutical ingredient, or API, and manufacture of our product candidates and the terms of such arrangements;
- the payment or receipt of milestones and receipt of other collaboration-based revenues, if any;
- the costs and timing of any future commercialization activities, including product manufacturing, sales, marketing and distribution, for any of our product candidates for which we may receive marketing approval;
- the amount and timing of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property related claims;
- the extent to which we acquire or in-license other products, product candidates, technologies or data referencing rights;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- our ability to access the private and public capital markets or to obtain financing at commercially reasonable rate;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- the costs of operating as a public company; and
- the impacts of the pandemic related to COVID-19 and its variants and potential future pandemics.

We believe that our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months and into the fourth quarter of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Critical Accounting Policies and Use of Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs 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 consolidated financial statements appearing at the end of this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Research and Development Costs

We incur substantial expenses associated with manufacturing and clinical trials. Accounting for clinical trials relating to activities performed by contract research organizations, or CROs, and other external vendors requires management to exercise significant estimates in regard to the timing and accounting for these expenses. We estimate costs of research and development activities conducted by service providers, which include the conduct of sponsored research, preclinical studies and contract manufacturing activities. The diverse nature of services being provided under CROs and other arrangements, the different compensation arrangements that exist for each type of service and the lack of timely information related to certain clinical activities complicates the estimation of accruals for services rendered by CROs and other vendors in connection with clinical trials. Because payments of research and development activities do not always line up with the provision of such services, the balance sheet may reflect either an accrued or prepaid position. In estimating the duration of a clinical study, we evaluate the start-up, treatment and wrap up periods, compensation arrangements and services rendered attributable to each clinical trial and fluctuations are regularly tested against payment plans and trial completion assumptions.

We estimate these costs based on factors such as estimates of the work completed and budget provided and in accordance with agreements established with our collaboration partners and third-party service providers. We make significant judgments and estimates in determining the accrued liabilities and prepaid expense balances in each reporting period. As actual costs become known, we adjust our accrued liabilities or prepaid expenses. We have not experienced any material differences between accrued costs and actual costs incurred since our inception.

Our expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that are used to conduct and manage clinical trials on our behalf. We accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

Stock-Based Compensation

We measure stock-based awards granted to employees, non-employees and directors based on their fair value on the date of the grant using the Black-Scholes option-pricing model for options or the difference between the purchase price per share of the award, if any, and the fair value of our common stock on the date of grant for restricted stock awards. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the award for employees and directors and the period during which services are performed for non-employees. We use the straight-line method to record the expense of awards with service-based vesting conditions.

The Black-Scholes option-pricing model uses as inputs, the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options, and our expected dividend yield.

Off-balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

Emerging Growth Company Status

As an emerging growth company, or EGC, under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for EGCs include presentation of only two years of audited consolidated financial statements, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board, and less extensive disclosure about our executive compensation arrangements.

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

We may remain classified as an EGC until the end of the fiscal year following the fifth anniversary of our IPO, although if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of June 30 of any year before that time, or if we have annual gross revenues of \$1.235 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than \$1.0 billion of non-convertible debt over a three-year period.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

As a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, we are not required to provide this information.

Item 8. Financial Statements and Supplementary Data

**Immuneering Corporation
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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Immuneering Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Immuneering Corporation and its subsidiaries (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, 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, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These 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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Our audits included performing procedures to assess the risks of material misstatement of the 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 audits 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 audits provide a reasonable basis for our opinion.

/s/ RSM US LLP

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

Boston, Massachusetts
March 6, 2023

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

IMMUNEERING CORPORATION
CONSOLIDATED BALANCE SHEETS

| | <u>December 31, 2022</u> | <u>December 31, 2021</u> |
|---|------------------------------|------------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 72,636,886 | \$ 74,888,145 |
| Marketable securities, current | 32,887,970 | 74,311,203 |
| Accounts receivable | 12,417 | 246,040 |
| Prepays and other current assets | 3,209,536 | 2,888,608 |
| Total current assets | <u>108,746,809</u> | <u>152,333,996</u> |
| Marketable securities, non-current | — | 996,560 |
| Property and equipment, net | 1,369,608 | 807,223 |
| Goodwill | 6,690,431 | 6,701,726 |
| Intangible asset | 408,947 | 439,000 |
| Right-of-use assets, net | 4,407,785 | 5,324,198 |
| Other assets | 743,703 | 102,129 |
| Total assets | <u>\$ 122,367,283</u> | <u>\$ 166,704,832</u> |
| Liabilities, convertible preferred stock and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 3,154,557 | \$ 1,394,340 |
| Accrued expenses | 4,500,993 | 3,965,447 |
| Other liabilities, current | 19,796 | — |
| Lease liabilities, current | 378,723 | 274,039 |
| Total current liabilities | <u>8,054,069</u> | <u>5,633,826</u> |
| Long-term liabilities: | | |
| Lease liabilities, non-current | 4,462,959 | 5,090,897 |
| Total liabilities | <u>12,517,028</u> | <u>10,724,723</u> |
| Commitments and contingencies (Note 13) | | |
| Stockholders' equity: | | |
| Preferred stock, \$0.001 par value; 10,000,000 shares authorized at December 31, 2022 and December 31, 2021; No shares issued or outstanding | — | — |
| Class A common stock, \$0.001 par value, 200,000,000 shares authorized at December 31, 2022 and December 31, 2021; 26,418,732 and 26,320,199 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively | 26,419 | 26,320 |
| Class B common stock, \$0.001 par value, 20,000,000 shares authorized at December 31, 2022 and December 31, 2021; 0 shares issued and outstanding at December 31, 2022 and December 31, 2021 | — | — |
| Additional paid-in capital | 219,640,912 | 215,276,186 |
| Accumulated other comprehensive loss | (30,120) | (49,009) |
| Accumulated deficit | <u>(109,786,956)</u> | <u>(59,273,388)</u> |
| Total stockholders' equity | <u>109,850,255</u> | <u>155,980,109</u> |
| Total liabilities, convertible preferred stock and stockholders' equity | <u>\$ 122,367,283</u> | <u>\$ 166,704,832</u> |

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

IMMUNEERING CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021

| | Year Ended December 31, | |
|---|-------------------------|-----------------|
| | 2022 | 2021 |
| Revenue | \$ 316,952 | \$ 2,079,961 |
| Cost of revenue | 158,122 | 1,153,073 |
| Gross profit | 158,830 | 926,888 |
| Operating expenses | | |
| Research and development | 36,267,116 | 26,540,959 |
| General and administrative | 15,606,529 | 8,271,998 |
| Amortization of intangible asset | 30,053 | — |
| Total operating expenses | 51,903,698 | 34,812,957 |
| Loss from operations | (51,744,868) | (33,886,069) |
| Other income (expense) | | |
| Interest income | 1,014,456 | 169,899 |
| Other income (expense) | 216,844 | (127,063) |
| Loss before income taxes | (50,513,568) | (33,843,233) |
| Income tax benefit | — | 307,485 |
| Net loss | \$ (50,513,568) | \$ (33,535,748) |
| Net loss per share attributable to common stockholders, basic and diluted | (1.91) | (2.46) |
| Weighted-average common shares outstanding, basic and diluted | 26,386,864 | 13,612,677 |
| Other comprehensive loss: | | |
| Unrealized gain (losses) from marketable securities | 18,889 | (49,009) |
| Comprehensive Loss | \$ (50,494,679) | \$ (33,584,757) |

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

IMMUNEERING CORPORATION
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
FOR THE YEAR ENDED DECEMBER 31, 2022 AND 2021

| | Convertible Preferred Stock | | | | | Stockholders' Equity | | | | | | | |
|--|-----------------------------|---------------|-------------|---------------|---|----------------------|-----------|----------------------|-----------|----------------------------------|--|------------------------|----------------------------------|
| | Series B | | Series A | | Total Convertible Preferred Stock | Class A Common Stock | | Class B Common Stock | | Additional Paid-In Capital | Accumulated other comprehensive loss | Accumulated Deficit | Total Stockholders' Equity |
| | Shares | Amount | Shares | Amount | | Shares | Par Value | Shares | Par Value | | | | |
| Balance at December 31, 2020 | 3,619,292 | \$ 36,983,910 | 2,495,933 | \$ 21,119,940 | \$ 58,103,850 | 4,950,129 | \$ 4,950 | — | \$ — | \$ 3,251,240 | \$ — | \$ (25,737,640) | \$ (22,481,450) |
| Issuance of Series B convertible preferred stock, net of issuance costs | 2,412,853 | 24,788,851 | — | — | 24,788,851 | — | — | — | — | — | — | — | — |
| Issuance of common stock upon exercise of stock options | — | — | — | — | — | 117,846 | 118 | — | — | 354,316 | — | — | 354,434 |
| Issuance of common stock upon exercise of warrants | — | — | — | — | — | 308,308 | 308 | — | — | 926,817 | — | — | 927,125 |
| Conversion of Preferred Stock into common stock | (6,032,145) | (61,772,761) | (2,495,933) | (21,119,940) | (82,892,701) | 11,939,281 | 11,939 | — | — | 82,880,762 | — | — | 82,892,701 |
| Issuance of common stock upon initial public offering, net of issuance costs (\$2,124,317) | — | — | — | — | — | 8,625,000 | 8,625 | — | — | 118,185,808 | — | — | 118,194,433 |
| Issuance of common stock for acquisition | — | — | — | — | — | 379,635 | 380 | — | — | 7,874,620 | — | — | 7,875,000 |
| Stock-based compensation expense | — | — | — | — | — | — | — | — | — | 1,802,623 | — | — | 1,802,623 |
| Net loss | — | — | — | — | — | — | — | — | — | — | — | (33,535,748) | (33,535,748) |
| Other comprehensive loss | — | — | — | — | — | — | — | — | — | — | (49,009) | — | (49,009) |
| Balance at December 31, 2021 | — | \$ — | — | \$ — | \$ — | 26,320,199 | \$ 26,320 | — | \$ — | \$ 215,276,186 | \$ (49,009) | \$ (59,273,388) | \$ 155,980,109 |
| Issuance of common stock upon exercise of stock options | — | — | — | — | — | 98,533 | 99 | — | — | 300,280 | — | — | 300,379 |
| Stock-based compensation expense | — | — | — | — | — | — | — | — | — | 4,064,446 | — | — | 4,064,446 |
| Net loss | — | — | — | — | — | — | — | — | — | — | — | (50,513,568) | (50,513,568) |
| Other comprehensive income | — | — | — | — | — | — | — | — | — | — | 18,889 | — | 18,889 |
| Balance at December 31, 2022 | — | \$ — | — | \$ — | \$ — | 26,418,732 | \$ 26,419 | — | \$ — | \$ 219,640,912 | \$ (30,120) | \$ (109,786,956) | \$ 109,850,255 |

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

IMMUNEERING CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEAR ENDED DECEMBER 31, 2022 and 2021

| | <u>2022</u> | <u>2021</u> |
|--|----------------------|----------------------|
| Cash flows from operating activities: | | |
| Net loss | \$ (50,513,568) | \$ (33,535,748) |
| Adjustment to reconcile to net loss to net cash used in operating activities: | | |
| Depreciation expense | 247,199 | 45,467 |
| Right-of-use asset amortization | 519,541 | 113,605 |
| Amortization of intangibles | 30,053 | — |
| Stock-based compensation expense | 4,064,446 | 1,802,623 |
| Net amortization of premium (accretion of discount) on marketable securities | (171,382) | 130,240 |
| Loss on disposal of fixed assets | 5,170 | — |
| Deferred tax benefit | — | (307,485) |
| Change in assets and liabilities: | | |
| (Increase) decrease in: | | |
| Accounts receivable | 233,623 | 279,713 |
| Prepaid expenses and other current assets | (284,346) | (2,408,986) |
| Other assets | (360,200) | — |
| Increase (decrease) in: | | |
| Accounts payable | 1,760,217 | (130,398) |
| Accrued expenses | 474,568 | 3,240,940 |
| Lease liability | (126,382) | (80,853) |
| Other liabilities | 19,796 | — |
| Net cash provided by (used in) operating activities | <u>(44,101,265)</u> | <u>(30,850,882)</u> |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (742,483) | (60,786) |
| Purchases of marketable securities | (50,104,515) | (75,625,529) |
| Maturities of marketable securities | 92,678,000 | — |
| Cash acquired in business combination | — | 70,348 |
| Net cash provided by (used in) investing activities | <u>41,831,002</u> | <u>(75,615,967)</u> |
| Cash flows from financing activities: | | |
| Proceeds from the issuance of Series B preferred stock, net of issuance costs | — | 24,788,851 |
| Proceeds from initial public offering of common stock, net of commissions and underwriting | — | 120,318,750 |
| Payment of initial public offering costs | — | (2,124,317) |
| Payment of public offering costs | (281,375) | — |
| Proceeds from exercise of stock options | 300,379 | 354,434 |
| Proceeds from exercise of warrants | — | 927,125 |
| Net cash provided by financing activities | <u>19,004</u> | <u>144,264,843</u> |
| Net increase (decrease) in cash and cash equivalents | <u>(2,251,259)</u> | <u>37,797,994</u> |
| Cash and cash equivalents at beginning of period | <u>74,888,145</u> | <u>37,090,151</u> |
| Cash and cash equivalents at end of period | <u>\$ 72,636,886</u> | <u>\$ 74,888,145</u> |
| Supplemental disclosures of noncash investing and financing information: | | |
| Conversion of convertible Series A and B preferred stock into common stock | \$ — | \$ 82,892,701 |
| Business combination non-cash | — | 7,804,652 |
| Class A common stock issued for business combination | — | 7,875,000 |
| Reduction of right-of-use asset and lease liability in connection with lease modification | 396,901 | — |
| Property and equipment in accounts payable/accrued expenses | <u>72,272</u> | <u>—</u> |

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

IMMUNEERING CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 – Organization and Nature of Business

Immuneering Corporation, a Delaware corporation, (“Immuneering” or the “Company”) was incorporated in 2008. Immuneering is a clinical-stage oncology company developing medicines for broad populations of cancer patients with an initial aim to therapeutically address universal-RAS. The company aims to achieve universal activity through deep cyclic inhibition of the MAPK pathway, impacting cancer cells while sparing healthy cells. Immuneering’s lead product candidate, IMM-1-104, is in a Phase 1/2a study in patients with advanced solid tumors harboring RAS mutations. The company’s development pipeline also includes IMM-6-415, which is designed to have an accelerated cadence relative to IMM-1-104, as well as several early-stage programs.

On October 30, 2019, Immuneering formed a wholly owned subsidiary, Immuneering Securities Corporation (“ISC”), a Massachusetts securities corporation, for the sole purpose of buying, selling and holding securities on the Company’s behalf.

On December 22, 2021, the Company acquired all outstanding shares of capital stock of BioArkive, Inc. (“BioArkive”), a California corporation, which as a result became a wholly owned subsidiary.

Immuneering, ISC and BioArkive are collectively referred to as “the Company” throughout these consolidated financial statements.

The Company is subject to a number of inherent risks associated with any biotechnology company that has substantial expenditures for research and development. These risks include, but are not limited to, the need to obtain adequate additional funding, possible failure of clinical trials or other events demonstrating lack of clinical safety or efficacy of its product candidates, dependence on key personnel, reliance on third-party service providers for manufacturing drug product and conducting clinical trials, the ability to successfully secure its proprietary technology, and risks related to the regulatory approval and commercialization of a product candidate. There can be no assurance that the Company’s research and development program will be successful. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its employees, advisors, and consultants.

On August 3, 2021, the Company completed its initial public offering (“IPO”) pursuant to which it issued and sold 8,625,000 shares of its Class A common stock, inclusive of 1,125,000 shares of its Class A common stock sold pursuant to the full exercise of the underwriters’ option to purchase additional shares. The aggregate net proceeds received by the Company from the IPO were \$120,318,750, after deducting underwriting discounts and commissions, but before deducting offering costs payable by the Company, which were \$2,124,317. Upon the closing of the IPO, all 8,528,078 shares of the Company’s convertible preferred stock then outstanding automatically converted into 11,939,281 shares of Class A common stock. Upon the conversion of the convertible preferred stock, the Company reclassified the carrying value of the convertible preferred stock to common stock (at par value) and additional paid-in capital.

To date, the Company has funded its operations through service revenues, and with proceeds from the sale of its capital stock and convertible notes and, most recently, with proceeds from the IPO. The Company has incurred recurring losses over the past several years and as of December 31, 2022, the Company had an accumulated deficit of \$109,786,956. The Company expects to continue to generate operating losses for the foreseeable future. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company’s inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurances that additional funding will be available on terms acceptable to the Company, or at all. If the Company is unable to raise additional funds when needed, it may be required to delay, reduce the scope of, or eliminate development programs, which may adversely affect its business and operations. Management considered whether or not there are conditions or events, in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern, and concluded that there are none as it estimates that its cash and cash equivalents and marketable securities will be

sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of the consolidated financial statements.

The full extent to which coronavirus (“COVID-19”) pandemic will directly or indirectly impact the Company’s business, results of operations and financial condition, including expenses and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and its variants and the actions taken to contain or treat COVID-19 and its variants, as well as the economic impact on local, regional, national and international markets. The Company has considered potential impacts arising from the pandemic related to COVID-19 and its variants and is not presently aware of any events or circumstances that would require the Company to update its estimates, judgements or revise the carrying values of its assets or liabilities.

Note 2 - Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in accordance with accounting standards set by the Financial Accounting Standards Board (“FASB”). The FASB sets generally accepted accounting principles (“GAAP”) to ensure the consolidated financial statements are consistently reported. References to GAAP issued by the FASB in these footnotes are to the FASB Accounting Standards Codifications (“ASC”). The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Stock Split

On July 23, 2021, the Company approved a one-for-1.4 stock split which was consummated in connection with the Company’s IPO. All information in the accompanying financial statements and notes thereto regarding share amounts of common stock, price per share of common stock and the conversion factor for Series A and Series B Preferred Stock into common stock have been adjusted to reflect the application of the stock split on a retroactive basis.

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, revenues and expenses during the reporting periods. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgements about the carrying values of assets, liabilities and the recording of expenses that are not readily apparent from other sources. Significant estimates reflected in these consolidated financial statements included but are not limited to, the research and development expenses, determination of fair value of stock-based awards, the valuation of common stock prior to the IPO, business combination, and the right-to-use assets and operating lease liability. Actual results may differ materially and adversely from these estimates.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker (“CODM”) in making decisions regarding resource allocation and assessing performance. The Company’s chief executive officer is the CODM, and he uses consolidated financial information in determining how to allocate resources and assess performance. The Company has determined that it operates in one segment.

Business Combination

Results of operations of acquired companies are included in the Company's results of operations as of the respective acquisition dates. Acquired businesses are accounted for using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recorded at fair value, with limited exceptions. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired Company are expensed as incurred. The operating results of the acquired business are reflected in the consolidated financial statements after the date of acquisition.

If the acquired net assets do not constitute a business under the acquisition method of accounting, the transaction is accounted for as an asset acquisition and no goodwill is recognized. Refer to Note 6, Business Combination for more information.

Cash and Cash Equivalents

Cash and cash equivalents are comprised of deposits at major financial banking institutions and highly liquid investments with an original maturity of three months or less at the date of purchase. Cash is maintained at Federal Deposit Insurance Company ("FDIC") insured financial institutions. At times, the Company has maintained cash in excess of FDIC limits, however it has not experienced any losses with respect to its cash balances. The Company regularly monitors the financial condition of the institutions in which it has depository accounts and believes the risk of loss is minimal.

Marketable Securities

Our marketable securities are classified as available-for-sale pursuant to ASC 320, Investments – Debt and Equity Securities and are recorded at fair value. Unrealized gains/(losses) are included as a component of accumulated other comprehensive loss in the consolidated balance sheets and statements of convertible preferred stock and stockholders' equity and a component of total comprehensive loss in the consolidated statements of comprehensive loss, until realized. The Company assesses its available-for-sale marketable securities for impairment on a quarterly basis. There were no impairments of the Company's available-for-sale marketable securities measured and carried at fair value during the year ended December 31, 2022. Realized gains and losses are included in other income (expense) on a specific-identification basis. There were no realized gains or losses on marketable securities for the year ended December 31, 2022 and 2021, respectively.

Fair Value Measurements

We record cash equivalents and marketable securities at fair value. ASC 820, Fair Value Measurements and Disclosures, establishes a fair value hierarchy for those instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and our own assumptions (unobservable inputs). The hierarchy consists of three levels:

Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 – Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, directly or indirectly, for substantially the full term of the asset or liability.

Level 3 – Unobservable inputs that reflect our own assumptions about the assumptions market participants would use in pricing the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

Our financial assets, which include cash equivalents and marketable securities, have been initially valued at the transaction price, and subsequently revalued at the end of each reporting period, utilizing third-party pricing services or other observable market data. The pricing services utilize industry standard valuation models, including both income and market based approaches, and observable market inputs to determine value. After completing our validation procedures, we did not adjust or override any fair value measurements provided by the pricing services as of December 31, 2022. Fair value

information for these assets, including their classification in the fair value hierarchy is included in Note 4 Fair Value Measurements.

There have been no changes to the valuation methods during the year ended December 31, 2022. We evaluate transfers between levels at the end of each reporting period.

The carrying amounts reflected in the consolidated balance sheets for cash, accounts receivable, accounts payable and accrued expenses approximate their respective fair values because of the short-term maturity of those financial instruments.

Accounts Receivable

Accounts receivable are stated at the amount management expects to collect from outstanding balances. An allowance for doubtful accounts is estimated for those accounts receivable considered to be uncollectible based upon historical experience and management's evaluation of outstanding accounts receivable. Bad debts are written off against the allowance when identified. At December 31, 2022 and 2021 there was no allowance for doubtful accounts.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of accounts receivable and revenue. To manage accounts receivable credit risk, the Company continuously evaluates the creditworthiness of its customers and the need for an allowance for potential credit losses. The Company has not experienced any losses in such accounts.

The following customers comprised 10% or more of the Company's total accounts receivable or revenues as of or for the period ended December 31, 2022 and 2021, respectively (customers with an asterisk are less than 10%):

| | Year Ended December 31, 2022 | | As of December 31, 2022 | |
|-------------|------------------------------|------------|-------------------------|------------|
| | Revenue | % of Total | Accounts Receivable | % of Total |
| Customer #1 | \$ 299,890 | 94.6 % | \$ 11,275 | 90.8 % |

| | Year Ended December 31, 2021 | | As of December 31, 2021 | |
|-------------|------------------------------|------------|-------------------------|------------|
| | Revenue | % of Total | Accounts Receivable | % of Total |
| Customer #1 | \$ 745,030 | 35.8 % | \$ 235,500 | 95.7 % |
| Customer #2 | 380,000 | 18.3 | * | * |
| Customer #5 | 353,050 | 17.0 | * | * |

Property and Equipment

Property and equipment are recorded at cost, net of accumulated depreciation. Expenditures for major replacements and improvements are capitalized, while expenditures for general repairs and maintenance are expensed as incurred. Upon retirements or disposition of property and equipment, the related cost and accumulated depreciation are removed from the consolidated balance sheet and any resulting gain or loss is recorded in the consolidated statement of operations. Depreciation is calculated using the straight-line method once assets are placed in service.

| Asset Class | Estimated Useful Lives |
|------------------------|------------------------|
| Computer equipment | 3 years |
| Furniture and fixtures | 5 years |
| Lab equipment | 7 years |
| Leasehold improvements | 1-10 years |

Impairment of Long-lived Assets

Periodically, 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. To date, no impairments have occurred.

Leases

In February 2016 the FASB issued Accounting Standards Update (“ASU”) No. 2016-02, Leases (Topic 842) (“ASC 842”), a standard issued to increase transparency and comparability among organizations related to their leasing activities. This standard established a right-of-use model that requires the recognition of right-of-use assets and lease liabilities for most leases as well as provides disclosure with respect to certain qualitative and quantitative information related to a company’s leasing arrangements to meet the objective of allowing users of financial statements to assess the amount, timing and uncertainty of cash flows arising from leases.

The Company adopted the leasing standard using the modified retrospective transition approach as of January 1, 2020, with no restatement of prior periods or cumulative adjustment to retained earnings. Upon adoption, the Company elected the package of transition practical expedients, which allowed the Company to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases, and initial direct costs for existing leases. The Company also made an accounting policy election to not recognize leases with an initial term of 12 months or less within its consolidated balance sheets, and to recognize those lease payments on a straight-line basis in its consolidated statements of operations over the lease term. The adoption of the leasing standard did not have an impact on the consolidated statement of operations.

The Company determines if an arrangement is a lease at contract inception. Right-of-use assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Right-of-use assets and lease liabilities are recognized at the commencement date of the lease based upon the present value of future lease payments over the expected lease term. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. As most of the Company’s leases do not provide an implicit interest rate, the Company uses its incremental borrowing rate, which is based on rates that would be incurred to borrow on a collateralized basis over a term equal to the lease payments in a similar economic environment, in determining the present value of lease payments.

The Company has elected not to separate lease and non-lease components as a single lease component. The Company’s lease are reflected in right-of-use assets and lease liabilities (current and non-current) in the consolidated balance sheets.

Revenue Recognition

In accordance with ASC 606, revenue is recognized when a customer obtains control of promised goods and services. The core principle of the standard is to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To achieve that core principle, the Company applies the following five-step model:

- Identify the contract with a customer
- Identify the performance obligations in the contract
- Determine the transaction price
- Allocate the transaction price to the performance obligations in the contract
- Recognize revenue when or as performance obligations are satisfied

The Company's contracts generally consist of the promise to provide computational biology professional services to pharmaceutical and biotechnology companies, which the Company has concluded constitutes one performance obligation that is delivered over time. The transaction price is the amount of consideration to which the Company expects to be entitled in exchange for transferring the services to the customer. The Company's contracts provide for either agreed upon rates per hour based on the level of the professional working on the project or a fixed fee for a defined scope of work. The Company recognizes revenue over time by measuring the progress toward complete satisfaction of the performance obligation using a single method of measuring progress, which depicts the performance in transferring control of the associated services to the customer. The Company uses input methods to measure the progress toward the complete satisfaction of performance obligations and evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment.

The Company's contract terms do not allow for a right of return or refund and do not contain significant financing components. Receivables associated with the contract will generally be collected within thirty to sixty days, in accordance with the underlying payment terms.

Income Taxes

The Company provides for income taxes in accordance with ASC Topic 740, Income Taxes. Deferred tax assets and liabilities are determined based on the difference between the financial reporting and tax bases of assets and liabilities using enacted tax rates and laws in effect in the years in which the differences are expected to reverse. A valuation allowance is provided if, based upon the weighted available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more likely than not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves (i.e., unrecognized tax benefits) that are considered appropriate as well as the related net interest. As of December 31, 2022 and 2021, the Company had uncertain tax positions of \$541,067 and \$380,902, respectively. The Company has classified the unrecognized tax benefits as reductions of its tax credit carryforwards.

Research and Development

Research and development costs are expensed as incurred. Research and development costs consist of expenses incurred in performing research and development activities, including salaries and benefits, materials and supplies, preclinical expenses, stock-based compensation expense, depreciation of equipment, contract services, and other outside expenses. The Company also incurs costs to develop software programs for internal use in identifying potential human drug targets which may then lead to the development of human drug candidates. To date the software programs have primarily been used for internal research and development activities and the costs incurred have been expensed as research and development.

Research and Manufacturing Contract Costs and Accruals

The Company has entered into various research, development and manufacturing contracts with research institutions and other companies in and outside the United States. These agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research, development and manufacturing costs. When billing terms under these contracts do not coincide with the timing of when the work is performed, the Company is required to make estimates of outstanding obligations to those third parties as of period end. Any accrual estimates are based on a number of factors, including the Company's knowledge of the progress

towards completion of the research, development and manufacturing activities, invoicing to date under the contracts, communication from the research institutions and other companies of any actual costs incurred during the period that have not yet been invoiced and the costs included in the contracts. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by the Company. The historical accrual estimates made by the Company have not been materially different from the actual costs.

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.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders.

Deferred Offering Costs

The Company capitalizes certain legal, professional, and other third-party charges related to ongoing equity financings as deferred offering costs until fully consummated. These costs are to be recorded as a reduction of the offering's proceeds which are recorded to additional paid-in capital within stockholders' equity. Should the Company choose not to initiate such financing, the deferred offering costs would be immediately expensed as operating expenses.

On August 10, 2022, the Company entered into an Equity Distribution Agreement ("the Sales Agreement") with Piper Sandler & Co. ("the Sales Agent") to sell shares of the Company's common stock, par value \$0.001 per share, with aggregate gross sales proceeds of up to \$50 million, from time to time, through an "at the market" equity offering program. Deferred offering costs associated with the Sales Agreement are reclassified to additional paid in capital on a pro-rata basis when the Company completes offerings under the Sales Agreement. Any remaining deferred costs will be expensed to the statement of operations should the planned offering be abandoned. The Company had approximately \$0.3 million and \$0 of deferred offering costs as of December 31, 2022 and 2021, respectively.

Net Income (Loss) per Share

Prior to the closing of the IPO, the Company followed the two-class method when computing net income (loss) per share, as the Company had issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net income (loss) attributable to common stockholders is computed by adjusting net income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders 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 Company's convertible preferred stock contractually entitled the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common

stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Subsequent to the closing of its IPO, the Company only has one class of shares outstanding and basic net income (loss) per common share is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock awards. For periods in which the Company reports a net loss, diluted net loss per common share is the same as basic net loss per common share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for each of the years ended December 31, 2022 and 2021.

Stock-based Compensation

The Company issues stock-based awards to employees and nonemployees in the form of stock options. The Company accounts for stock-based awards in accordance with ASC 718, Compensation — Stock Compensation (“ASC 718”), which requires all stock-based payments to employees and nonemployees, including grants of employee stock options and modifications to existing stock options, to be recognized in the consolidated statement of operations based on their fair values.

The fair value of options is estimated on the grant date using the Black-Scholes option-pricing model (“Black-Scholes”). Black-Scholes requires the Company to make assumptions and judgments about the variables used in the calculation including the expected term of its stock option, the volatility of the Company’s common stock, and an assumed risk-free interest rate. The Company uses the simplified calculation of expected life and volatility, which is based on an average of the historical volatility of a group of publicly traded companies in a similar industry that the Company believes would be considered a peer group had it been a publicly held company for the duration of the expected life of the award. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. Forfeitures are recognized as they occur. No dividend yield was assumed as the Company does not pay, and does not expect to pay, dividends on its common stock. The assumptions underlying these valuations represent management’s best estimates, which involve inherent uncertainties and the application of management’s judgement.

As there had been no public market for the Company’s common stock prior to the IPO, the estimated fair value of its common stock has been determined by its board of directors as of the date of each option grant, with input from management, considering the Company’s most recently available third-party valuations of common stock and its board of directors’ assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants’ Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Each valuation methodology included estimates and assumptions that required the Company’s judgment. These estimates and assumptions included a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company’s common stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale.

The assumptions underlying these valuations represented management’s best estimates, which involved inherent uncertainties and the application of management’s judgment. As a result, if the Company had used different assumptions or estimates, the fair value of its common stock and its stock-based compensation expense could be materially different.

Goodwill

Goodwill represents the excess of the fair value of the acquiree over the recognized bases of the net identifiable assets acquired and includes the future economic benefits from other assets that could not be individually identified and separately recognized. Goodwill is not amortized, but instead is periodically reviewed for impairment and an impairment charge is recorded in the periods in which the recorded carrying value of goodwill exceeds its fair value.

On a quarterly basis, the Company performs a review of its business to determine if events or changes in circumstances have occurred which could have a material adverse effect on the fair value of the Company and its goodwill. If such events or changes in circumstances were deemed to have occurred, the Company would perform an impairment test of goodwill as of the end of the quarter and record any noted impairment loss.

The Company's market capitalization has declined which may be an indicator of impairment. The Company will continue to assess the impact of its market capitalization and any other indicators of potential impairment. It is possible that if the Company's market capitalization decline is more than temporary, or if other indicators of impairment are identified, an interim impairment analysis may be necessary, which could result in an impairment of goodwill, intangible assets and other long-lived assets in future periods.

The goodwill test is performed at least annually, or more frequently if events or changes in circumstances indicate that the asset might be impaired.

The Company performs its annual impairment test during the fourth quarter of each fiscal year. There were no impairments during the years ended December 31, 2022 or 2021.

Intangible Assets

Intangible assets are recognized at fair value, as an asset apart from goodwill if the asset (i) arises from contractual or other legal rights, or (ii) is separable. Intangible assets, principally representing technology acquired, are capitalized and amortized on the straight-line method over their expected useful lives.

The Company reviews the recoverability of its long-lived assets (including amortizable intangible assets), other than goodwill, when events or changes in circumstances occur that indicate that the carrying value of the asset may not be recoverable.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company is an "emerging growth company" as defined in the JOBS act. 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. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company elected to avail itself of this extended transition period and, as a result, we will not be required to adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

In 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements. The new standard, as amended, requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The targeted transition relief standard allows filers an option to irrevocably elect the fair value option of ASC 825-10, Financial Instruments - Overall, applied on an instrument-by-instrument basis for eligible instruments. ASU 2016-13, Financial Instruments - Credit Losses (Topic 326) will become effective for the Company on January 1, 2023. The Company is currently evaluating the new guidance and assessing the potential impact on its consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, Intangibles - Goodwill and Other (Topic 350), which eliminates Step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. Instead, entities will record an impairment charge based on the excess of a reporting unit's carrying amount over its fair value (i.e., measure the charge based on today's Step 1). This update is effective for annual and interim impairment tests performed in periods beginning after December 15,

2022. Early adoption of the standard is permitted. The Company is currently evaluating the new guidance and assessing the potential impact on its consolidated financial statements.

Note 3 – Marketable Securities

Marketable securities consisted of the following as of December 31, 2022 and 2021, respectively:

| | December 31, 2022 | | | Fair Value |
|------------------------------------|--------------------------|-------------------------|--------------------------|----------------------|
| | Amortized Cost | Unrealized Gains | Unrealized Losses | |
| Assets: | | | | |
| Current: | | | | |
| U.S. Treasuries | \$ 12,986,424 | \$ - | \$ (25,649) | \$ 12,960,775 |
| Government securities | 8,084,107 | 1,099 | (12,021) | 8,073,185 |
| Commercial Paper | 11,847,902 | 6,847 | (739) | 11,854,010 |
| Total marketable securities | \$ 32,918,433 | \$ 7,946 | \$ (38,409) | \$ 32,887,970 |

| | December 31, 2021 | | | Fair Value |
|------------------------------------|--------------------------|-------------------------|--------------------------|----------------------|
| | Amortized Cost | Unrealized Gains | Unrealized Losses | |
| Assets: | | | | |
| Current: | | | | |
| U.S. Treasuries | \$ 42,147,385 | \$ - | \$ (28,575) | \$ 42,118,810 |
| Government securities | 19,218,057 | - | (13,689) | 19,204,368 |
| Commercial Paper | 12,992,165 | 57 | (4,197) | 12,988,025 |
| Total Current | 74,357,607 | 57 | (46,461) | 74,311,203 |
| Non-current: | | | | |
| U.S. Treasuries | 999,186 | - | (2,626) | 996,560 |
| Government securities | - | - | - | - |
| Total Non-current | 999,186 | - | (2,626) | 996,560 |
| Total marketable securities | \$ 75,356,793 | \$ 57 | \$ (49,087) | \$ 75,307,763 |

There were no impairments of the Company’s available-for-sale marketable securities measured and carried at fair value during the year ended December 31, 2022 or December 31, 2021. Realized gains and losses are included in other expense on a specific-identification basis. There were no realized gains or losses on marketable securities for the years ended December 31, 2022 and 2021.

Note 4 – Fair Value Measurements

The following table summarizes our cash equivalents and marketable securities measured at fair value on a recurring basis as of December 31, 2022 and 2021, respectively:

| | December 31, 2022 | | | |
|--|--------------------------|----------------------|----------------|-----------------------|
| | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Cash equivalents | | | | |
| Money market | \$ 19,118,892 | \$ - | \$ - | \$ 19,118,892 |
| Commercial paper | - | 1,249,575 | - | 1,249,575 |
| Government securities | - | 2,742,025 | - | 2,742,025 |
| Total cash equivalents | <u>19,118,892</u> | <u>3,991,600</u> | <u>-</u> | <u>23,110,492</u> |
| Marketable securities: | | | | |
| U.S. Treasuries | \$ 12,960,775 | \$ - | \$ - | \$ 12,960,775 |
| Government securities | - | 8,073,185 | - | 8,073,185 |
| Commercial paper | - | 11,854,010 | - | 11,854,010 |
| Total marketable securities | <u>12,960,775</u> | <u>19,927,195</u> | <u>-</u> | <u>32,887,970</u> |
| Total cash equivalents and marketable securities | <u>\$ 32,079,667</u> | <u>\$ 23,918,795</u> | <u>\$ -</u> | <u>\$ 55,998,462</u> |
| | December 31, 2021 | | | |
| | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Cash equivalents | | | | |
| Money market | \$ 33,961,344 | \$ - | \$ - | \$ 33,961,344 |
| Commercial paper | - | 2,000,000 | - | 2,000,000 |
| Total cash equivalents | <u>33,961,344</u> | <u>2,000,000</u> | <u>-</u> | <u>35,961,344</u> |
| Marketable securities: | | | | |
| U.S. Treasuries | \$ 43,115,370 | \$ - | \$ - | \$ 43,115,370 |
| Government securities | - | 19,204,368 | - | 19,204,368 |
| Commercial paper | - | 12,988,025 | - | 12,988,025 |
| Total marketable securities | <u>43,115,370</u> | <u>32,192,393</u> | <u>-</u> | <u>75,307,763</u> |
| Total cash equivalents and marketable securities | <u>\$ 77,076,714</u> | <u>\$ 34,192,393</u> | <u>\$ -</u> | <u>\$ 111,269,107</u> |

There were no transfers between Level 1 and Level 2 and we had no financial assets or liabilities that were classified as Level 3 at any point during the years ended December 31, 2022 and 2021.

Note 5 – Property and Equipment, net

Property and equipment, net consisted of the following:

| | December 31, 2022 | December 31, 2021 |
|-----------------------------|------------------------------|------------------------------|
| Computer equipment | \$ 437,346 | \$ 281,666 |
| Furniture and fixtures | 91,317 | 84,477 |
| Lab equipment | 970,374 | 463,182 |
| Leasehold improvements | 288,908 | 152,117 |
| Total | <u>1,787,945</u> | <u>981,442</u> |
| Accumulated depreciation | <u>(418,337)</u> | <u>(174,219)</u> |
| Property and equipment, net | <u>\$ 1,369,608</u> | <u>\$ 807,223</u> |

Depreciation expense totaled \$247,199 and \$45,467 for the years ended December 31, 2022 and 2021, respectively.

Note 6 – Business Combination

BioArkive Acquisition

On December 22, 2021, the Company completed the acquisition of all outstanding shares of capital stock of BioArkive, Inc., a California corporation, for a market value of \$8.75 million.

BioArkive is a San Diego based contract research organization that has previously provided preclinical research services and biosample storage to the Company and other biotechnology companies. BioArkive has been fully integrated into the Company to exclusively support the Company's internal preclinical research activities for its oncology pipeline.

In connection with the acquisition, the Company has assumed the obligations under BioArkive's three lease agreements.

The purchase price was paid by Immuneering through the issuance of an aggregate of 379,635 shares of Immuneering's Class A common stock. The number of shares of common stock issued was calculated using a value based on the average of the daily volume weighted average prices of the common stock on the Nasdaq Stock Exchange for the 30-trading day period ending on and including the trading day immediately prior to the closing date. The sellers of BioArkive were restricted from selling these shares for a six-month period from the date of the acquisition. As such, we estimated that there was an approximate 10% discount for the lack of marketability of the shares. The fair value of the purchase price in the acquisition was \$7,875,000.

Prior to the acquisition, Brett Hall, Chief Scientific Officer of Immuneering and the Founder and Chairman of the board of directors of BioArkive, held the majority of the outstanding shares of BioArkive capital stock. BioArkive provided contract services to the Company. Research and development expenses in the consolidated statement of operations include the cost of services provided by BioArkive to the Company which amounted to \$4,548,780 in 2021 through the date of the acquisition. The results of BioArkive's operations are included in the consolidated balance sheets.

Assets Acquired and Liabilities Assumed at Fair Value

The BioArkive acquisition has been accounted for using the acquisition method of accounting. This method requires that assets acquired and liabilities assumed in a business combination to be recognized at their fair values as of the acquisition date. As of March 31, 2022, the purchase accounting had been finalized, and there was an immaterial measurement period adjustment related to accrued expenses and goodwill. No other adjustments were identified.

Intangible Assets

The estimated fair value of the intangible assets was determined using the relief from royalty approach.

Goodwill

Goodwill is the excess of the consideration transferred over the net assets recognized and represents the expected cost savings of the combined company and assembled workforce. One of the key factors that contributes to the recognition of goodwill, and a driver for the Company's acquisition of BioArkive, is the planned investment in the internal preclinical research activities for our oncology pipeline. Goodwill recognized as a result of this acquisition is non-deductible for income tax purposes.

Pro forma results are not presented for this acquisition as they are not material to the consolidated results of the Company's operations.

| | Preliminary Valuation | Measurement Period Adjustment | Final Valuation | Weighted Average Life |
|--|--------------------------|-------------------------------------|---------------------|--------------------------|
| Cash | \$ 70,348 | \$ - | \$ 70,348 | |
| Other current assets | 225,790 | - | 225,790 | |
| Other long term assets | 87,796 | - | 87,796 | |
| Property, plant and equipment, net | 727,539 | - | 727,539 | |
| Right of use assets | 4,824,700 | - | 4,824,700 | |
| Intangible asset | | | | |
| Technology | 439,000 | - | 439,000 | 15 years |
| Goodwill | 6,701,726 | 11,295 | 6,690,431 | |
| Total assets acquired | 13,076,899 | 11,295 | 13,065,604 | |
| Accounts payable, accrued expenses and other liabilities | 69,714 | (11,295) | 58,419 | |
| Deferred tax liabilities | 307,485 | - | 307,485 | |
| Lease liabilities | 4,824,700 | - | 4,824,700 | |
| Net assets acquired | \$ 7,875,000 | \$ - | \$ 7,875,000 | |

Note 7 – Accrued Expenses

Accrued expenses consisted of the following:

| | December 31, 2022 | December 31, 2021 |
|------------------------------------|----------------------|----------------------|
| Accrued professional services | \$ 297,234 | \$ 250,977 |
| Accrued employee expenses | 3,631,082 | 2,917,282 |
| Accrued contract research expenses | 425,846 | 585,416 |
| Accrued other | 146,831 | 211,772 |
| Total | \$ 4,500,993 | \$ 3,965,447 |

Note 8 – Convertible Preferred Stock

Series B Preferred Stock

In April and May 2021, 2,412,853 shares of the second tranche of Series B Preferred Stock were issued based on the voluntary election of substantially all of the holders of Series B Preferred Stock. The Company received gross proceeds of \$24,799,786. The Company incurred issuance costs of \$10,935 in connection with the second tranche of Series B Preferred Stock.

Upon the closing of the IPO on August 3, 2021, all 8,528,078 shares of the Company's convertible Series A and B Preferred Stock then outstanding automatically converted into 11,939,281 shares of Class A common stock.

Note 9 - Common Stock

The Company had 200,000,000 authorized shares of Class A common stock, \$0.001 par value per share as of December 31, 2022 and December 31, 2021 of which 26,418,732 and 26,320,199 were issued and outstanding, respectively. The holders of Class A common stock are entitled one vote for each share of common stock. Dividends may be paid when, and if declared by the board of directors, subject to the limitations, powers and preferences granted to the Preferred Stockholders and on a proportionate basis with holders of Class B common stock.

As of December 31, 2022 and December 31, 2021, the following number of shares of Class A common stock have been reserved:

| | <u>December 31, 2022</u> | <u>December 31, 2021</u> |
|----------------------------------|------------------------------|------------------------------|
| Exercise of common stock options | 3,559,041 | 2,859,544 |
| | <u>3,559,041</u> | <u>2,859,544</u> |

The Company had 20,000,000 authorized shares of Class B common stock, \$0.001 par value per share as of December 31, 2022 and December 31, 2021 of which no shares have been issued nor are outstanding. The holders of Class B common stock have no voting rights. Dividends may be paid when, and if, declared by the Board of Directors, subject to the limitations, powers and preferences granted to the preferred stockholders and on a proportionate basis with holders of Class A common stock.

Initial Public Offering

On August 3, 2021, the Company completed its initial public offering pursuant to which it issued and sold 8,625,000 shares of its Class A common stock, inclusive of 1,125,000 shares of its Class A common stock sold pursuant to the full exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds received by the Company from the IPO were \$120,318,750, after deducting underwriting discounts and commissions, but before deducting offering costs payable by the Company, which were \$2,124,317. Upon the closing of the IPO, all 8,528,078 shares of the Company's convertible preferred stock then outstanding automatically converted into 11,939,281 shares of Class A common stock. Upon the conversion of the convertible preferred stock, the Company reclassified the carrying value of the convertible preferred stock to common stock (at par value) and additional paid-in capital.

On August 3, 2021 in connection with the closing of the IPO, the Company filed a restated certificate of incorporation, which amended and restated the Company's certificate of incorporation to, among other things: (i) increase the number of authorized shares of common stock to 200,000,000 shares of Class A common stock, 20,000,000 shares of Class B common stock, par value \$0.001 per share, and (ii) authorize 10,000,000 shares of Preferred Stock; and (iii) authorize the Board of Directors to establish the rights, preferences and restrictions on any unissued series of Preferred Stock.

Note 10 - Net Loss Per Share Attributable to Common Stockholders

Basic and diluted net loss per share attributable to common stockholders was calculated at December 31, 2022 and 2021 as follows:

| | <u>Year Ended December 31,</u> | |
|---|--------------------------------|------------------|
| | <u>2022</u> | <u>2021</u> |
| Numerator: | | |
| Net loss | \$ (50,513,568) | \$ (33,535,748) |
| Denominator - basic and diluted: | | |
| Weighted-average common shares outstanding, basic and diluted | 26,386,864 | 13,612,677 |
| Net loss per share - basic and diluted | <u>\$ (1.91)</u> | <u>\$ (2.46)</u> |

The following table sets forth the potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to include them would be anti-dilutive (in common stock equivalent shares) at December 31, 2022 and 2021:

| | <u>2022</u> | <u>2021</u> |
|--|------------------|------------------|
| Options to purchase common stock | 3,559,041 | 2,859,544 |
| Total shares of common stock equivalents | <u>3,559,041</u> | <u>2,859,544</u> |

Note 11 – Stock-Based Compensation

During 2015, the Company established the Long Term Incentive Plan (“Incentive Plan”), under which incentive stock options, nonqualified stock options, restricted stock or other awards may be awarded to employees, directors or consultants of the Company. The options typically vest over a four-year period. As of December 31, 2022, the maximum number of shares available for issuance under the Incentive Plan was 2,825,173 shares. Upon the effectiveness of the Company’s 2021 Incentive Award Plan, the Company ceased granting awards under the Incentive Plan. However, the Incentive Plan continues to govern awards outstanding thereunder.

On July 23, 2021, the Company’s Board of Directors adopted, and on July 23, 2021 its stockholders approved, the 2021 Incentive Award Plan (the “2021 Plan”), which became effective on July 29, 2021. The 2021 Plan provides for the grant of incentive stock options, stock appreciation rights, restricted stock awards, restricted stock units, and other stock-based awards. The number of shares reserved for issuance under the 2021 Plan was initially equal to 2,590,000 plus an annual increase on the first day of each calendar year, beginning on January 1, 2022 and ending on and including January 1, 2031, equal to the lesser of (i) 4% of the aggregate number of shares of Class A common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of Class A common stock as determined by the Board of Directors. No more than 15,350,000 shares of Class A common stock may be issued under the 2021 Plan upon the exercise of incentive stock options. Shares issued under the 2021 Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares. If an award under the 2021 Plan expires, lapses or is terminated, exchanged for or settled in cash, surrendered, repurchased, cancelled without having been fully exercised/settled or forfeited, any unused shares subject to the award will again be available for new grants under the 2021 Plan. In addition, shares subject to stock options issued under the Incentive Plan may become available for issuance under the 2021 Plan to the extent such stock options are canceled, forfeited, exchanged, settled in cash or otherwise terminated. As of December 31, 2022, there were 2,553,210 shares available for future issuance under the 2021 Plan.

On July 23, 2021, the Company’s Board of Directors adopted, and on July 23, 2021 its stockholders approved, the 2021 Employee Stock Purchase Plan (the “2021 ESPP”), which became effective on July 29, 2021. A total of 250,000 shares of Class A common stock were initially reserved for issuance under this plan. The number of shares of Class A common stock that may be issued under the 2021 ESPP will automatically increase on the first day of each calendar year, beginning on January 1, 2022 and ending on and including January 1, 2031, equal to the lesser of (i) 1% of the shares of Class A common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of Class A common stock as determined by the board of directors, provided that not more than 3,340,000 shares of Class A common stock may be issued under the 2021 ESPP. As of December 31, 2022, no shares had been issued under the 2021 ESPP.

During the years ended December 31, 2022 and 2021, the Company recognized stock-based compensation expense of \$4,064,446 and \$1,802,623, respectively. As of December 31, 2022, compensation expense remaining to be recognized for outstanding stock options was \$9,830,063 and to be recognized over a weighted-average period of 2.47 years.

The fair value of options granted is calculated on the grant date using the Black-Scholes option valuation model. The Company was a private company until its initial public offering in August 2021 and continues to lack company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer public companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. For the year ended December 31, 2022, the Company granted 1,227,810 shares of stock options at a weighted-average grant date fair value of \$9.83. For the year ended December 31, 2021, the Company granted 1,452,462 shares at a weighted-average grant date fair value of \$6.29.

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The Company used the following assumptions in its application of the Black-Scholes option pricing model for grants during the year ended December 31, 2022 and 2021:

| | <u>Year Ended December 31,</u> | |
|--|--------------------------------|-----------------|
| | <u>2022</u> | <u>2021</u> |
| Weighted-average risk-free interest rate | 1.35% - 4.15% | 0.89% - 1.71% |
| Expected term (in years) | 5 - 10 years | 5.83 - 10 years |
| Expected dividend yield | 0% | 0% |
| Expected volatility | 64.67% - 78.12% | 66.76% - 80.99% |

The following table summarizes the stock option activity during the year ended December 31, 2022 under the 2021 Plan:

| | <u>Number of Options</u> | <u>Weighted- Average Exercise Price per Share</u> | <u>Weighted Average Remaining Contractual Term (in Years)</u> | <u>Aggregate Intrinsic Value</u> |
|--|------------------------------|---|---|--------------------------------------|
| Outstanding at of December 31, 2021 | 2,859,544 | \$ 6.55 | | |
| Granted | 1,227,810 | 9.83 | | |
| Exercised | (98,533) | 3.01 | | |
| Cancelled | (429,780) | 10.03 | | |
| Outstanding at December 31, 2022 | <u>3,559,041</u> | <u>\$ 7.36</u> | 7.68 | \$ 2,715,408 |
| Vested and exercisable at December 31, 2022 | 1,846,663 | \$ 5.35 | 6.81 | \$ 2,314,676 |
| Vested and expected to vest at December 31, 2022 | 3,559,041 | \$ 7.36 | 7.68 | \$ 2,715,408 |

For the year ended December 31, 2022 and 2021, the Company recognized share-based compensation expense recognized on the accompanying consolidated statements of operations as follows:

| | <u>Year Ended December 31,</u> | |
|----------------------------|--------------------------------|---------------------|
| | <u>2022</u> | <u>2021</u> |
| Cost of revenue | \$ 9,703 | \$ 103,329 |
| Research and development | 1,978,169 | 768,679 |
| General and administrative | 2,076,574 | 930,615 |
| Total | <u>\$ 4,064,446</u> | <u>\$ 1,802,623</u> |

Note 12 – Income Taxes

A reconciliation of the effect of applying the federal statutory rate to the net loss and the effective income tax rate are as follows:

| | <u>2022</u> | <u>2021</u> |
|--|--------------|--------------|
| Statutory federal income tax rate | 21.0 % | 21.0 % |
| State tax, net of federal benefit | 6.1 % | 5.5 % |
| Permanent differences | (0.9)% | (0.6)% |
| Federal research and development credits | 2.3 % | 5.6 % |
| State research and development credits | 0.2 % | 0.4 % |
| Uncertain tax positions | (0.3)% | (0.6)% |
| Other differences | 0.9 % | 0.7 % |
| Change in valuation allowance | (29.3)% | (31.1)% |
| Effective income tax rate | <u>0.0 %</u> | <u>0.9 %</u> |

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As of December 31, 2022 and 2021, the components and tax effects of each type of item that gave rise to the net deferred tax assets were as follows:

| | 2022 | 2021 |
|------------------------------------|--------------|--------------|
| Deferred tax assets: | | |
| Stock-based compensation expense | \$ 1,059,866 | \$ 373,602 |
| Research expenses | 6,758,291 | — |
| Unrealized losses | 10,419 | 12,990 |
| R&D credit carryforward | 4,146,850 | 3,346,097 |
| NOL carryforward | 20,842,910 | 14,699,524 |
| Gross deferred tax assets | 32,818,336 | 18,432,213 |
| Valuation allowance | (32,039,948) | (17,677,899) |
| Net deferred tax assets | 778,388 | 754,314 |
| Net deferred tax liabilities: | | |
| Prepaid expenses deducted for tax | (353,224) | (425,755) |
| Right of use | (117,445) | — |
| Tax depreciation in excess of book | (307,719) | (328,559) |
| Total deferred tax liabilities | (778,388) | (754,314) |
| Net deferred taxes | \$ — | \$ — |

Federal net operating losses (“NOL”) generated in tax years ended after December 31, 2017 are limited to 80% of taxable income, only carried forward and carried forward indefinitely under the Internal Revenue Code (“IRC”). The Company recorded a deferred tax liability of \$304,485 on the acquisition of BioArkive. It had pre-existing deferred tax assets for which there was a full valuation allowance. As a result of the taxable temporary differences recognized in the business combination, the Company released \$304,485 of its valuation allowance and recognized the income tax benefit in the income statement at the acquisition date in accordance with ASC 740. There was no income tax expense or benefit in 2022. The Company has provided a valuation allowance for the full amount of the net deferred tax assets as, based on all available evidence, it is considered more likely than not that all the recorded deferred tax assets will not be realized in a future period. At December 31, 2022, the Company has federal and state NOLs of \$77,015,618 and \$76,232,037, respectively all generated after the tax year ended December 31, 2017. At December 31, 2022, the Company has federal and state research and development credit carryforwards, \$3,802,780 and \$435,533, respectively, that start to expire beginning in 2025.

As the Company has not yet achieved profitable operations, management believes the tax benefits as of December 31, 2022 did not satisfy the realization criteria set forth in ASC Topic 740, Income Taxes and, therefore, has recorded a full valuation allowance for the entire deferred tax asset. The valuation allowance increased in 2022 by \$14,362,049 due to the increase in the deferred tax assets by the same amount, primarily due to NOL and research and development expenses.

Utilization of the U.S. net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company’s stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed by the Company and any limitation is known, no amounts are being presented as an uncertain tax position.

As of December 31, 2022 and 2021, the Company had uncertain tax positions of \$541,067 and \$380,902. The Company has classified the unrecognized tax benefits as reductions of its tax carryforwards. The Company has elected to recognize interest and penalties related to income tax matters as a component of income tax expense, of which no interest or penalties were recorded for the years ended December 31, 2022 and 2021.

As of December 31, 2022 and 2021, unrecognized tax benefits were as follows:

| | 2022 | 2021 |
|---|-------------------|-------------------|
| Beginning balance | \$ 380,902 | \$ 174,950 |
| Increase due to current year tax position | 160,165 | 205,952 |
| Ending balance | <u>\$ 541,067</u> | <u>\$ 380,902</u> |

The Company files tax returns in the United States including California, New York, Pennsylvania, Massachusetts and Texas. All tax years from 2017 to 2021 remain open to examination by the major taxing jurisdictions to which the Company is subject, as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service (“IRS”) or other authorities if they have or will be used in a future period. The Company is not currently under examination by the IRS or any other jurisdictions for any tax years.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2019, 2020, and 2021 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. The enactment of the CARES Act resulted in increased federal and state research and development carryforwards from 2013 through 2018 of \$93,437 and decreased federal NOL of \$759,794 from 2018.

Note 13 – Commitments and Contingencies

Operating Leases

The Company leases office space in Cambridge, Massachusetts, New York, New York and San Francisco, California, pursuant to short-term arrangements. The Cambridge lease is on a month-to-month basis, requiring one month’s notice before termination. The New York and San Francisco lease is renewable on a yearly basis and the last renewal extended the lease term until February 28, 2024 and July 31, 2023 respectively. These lease agreements include payments for lease and non-lease components and the Company has elected to not separate such components and these payments were recognized as rent expense.

As of December 31, 2022, total future minimum lease payments for its short-term leases in Cambridge, Massachusetts, New York, New York and San Francisco, California was \$36,827 due in 2023.

In October 2020, the Company entered into an office lease (“Via Frontera Lease”) in San Diego, California with a lease term of 67 months. At the lease commencement date, a right-to-use asset and lease liability was recognized by the Company for \$637,863. In January 2022, the Company exercised its option to terminate the Via Frontera Lease 20 months early. The lease will terminate on October 1, 2023. This was accounted for as a lease modification which reduces the term of the existing lease and the Company adjusted the value of its right-of-use asset and operating lease liability by \$347,739 using an incremental borrowing rate of approximately 6%.

The modification is reflected as a non-cash operating activity in the statement of cash flows for the year ended December 31, 2022.

The Company subsequently entered into a sublease of the Via Frontera Lease, the term of which commenced in March 2022 and continues through the full remaining obligation. Sublease income will be accounted for as a reduction of rent expense in the statement of operations.

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As part of the BioArkive acquisition, the Company assumed the obligations of three leases in San Diego, California. One is for 38,613 square feet of office and laboratory space, under a lease that terminates on April 30, 2032, the second is for a 6,100 square feet of office and laboratory space under a lease that terminates on December 31, 2022 (the "Site 2 Lease"), and the third is for a lease for 4,760 square feet of office and laboratory space under a lease that terminates on March 31, 2024 (the "Site 3 Lease"). As a result, the Company recorded right-to-use assets and lease liabilities of \$4,824,700 on the acquisition date of December 22, 2021. In February 2022, the Company entered into a sublease of the Site 2 Lease, the term of which continues through the remaining term of the Site 2 Lease. In August 2022, the Company terminated the Site 2 lease and sublease early as the building was sold. As such, the remaining right-of-use asset and lease liability were written off during the year ended December 31, 2022. This is reflected as a non-cash operating activity in the statement of cash flows for the year ended December 31, 2022. In February 2023, the Company entered into a sublease of the Site 3 Lease, the term of which continues through the remaining term of the Site 3 Lease.

Future minimum lease payments for operating leases with initial or remaining terms in excess of one year at December 31, 2022 were as follows:

| | <u>Amount</u> |
|-----------------------------------|---------------------|
| 2023 | \$ 843,463 |
| 2024 | 732,546 |
| 2025 | 739,689 |
| 2026 | 761,877 |
| 2027 | 784,737 |
| Thereafter | 3,682,509 |
| Total future lease payments | 7,544,821 |
| Less: Imputed interest | 2,703,139 |
| Total lease liabilities | <u>\$ 4,841,682</u> |
| Current portion lease liabilities | 378,723 |
| Lease liabilities, noncurrent | 4,462,959 |
| Total lease liabilities | <u>\$ 4,841,682</u> |

Quantitative information regarding the Company's leases for the year ended December 31, 2022 and 2021 is as follows:

| | <u>December 31, 2022</u> | <u>December 31, 2021</u> |
|---|------------------------------|------------------------------|
| Lease costs: | | |
| Operating lease cost | \$ 1,002,989 | \$ 160,872 |
| Short-term lease cost | 282,775 | 258,357 |
| Variable lease cost | (178,620) | — |
| Total lease costs | <u>\$ 1,107,144</u> | <u>\$ 419,229</u> |
| Cash paid for amounts included in the measurement of lease liabilities: | | |
| Operating cash flows from operating leases | \$ 609,790 | \$ 111,527 |
| Operating cash flows from short-term leases | 282,775 | 236,700 |
| | <u>\$ 892,565</u> | <u>\$ 348,227</u> |
| Weighted-average remaining lease term - operating leases | 9.16 years | 9.62 years |
| Weighted-average discount rate - operating leases | 9.1% | 9.7% |

As the Company's leases typically do not provide an implicit rate, the Company uses an estimate of its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments.

Litigation

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities and may be exposed to litigation in connection with its products and operations. The Company's policy is to

assess the likelihood of any adverse judgments or outcomes related to legal matters, as well as ranges of probable losses. When it is probable that future expenditures will be made and can be reasonably estimated the Company will accrue a liability for such matters. Significant judgement is required to determine both probability and estimated amount. The Company is not aware of any material legal matters.

Clinical Research Contracts

The Company may enter into contracts in the normal course of business with clinical research organizations for clinical trials, with contract manufacturing organizations for clinical supplies, and with other vendors for preclinical studies, supplies and other services for our operating purposes. These contracts generally provide for termination with a 30-day notice.

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

None.

Item 9A. Controls and Procedures.

Limitations on effectiveness of controls and procedures

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.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer (who is our principal executive officer) and our Vice President, Finance and Treasurer (who is our principal financial officer), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2022. Based on this evaluation, our Chief Executive Officer and Vice President, Finance and Treasurer concluded that, as of December 31, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Management’s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in “Internal Control - Integrated Framework (2013)” issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2022, our internal control over financial reporting was effective. As an "emerging growth company" as defined in the JOBS Act and a non-accelerated filer, we are not required to comply with the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during fourth quarter of 2022 that have materially affected, or are 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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item 11 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 12, including information regarding securities authorized for issuance under equity compensation plans pursuant to Item 5(a), Part II of Form 10-K, will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) 1. Financial Statements

For a list of the financial statements included herein, see Index to Consolidated Financial Statements in this Annual Report on Form 10-K, incorporated into this Item by reference.

2. Financial Statement Schedules

Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

3. Exhibits

See the Exhibit Index in Item 15(b) below.

(b) EXHIBIT INDEX

| Exhibit Number | Exhibit Description | Incorporated by Reference | | | | Filed/ Furnished Herewith |
|----------------|--|---------------------------|------------|---------|-------------|---------------------------------|
| | | Form | File No. | Exhibit | Filing Date | |
| 2.1 | Share Purchase Agreement by and among Immuneering Corporation, BioArkive, Inc. and BioArkive's shareholders, dated as of December 22, 2021 | 8-K | 001-40675 | 2.1 | 12/22/2021 | |
| 3.1 | Amended and Restated Certificate of Incorporation of Immuneering Corporation | 10-Q | 001-40675 | 3.1 | 09/09/2021 | |
| 3.2 | Amended and Restated Bylaws of Immuneering Corporation | 10-Q | 001-40675 | 3.2 | 09/09/2021 | |
| 4.1 | Form of Specimen Stock Certificate | S-1/A | 333-257791 | 4.1 | 07/26/2021 | |
| 4.2 | Amended and Restated Investors' Rights Agreement, dated December 21, 2020, by and among the Registrant and the other parties thereto. | S-1/A | 333-257791 | 4.2 | 07/26/2021 | |
| 4.3 | Description of Securities | 10-K | 001-40675 | 4.3 | 3/10/2022 | |
| 10.1† | Employment Agreement, dated July 23, 2021, by and between Brett Hall, Ph.D. and Immuneering Corporation | S-1/A | 333-257791 | 10.6 | 07/26/2021 | |
| 10.2† | Employment Agreement, dated July 23, 2021, by and between Scott Barrett, M.D. and Immuneering Corporation | S-1/A | 333-257791 | 10.7 | 07/26/2021 | |
| 10.3† | Employment Agreement, dated July 23, 2021, by and between Benjamin J. Zeskind, Ph.D. and Immuneering Corporation | S-1/A | 333-257791 | 10.8 | 07/26/2021 | |
| 10.4† | Immuneering Corporation 2008 Stock Incentive Plan and form of option agreement thereunder. | S-1 | 333-257791 | 10.4 | 07/09/2021 | |
| 10.5† | Immuneering Corporation Long Term Incentive Plan and form of option agreement thereunder. | S-1 | 333-257791 | 10.5 | 07/09/2021 | |
| 10.6† | Immuneering Corporation 2021 Incentive Award Plan and forms of award agreements thereunder. | S-1/A | 333-257791 | 10.10 | 07/26/2021 | |
| 10.7† | Immuneering Corporation 2021 Employee Stock Purchase Plan. | S-1/A | 333-257791 | 10.11 | 07/26/2021 | |
| 10.8† | Equity Distribution Agreement, dated as of August 10, 2022, by and between Immuneering Corporation and Piper Sandler & Co. | S-3 | 333-266738 | 1.2 | 8/10/2022 | |
| 10.9† | Form of Indemnification Agreement by and among the Registrant and its directors and officers. | S-1/A | 333-257791 | 10.12 | 07/26/2021 | |
| 10.10† | Immuneering Corporation Non-Employee Director Compensation Program. | S-1/A | 333-257791 | 10.13 | 07/26/2021 | |
| 10.11 | Lease Agreement, by and between BioArkive, Inc. and Thornmint 13, LLC, dated as of July 22, 2021 | 8-K | 001-40675 | 10.1 | 12/22/2021 | |
| 21.1 | Subsidiaries of Immuneering Corporation | 10-K | 001-40675 | 21.1 | 03/10/2022 | |
| 23.1 | Consent of RSM US, LLP, Independent Registered Public Accounting Firm | | | | | * |
| 31.1 | Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a). | | | | | * |
| 31.2 | Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a). | | | | | * |
| 32.1 | Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350. | | | | | ** |
| 32.2 | Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350. | | | | | ** |
| 101.INS | Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document. | | | | | * |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document. | | | | | * |

| Exhibit Number | Exhibit Description | Incorporated by Reference | | | Filed/ Furnished Herewith |
|-------------------|--|---------------------------|----------|---------|---------------------------------|
| | | Form | File No. | Exhibit | |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document. | | | | * |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document. | | | | * |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document. | | | | * |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document. | | | | * |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) | | | | * |

* Filed herewith.

** Furnished herewith.

† Indicates a management contract or compensatory plan or arrangement.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, duly authorized.

IMMUNEERING CORPORATION

Date: March 6, 2023

By: /s/ Benjamin J. Zeskind
Name: Benjamin J. Zeskind, Ph.D.
Title: Co-Founder, President, Chief Executive Officer and Director
(Principal Executive Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Benjamin J. Zeskind, and Mallory Morales and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to 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, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

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| <u>Name</u> | <u>Title</u> | <u>Date</u> |
|---|--|---------------|
| <u>/s/ Benjamin J. Zeskind</u> Benjamin J. Zeskind, Ph.D. | President, Chief Executive Officer and Director (Principal Executive Officer) | March 6, 2023 |
| <u>/s/ Mallory Morales</u> Mallory Morales | Vice President Finance and Treasurer (Principal Financial and Accounting Officer) | March 6, 2023 |
| <u>/s/ Ann E. Berman</u> Ann E. Berman | Director | March 6, 2023 |
| <u>/s/ Robert J. Carpenter</u> Robert J. Carpenter | Director | March 6, 2023 |
| <u>/s/ Peter Feinberg</u> Peter Feinberg | Director | March 6, 2023 |
| <u>/s/ Diana F. Hausman, MD</u> Diana F. Hausman, MD | Director | March 6, 2023 |
| <u>/s/ Laurie B. Keating</u> Laurie B. Keating | Director | March 6, 2023 |

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (No. 333-266738) on Form S-3 and Registration Statement (No. 333-258416) on Form S-8 of Immuneering Corporation of our report dated March 6, 2023, relating to the consolidated financial statements of Immuneering Corporation and subsidiaries, appearing in this Annual Report on Form 10-K of Immuneering Corporation for the year ended December 31, 2022.

/s/ RSM US LLP

Boston, Massachusetts
March 6, 2023

CERTIFICATION

I, Benjamin J. Zeskind, certify that:

1. I have reviewed this Annual Report on Form 10-K of Immuneering Corporation;
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 6, 2023

By: /s/ Benjamin J. Zeskind

Name: Benjamin J. Zeskind, Ph.D

Title: Co-Founder, President, Chief Executive Officer and
Director (Principal Executive Officer)

CERTIFICATION

I, Mallory Morales, certify that:

1. I have reviewed this Annual Report on Form 10-K of Immuneering Corporation;
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 6, 2023

By: /s/ Mallory Morales

Name: Mallory Morales

Title: Vice President Finance and Treasurer
(Principal Financial Officer and Principal
Accounting Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

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

- (1) The Report fully complies with the requirements of Section 13(a) or Section 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 6, 2023

By: /s/ Benjamin J. Zeskind
Name: Benjamin J. Zeskind, Ph.D.
Title: Co-Founder, President, Chief Executive Officer and
Director (Principal Executive Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

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

- (1) The Report fully complies with the requirements of Section 13(a) or Section 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 6, 2023

By: /s/ Mallory Morales
Name: Mallory Morales
Title: Vice President Finance and Treasurer
(Principal Financial Officer and Principal Accounting Officer)
