UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **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

o **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 001-38560

AADI BIOSCIENCE, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**EIN 61-1547850**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
17383 Sunset Boulevard Suite A250, Pacific Palisades, CA	**90272**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (424) 744-8055

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.0001 par value per share	AADI	The Nasdaq Stock Market LLC

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

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

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

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 x No o

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 x No o

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	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
Emerging growth company	o		

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. o

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. o

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the shares of common stock on The NASDAQ Stock Market on June 30, 2022 was approximately $177,896,069.

The number of shares of registrant's common stock outstanding as of March 23, 2023 was 24,436,990.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement relating to its 2023 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K are incorporated herein by reference in Part III of this Annual Report on Form 10-K where indicated.

Table of Contents

Forward-Looking Statements

This Annual Report on Form 10-K ("Annual Report") contains express or implied forward-looking statements which are made pursuant to the safe harbor provisions of 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 (the "Exchange Act"), that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Annual Report include, but are not limited to, statements about:

- our ability to maintain regulatory approval for FYARRO® in advanced malignant perivascular epithelioid cell tumor ("PEComa"), or to obtain and maintain regulatory approval for FYARRO in additional indications, or any other product candidates we may develop in the future, and any related restrictions, limitations or warnings in the label of an approved product candidate;
- our plans and potential for success relating to commercializing FYARRO, or any other product candidate that we may develop, if approved;
- our plans related to the further development and manufacturing of FYARRO;
- the timing, scope or likelihood of regulatory filings and approvals for FYARRO for advanced malignant PEComa in foreign jurisdictions and any additional indications we may pursue and any other product candidates we may develop in the future;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the pricing and reimbursement of FYARRO and any other product candidates we may develop in the future, if approved;
- the rate and degree of market acceptance of FYARRO and any other product candidates we may develop in the future, if approved;
- the timing, progress and results of preclinical studies and clinical trials for our programs and product candidates, including the impact of the COVID-19 pandemic, the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- our ability to recruit and enroll suitable patients in our clinical trials;
- the expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of FYARRO and any other product candidates that we may develop in the future;
- our ability to develop and advance product candidates into, and successfully complete, clinical studies;
- the implementation of our business model and our strategic plans for our business;
- our ability to establish or maintain collaborations or strategic relationships or obtain additional funding;
- our ability to contract with and rely on third parties to assist in conducting our clinical trials and manufacturing FYARRO and any other product candidates we may develop in the future;
- the size and growth potential of the markets for FYARRO and any other product candidates we may develop in the future, if approved, and our ability to serve those markets, either alone or in partnership with others;
- our ability to obtain funding for our operations, including funding necessary to commercialize FYARRO and to complete further development, approval and, if approved, commercialization of FYARRO in additional indications and any other product candidates we may develop in the future;
- the period over which we anticipate our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements;
- the potential for our business development efforts to maximize the potential value of our portfolio;
- our ability to compete with other companies currently marketing or engaged in the development of treatments for the indications that we are pursuing for FYARRO and any other product candidates we may develop in the future;

- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- our financial performance;
- statements regarding the legal proceedings related to the termination of the EOC License Agreement (as defined herein);
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals, including due to the recent leadership transitions and identifying a new permanent chief executive officer;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- other factors including but not limited to those detailed under the section entitled "*Risk Factors*."

Forward-looking statements are not historical facts, but rather are based on current expectations, estimates, assumptions, and projections about the business and future financial results of the pharmaceutical industry, and other legal, regulatory and economic developments. In some cases, you can identify forward-looking statements by terms such as "may," "will," "intend," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "predict," "potential," "continue," "likely," and similar expressions (including their use in the negative) intended to identify forward-looking statements although not all forward-looking statements contain these identifying words. Actual results could differ materially from the results contemplated by these forward-looking statements due to a number of factors, including, but not limited to, those described in Part I, Item 1A (Risk Factors) of this Annual Report.

You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Annual Report and the documents that we reference in this Annual Report and have filed with or furnished to the U.S. Securities and Exchange Commission (the "SEC") completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Annual Report represent our views as of the date of this Annual Report. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

References in the following discussion to "we," "our," "us," or "Aadi" refer to Aadi Bioscience, Inc. and its subsidiaries.

PART I

Item 1. Business.

Overview

We are a biopharmaceutical company focused on developing and commercializing precision therapies for genetically defined cancers with alterations in mTOR pathway genes. Our lead drug product, FYARRO®, is a form of sirolimus bound to albumin. Sirolimus is a potent inhibitor of the mTOR biological pathway, the activation of which pathway can promote tumor growth. We believe our approach to utilizing albumin bound sirolimus has the potential to produce transformational therapies for cancer patients with mTOR pathway driver alterations where other mTOR inhibitors have not or cannot be effectively exploited due to problems of pharmacology, effective drug delivery, safety, or effective targeting to the disease site.

We exclusively license FYARRO, previously called ABI-009, *nab*-sirolimus, from Abraxis BioScience, LLC, a wholly owned subsidiary of Celgene Corporation, which is a wholly owned subsidiary of Bristol-Myers Squibb Company (“BMS”). Throughout this document we refer to FYARRO (*nab*-sirolimus, sirolimus protein-bound particles for injectable suspension (albumin-bound)) as FYARRO in the context of commercialization for the treatment of advanced malignant perivascular epithelioid cell tumor (“PEComa”), investigational use, our clinical trials, regulatory matters such as orphan drug designation and our license agreement with BMS, all further discussed below and throughout this document.

On November 22, 2021, the U.S. Food and Drug Administration (the “FDA”) approved FYARRO sirolimus protein-bound particles for injectable suspension (albumin-bound) for the treatment of adult patients with locally advanced unresectable or metastatic malignant PEComa. On February 22, 2022, we launched FYARRO in the United States for treatment of advanced malignant PEComa and recognized net revenue from product sales of $15.2 million for the year ended December 31, 2022.

In addition to advanced malignant PEComa, based on exploratory data from the completed Phase 2 registrational study, Advanced Malignant PEComa Trial (“AMPECT”) and our expanded access program (the "Expanded Access Program"), we initiated a registration-directed tumor-agnostic Phase 2 study (“PRECISION 1”) of FYARRO in patients with Tuberous Sclerosis Complex 1 and 2 (“*TSC1”* & “*TSC2”*) alterations. We have completed a Type B meeting with the FDA in which we discussed the trial design and the PRECISION 1 trial was opened for enrollment in the United States during the first quarter of 2022, with dosing of our first patient in March 2022.

Our Strategy

Our objective is to develop and commercialize innovative drugs that address the serious unmet medical needs of cancer patients and patients with other diseases that are driven by alterations in the mTOR pathway. The principal components of our strategy include:

- ***Commercialize FYARRO in advanced malignant PEComa.***

  For FYARRO, we are initially targeting advanced malignant PEComa, an ultra-rare sarcoma with no approved therapies other than FYARRO. In May 2021, we completed the filing of a rolling new drug application ("NDA") submission with the FDA for FYARRO for the treatment of advanced malignant PEComa based on the positive results from AMPECT, our pivotal Phase 2 study in this patient population, which met its primary endpoint. The FDA accepted the NDA in July 2021 and we were granted approval for commercial sale of FYARRO on November 22, 2021. We built a cross functional commercial team and infrastructure and launched FYARRO for advanced malignant PEComa in the United States in the first quarter of 2022.

- ***Expand the market opportunity for FYARRO by pursuing development of a tumor-agnostic indication in cancer patients with alterations in the TSC1 or TSC2 genes.***

  We have presented initial data for FYARRO in patients with different cancer types having alterations in the *TSC1* or *TSC2* genes as part of the Expanded Access Program. Based on exploratory data in patients with *TSC1* or *TSC2* alterations from the completed AMPECT and the Expanded Access Program, in the first quarter of 2022, we initiated a registration-directed tumor-agnostic study called PRECISION 1 in patients with malignant solid tumors driven by *TSC1* or *TSC2* alterations. The PRECISION 1 trial was opened for enrollment in the United States during the first quarter of 2022 and our first patient was dosed in March 2022.

- ***Expand the application of FYARRO as a monotherapy and combination therapy with other agents.***

  We believe there is a significant opportunity to utilize FYARRO in other indications as a monotherapy as well as in combination with other targeted therapies, particularly in mTOR adjacent signaling pathways. These additional indications may be important drivers of commercial value and we believe that strategic partnerships, particularly in combination therapies, may be an effective means of developing and commercializing these opportunities. While we are primarily focused on cancer, the mTOR pathway is also relevant in other indications and we may opportunistically study these indications to broaden the application of FYARRO or satisfy unmet medical needs. In October 2022, we entered into a collaboration and supply agreement with Mirati Therapeutics, Inc. (“Mirati”) to evaluate the combination of Mirati’s adagrasib, a $KRAS^{G12C}$ selective inhibitor, and FYARRO in $KRAS^{G12C}$ mutant non-small cell lung cancer ("NSCLC") and other solid tumors. Under the terms of the agreement, Mirati is responsible for sponsoring and operating the Phase 1/2 study and we will supply study drug and jointly share the cost of the study.

- ***Establish capabilities and/or partnerships outside the United States to effectively commercialize and maximize the value of FYARRO.***

  We have built capabilities in the United States to commercialize our products. Outside the United States, we intend to selectively evaluate strategic partnerships with partners whose development and commercial capabilities complement our own.

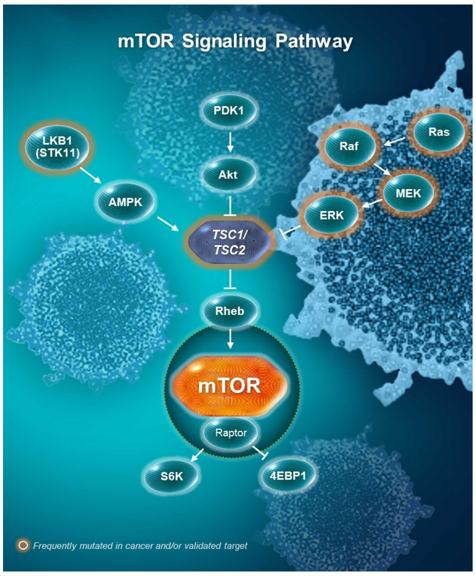
Our management team has extensive experience in the discovery, development, and commercialization of cancer therapeutics, including in senior roles at leading oncology companies. We are supported by our board of directors and specialized scientific advisors, who contribute their deep understanding of drug discovery and development, as well as expertise in building public companies and business development. We believe that our team is well positioned to execute on our strategy to develop and commercialize FYARRO and future pipeline assets to ultimately bring significant benefit to cancer patients worldwide.

Our Science

Importance of the mTOR Pathway in Cancer

mTOR is a serine–threonine kinase that is the key component of two multi-subunit complexes with non-overlapping downstream targets: mTOR Complex 1 (“mTORC1”) and mTOR Complex 2 (“mTORC2”). mTORC1 plays a vital role in the regulation of cell growth and division by controlling the balance between anabolic and catabolic cellular processes and facilitates the progression of cell-cycle from G1 to S phase. Due to its key role in anabolic processes needed for cell division, the majority of cancer cells have activation of mTORC1 through one mechanism or another. Thus, the effective inhibition of mTORC1 in cancer cells may inhibit their proliferation. Activation of mTORC1 may occur downstream of the PI3K/AKT or Ras/MEK/ERK pathways, or through inactivating alterations in negative regulators of the mTORC1 pathway, including *TSC1* or *TSC2*. Downstream signaling nodes of mTORC1, specifically S6K and 4EBP1, are key drivers of mTORC1 activity. Decreased phosphorylation of S6K leads to decreased activity, while decreased phosphorylation of 4EBP1 leads to increased activity. Sirolimus (also known as rapamycin) is an allosteric inhibitor of mTOR, which binds to the 12-kDa FK506-binding protein 12 ("FKBP12"), and the complex directly and strongly inhibits mTORC1.

Figure 1



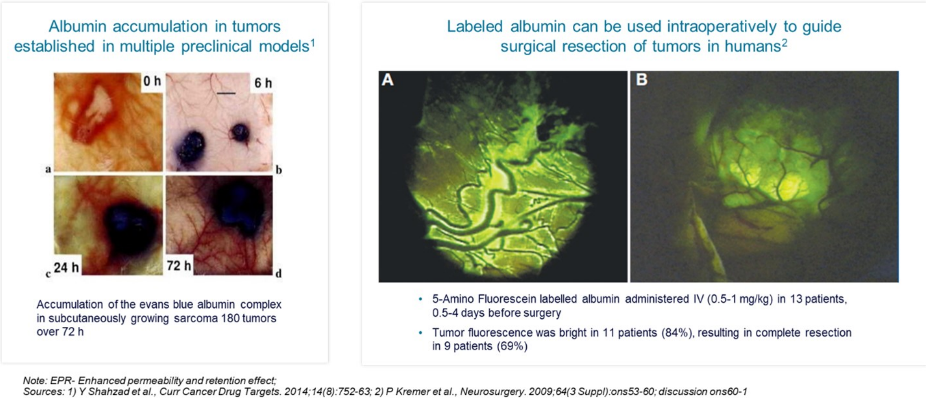
Currently approved mTOR inhibitors are limited in their applicability due to poor and variable absorption of the oral drugs (sirolimus and everolimus) or variable conversion from prodrug to active drug (temsirolimus) and premedication requirements (temsirolimus). These drugs have a narrow therapeutic index and a reduction from the labelled dose can result in a decrease in efficacy. Preclinical study comparisons with FYARRO showed significantly higher tumor uptake, greater downstream mTOR target suppression and increased suppression of tumor growth for FYARRO compared to the oral mTOR inhibitors. A literature comparison of the clinical pharmacokinetic profiles of the drugs shows that FYARRO has a longer half-life, higher peak blood concentration and greater total exposure than the other approved mTOR inhibitors. FYARRO is administered in cycles that are given weekly for two weeks followed by a week off and does not require therapeutic monitoring to ensure adequate blood levels.

Nanoparticle Albumin-Bound (nab) Technology

The nanoparticle albumin-bound, or nab, technology was created and developed by Neil Desai, our founder and Executive Chairman, and former colleagues while at Abraxis Bioscience. This technology takes advantage of the protein albumin, a natural carrier of water insoluble molecules (e.g., various nutrients, vitamins and hormones) found in humans. Due to various active and passive transport processes in the body, albumin can accumulate preferentially in different tissues including tumors, areas of inflammation, or areas of tissue remodeling, i.e., at sites of disease. The nab technology takes advantage of these transport properties of albumin and its affinity of binding to certain drug molecules to increase the efficiency with which these molecules may be brought to these sites of disease. The first clinical and commercial validation of this technology is BMS's Abraxane®, which is approved in the United States and worldwide for the treatment of breast cancer, non-small cell lung cancer and pancreatic cancer. Abraxane has generated >$1.0 billion of sales in the United States every year since 2018.

We are applying the nab technology to the molecule sirolimus, a potent inhibitor of the mTOR pathway that is hindered in large part by a poor pharmacologic profile (e.g., poor and variable absorption with incomplete target suppression). The relevance of albumin transport in cancer has been extensively studied and albumin is known to accumulate in tumor tissues due to the leaky capillary system within the tumor, defective lymphatic drainage of tumors, and active caveolae-mediated transport across tumor blood vessel endothelium. In addition, albumin can be taken up by proliferating tumor cells via endocytosis and macropinocytosis, then catabolized by lysosomal degradation to support de novo protein synthesis, energy, and tumor growth. Ultimately, nab technology allows FYARRO to take advantage of albumin transport pathways to accumulate at high levels in tumors and deliver sirolimus directly to cancer cells where it can effectively inhibit mTOR. The accumulation of albumin in tumors can be easily visualized by using the dye evans blue which has a high affinity for albumin. Intravenous injection of albumin-evans blue complex in animals bearing tumors resulted in rapid accumulation of the complex within the tumors which could be easily visualized in a few hours after injection. Similarly, a fluorescent labelled albumin when injected into human glioblastoma patients 24-48 hours before surgery resulted in excellent visualization of the tumors during surgery under fluorescent light and allowed the complete resection of the tumor margins in the majority of the patients treated.

Figure 2 – Albumin Accumulation

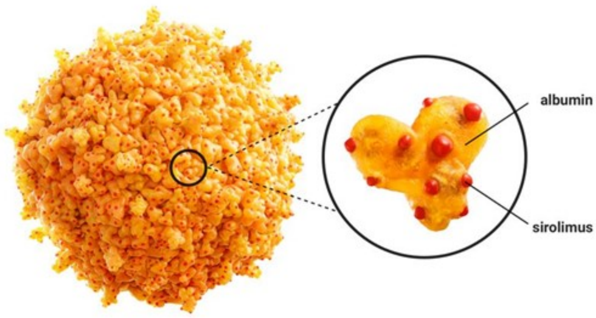


Our Product

FYARRO® (*nab*-sirolimus, sirolimus protein-bound particles for injectable suspension (albumin-bound))

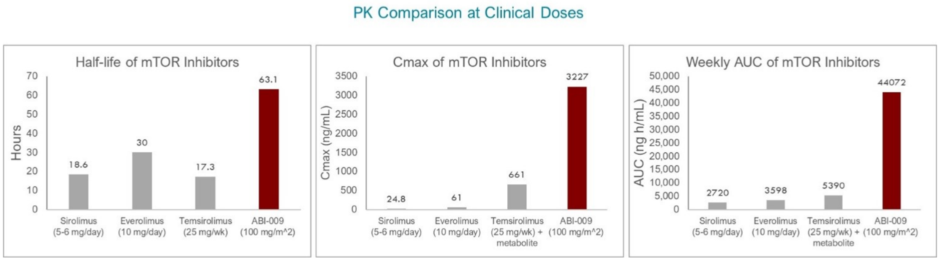
FYARRO is a form of sirolimus bound to albumin. Sirolimus is a potent inhibitor of the mTOR biological pathway and inhibits downstream signaling from mTOR, which can promote tumor growth. FYARRO is composed of nanoparticles of sirolimus bound to human albumin with average size less than 100 nanometers. An artist's impression of these nanoparticles is shown below.

Figure 3 – Nanoparticle artist impression



The orally available mTOR inhibitors have poor and variable absorption, often require therapeutic drug monitoring, and have incomplete target suppression. The combination of sirolimus with human albumin in FYARRO achieves higher area under the curve (AUC), Cmax and longer half-life in humans at its clinical dose when compared with published clinical data for other mTOR inhibitors, demonstrating FYARRO's differentiated clinical pharmacologic and pharmacokinetic profile.

Figure 4 – FYARRO PK Profile



These differences in pharmacology can result in advantageous differences in the clinical behavior of FYARRO when compared to the other mTOR inhibitors. This is effectively illustrated in comparative experiments in animals bearing bladder cancer tumors or liver cancer tumors. Data from these tumor-bearing animal models showed many-fold higher tumor drug levels for FYARRO at equal dose to the other mTOR inhibitors which was correlated with a greater degree of mTOR target suppression as indicated by inhibition of phosphorylation of S6 and 4EBP1 (downstream signaling nodes of mTORC1 that are known to play a role in downstream activity of mTOR as well as resistance to mTOR suppression), and a correspondingly higher suppression of tumor growth.

We believe that other mTOR inhibitors on the market or active in clinical development do not have the required favorable pharmacological profile to fully exploit the benefits of mTOR inhibition. We believe that FYARRO's differentiated pharmacologic profile, high tumor accumulation, and ability to effectively inhibit important targets in the mTOR pathway make it a well-positioned drug to address resistance and suboptimal efficacy of existing mTOR inhibitors.

We are studying FYARRO in cancers with known mTOR pathway activation, including tumor-agnostic indications targeting specific genomic alterations that activate the mTOR pathway. In addition, we have ongoing studies as well as studies in planning for testing the safety and efficacy of FYARRO in combination with other targeted agents, such as our current collaboration with Mirati to evaluate the combination of Mirati's adagrasib, a KRASG12C selective inhibitor, and FYARRO in KRASG12C mutant non-small cell lung cancer (NSCLC) and other solid tumors. Our ongoing studies and studies in planning are summarized in the figure below.

Figure 5 – Pipeline

Our EAP was opened to bridge access to FYARRO until market authorization and has since been closed in the United States following the commercial availability of FYARRO. The EAP is available for advanced malignant PEComa patients in certain countries outside the United States.

FYARRO - Commercial

Advanced Malignant PEComa. PEComas are mesenchymal neoplasms, composed of histologically and immunohistochemically distinctive cells, perivascular epithelioid cells ("PEC"s). Most PEComas are clinically benign and do not metastasize, but malignant PEComas can demonstrate local invasion and aggressive metastatic spread. PEComas show a wide anatomical distribution, but most often arise in the retroperitoneum, abdominopelvic region, uterus and gastrointestinal tract, and have a 4:1 female predominance. Malignant PEComas are classified as one of the ultra-rare soft-tissue sarcomas with an estimated annual incidence of roughly 100-300 patients per year in the United States, although formal epidemiology studies have yet to be conducted.

FYARRO is the first FDA approved treatment specifically for malignant PEComa. The disease is often treated with the cytotoxic chemotherapy regimens used in soft tissue sarcomas, which have shown only modest benefit for malignant PEComa. PEComas commonly show evidence of mTORC1 activation at least in part due to loss-of-function mutations in or deletions of the *TSC1* or *TSC2* genes. In a retrospective analysis, patients with malignant PEComa treated with available mTOR inhibitors (mTORi, sirolimus, everolimus, and temsirolimus) benefited from treatment suggesting that mTORC1 inhibition may be a promising therapeutic approach for malignant PEComa. As a result, available mTOR inhibitors may also be used to treat malignant PEComa.

In May 2021, we completed the filing of a rolling NDA for FYARRO to the U.S. Food and Drug Administration (the "FDA"), for approval to treat patients with advanced malignant PEComa. The NDA was based on results from our Phase 2 registration-directed study, Advanced Malignant PEComa Trial, ("AMPECT"), in advanced malignant PEComa for which there were, prior to FYARRO, no approved therapies in the United States and for which there had never been a prior prospective clinical trial.

In advanced malignant PEComa, other than FYARRO, there are no existing FDA approved therapies or drugs that have been studied in prospective clinical trials. Following FDA approval, the National Comprehensive Cancer Network ("NCCN") Sarcoma panel included FYARRO as the only preferred regimen for treatment of malignant PEComa.

On February 22, 2022, we launched FYARRO in the United States for treatment of advanced malignant PEComa and recognized net product sales of $15.2 million for the year ended December 31, 2022.

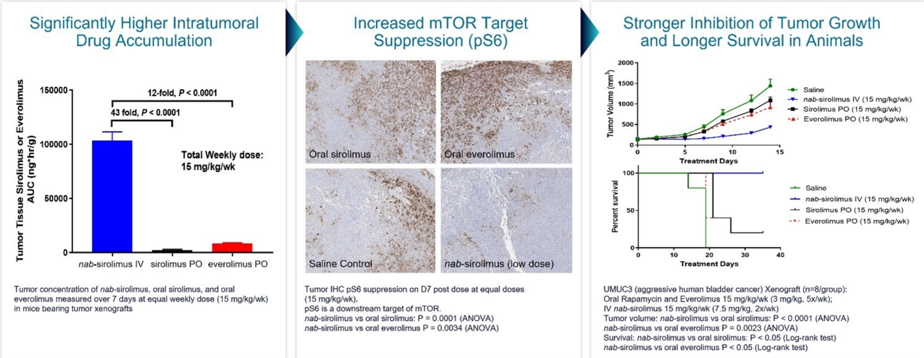
FYARRO - Clinical Development

Preclinical profile FYARRO

We demonstrated the antitumor activity of FYARRO in a series of nonclinical pharmacology studies. FYARRO exhibited antitumor activity as a single agent and in combination with other therapeutic agents in a wide range of tumor types. As a single agent, FYARRO significantly inhibited tumor growth of multiple human and mouse tumor models with known mTOR pathway activation including colon, breast, ovarian, bladder, and liver human tumor xenograft models, and in a melanoma mouse tumor model. In nonclinical PK studies, we have shown that FYARRO intravenous ("IV") administration resulted in significant, rapid, and prolonged sirolimus distribution to different organs and in tumors. As a single agent monotherapy and in combination with other therapies, FYARRO was well tolerated with limited body weight loss.

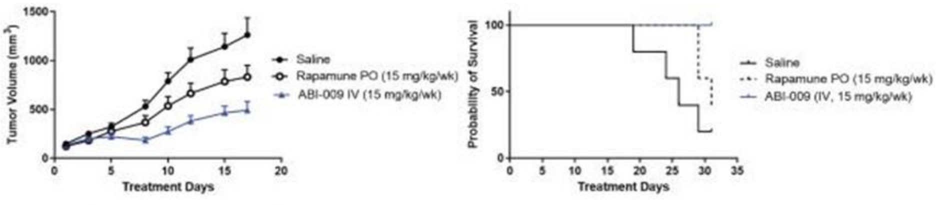
In March 2019, at the American Association for Cancer Research Annual Meeting, we presented preclinical data that describes the tumor accumulation, mTOR target inhibition, and antitumor activity of FYARRO IV in comparison to oral sirolimus and oral everolimus in athymic mice bearing UMUC3 human bladder tumor xenografts. At a clinically relevant dose of 15 mg/kg/week for all agents, FYARRO resulted in higher drug accumulation in tumors and stronger suppression of mTOR target pS6, which correlated with significantly greater tumor growth inhibition and prolonged survival compared with equal weekly dose of oral sirolimus and everolimus.

Figure 6



We also determined the antitumor activity of FYARRO in comparison to oral Rapamune against TSC2-null SNU-398 human liver tumor xenografts. At equal weekly dose of 15 mg/kg/week, FYARRO IV resulted in significantly greater tumor growth inhibition and longer animal survival, which correlated with stronger suppression of mTOR downstream targets pS6K, pS6, and p4EBP1 as measured by western blot.

Figure 7



Both as a single agent and in combination, the nonclinical studies support the clinical development of FYARRO as an anticancer therapy.

Advanced Malignant PEComa Trial (AMPECT)

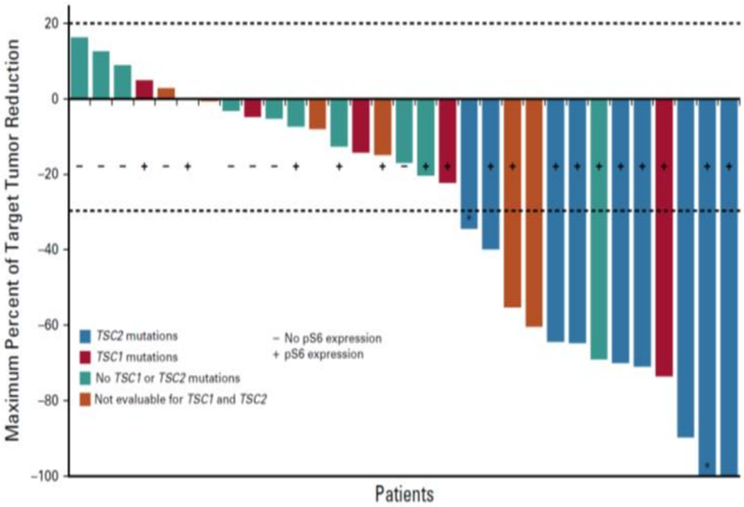
PEComa. AMPECT was the first prospective clinical trial in advanced malignant PEComa. Patients with metastatic or inoperable locally advanced disease were treated with FYARRO at 100 mg/m2 administered as an IV infusion over 30 minutes on Days 1 and 8 of a 21-day cycle. The primary endpoint for the study was ORR evaluated by independent radiology review. Secondary efficacy endpoints included duration of response (“DOR”), progression free survival (“PFS”) and overall survival (“OS”). The sample size estimation assumed an observed ORR of 30% for a sample size of 30 patients, which would exclude values less than 14.7% for the lower bound of the 95% confidence interval.

This registrational trial met its primary endpoint demonstrating the efficacy of *nab*-sirolimus in this rare disease for which there was no FDA approved treatment, with an independently assessed ORR of 39% (95% CI: 22%, 58%). Disease control (defined as complete or partial response (“CR” or “PR”) + stable disease ≥12 weeks) was achieved in 71% of patients. FYARRO (*nab*-sirolimus) was subsequently approved by the FDA for the treatment of advanced malignant PEComa on November 22, 2021.

Sixty-seven percent (8 of 12) of responses were seen at the first scan after baseline at week six (median time to response 1.4 months, 95% CI: 1.3 to 2.8 months). At the time of the primary analysis (predefined as when all patients had an opportunity to be treated for 6 months), the median for the key secondary endpoint of DOR was not yet reached, with 9 of 12 responders still on treatment (DOR range 4.2+, 27.7+ months). At 1.5-years of follow-up after the primary analysis date (i.e., 2-years after the last patient-initiated treatment), 7 of 12 responders were still receiving treatment and the median DOR was still not reached, with 50% of patients exceeding 2.5 years (DOR range 5.6, 47.2+ months).

Figure 6 shows the target tumor responses (waterfall plot). One patient with a primary renal PEComa metastatic to the lungs and lymph nodes had a PR for 10 months that converted to a CR. Responses were independent of the primary site and were observed in tumors originating in the uterus (3), kidney (3), retroperitoneum (2), pelvis (2), liver (1), and small bowel (1). Notably, 43% (3/7) of patients with uterine PEComa had a partial response. Responses were also observed in 3/4 patients who had previously received chemotherapy.

Figure 8 – Waterfall plot of Maximum Reduction in Target Lesions, Two-year Follow-up (Wagner et al., JCO 2021)



*A patient with unconfirmed PR is considered having SD as best response (trial required confirmation of responses per RECIST v1.1). Additionally, a patient with a complete response of target tumor reduction had a PR as best response because of unresolved nontarget lesions at the 2-year data cutoff (Wagner et al, JCO 2021); however, this patient later achieved a confirmed complete response (FYARRO Prescribing Information).

Treatment-related adverse events (“TRAE”) were consistent with those reported for other mTOR inhibitors. The most common hematologic events were anemia and thrombocytopenia, and the most common nonhematologic events were mucositis, rash and fatigue. The details are provided in Table 1 below. There were no grade 4 or 5 TRAEs. Noninfectious pneumonitis occurred in 6/34 (18%) patients and all were low grade (G1/G2). Patient discontinuation due to adverse events occurred on 3/34 (9%) patients (one grade 2 anemia and one grade 1 cystitis). Dose reductions occurred in 12/34 (35%) patients; 11 patients had a one dose reduction from 100 mg/m2 to 75 mg/m2 and 2 patients had two dose reductions to 56 mg/m2.

Table 1

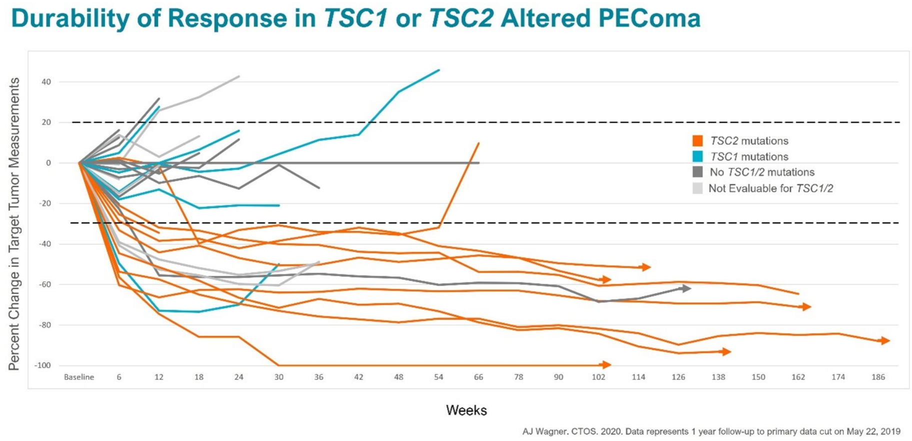
TRAE	Any Grade ≥ 25%, No. (%)	Grade 3, No. (%)
Patients with any TRAEs	34 (100)	
Hematologic TRAEs		
Anemia[a]	16 (47)	4 (12)
Thrombocytopenia[a]	11 (32)	1 (3)
Nonhematologic TRAEs		
Mucositis[a]	27 (79)	6 (18)
Rash[a]	19 (56)	—
Fatigue	20 (59)	1 (3)
Nausea	16 (47)	—
Diarrhea	13 (38)	—
Weight decreased	13 (38)	—
Hyperglycemia[a]	12 (35)	3 (9)
Hypertriglyceridemia[a]	11 (32)	1 (3)
Hypercholesterolemia[a]	11 (32)	—
Decreased appetite	11 (32)	—
Dermatitis[a]	10 (29)	—
Dysgeusi[a]	10 (29)	—
Headache	10 (29)	—
Peripheral edema	9 (26)	—

- “a” Indicates groupings of preferred terms defined by standardized queries in the Medical Dictionary for Regulatory Activities.
- Additional G3 TRAEs were 6% hypokalemia, and 3% each of AST/ALT, amylase, hypophosphatemia, insomnia, lipase, lymphocyte, skin infection, vomiting. No G4 TRAEs were reported.

In December 2017, we received Orphan Drug Designation (“ODD”) for FYARRO for the treatment of PEComa. In October 2018, the FDA granted Fast Track designation for FYARRO for the treatment of patients with advanced (metastatic or locally advanced) malignant PEComa. In December 2018, the FDA granted Breakthrough Therapy Designation (“BTD”) for FYARRO for the treatment of patients with advanced (metastatic or locally advanced) malignant PEComa. The FDA accepted the NDA in July 2021 and granted full approval on November 22, 2021. In January 2023, the FDA granted us orphan drug exclusivity ("ODE") for FYARRO for the treatment of patients with advanced malignant PEComa. As a result of ODE for FYARRO in the advanced malignant PEComa indication, the FDA may not approve any other application to market the same drug for the same indication for a period of seven years from NDA approval of FYARRO (November 22, 2028), except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity.

TSC1 and TSC2 Alterations. An exploratory mutational analysis was conducted on patients treated with FYARRO in the AMPECT study in advanced malignant PEComa. In 25 patients with available mutational analysis, *TSC1* or *TSC2* alterations were found in 14 patients (56%). In this subset of patients with *TSC1* or *TSC2* alterations, the response rate was 64% (9/14) (Figure 8). In particular, *TSC2* mutations were significantly associated with response (89% of patients) to FYARRO.

Figure 9 – Spider plot demonstrating change in the sum of target tumor measurements over time, based on mutation status**.**

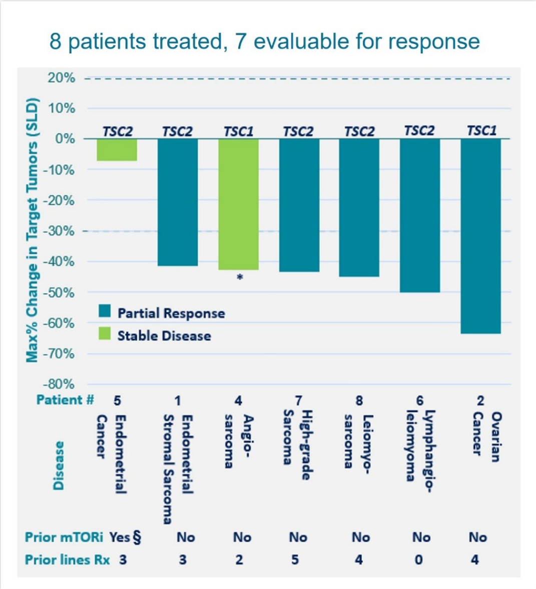


* Arrowheads indicate patients who were still on treatment

TSC1 and TSC2 Alterations in the Expanded Access Program

The Expanded Access Program was opened to bridge access to FYARRO until market authorization for patients with advanced malignant PEComa; this program also included patients with various other malignancies having relevant genetic mutations in the mTOR pathway. Preliminary data was presented at American Society of Clinical Oncology ("ASCO") Annual Meeting in 2021 showing the early results in tumors bearing *TSC1* or *TSC2* inactivating alterations in patients with histologies other than advanced malignant PEComa. Of the 8 patients treated with FYARRO, 7 patients were evaluable for response analysis and 1 patient progressed before the first scan. Five of 8 patients (63%, 95% CI: 25%-92%) achieved a confirmed PR. Amongst the patients who were mTOR inhibitor-naïve, 5 of 6 (83%, 95% CI: 36%-99+%) achieved a confirmed PR. Duration of response at data cutoff ranged from 3.1 to 9.7+ months and 3 of 5 responders continue on treatment. A waterfall plot of tumor response is provided below Figure 9. Figure 10 shows the prior therapy and duration of treatment for each patient. Patients with inactivating alterations in either *TSC1* or *TSC2* achieved tumor shrinkage and clinical benefit.

Figure 10



Source: MA Dickson. ASCO. 2021. Abstract # 3111

Figure 11

Source: MA Dickson. ASCO. 2021. Abstract # 3111

TEAEs (30%) included edema, infections, mucositis, and pain (71% each), nail changes and vomiting (57% each), and hypertension and nausea (43% each). The majority of the events were G1/G2. Treatment-related serious adverse events ("TESAE") were reported in 2 patients and included hyperglycemia and infection (patients #4 and #5) and acute kidney injury (patient #7) possibly also related to administration of contrast. Dose reductions occurred in 3/8 patients (38%) from 100 mg/m2 to 75 mg/m2.

A recent published case report summarized the results of a patient with malignant PEComa patient with a *TSC1* alteration who enrolled in the EAP after having progressed through treatment with the mTOR inhibitor everolimus. The patient demonstrated a rapid and durable response to FYARRO.

FYARRO in patients with prior mTOR inhibitors

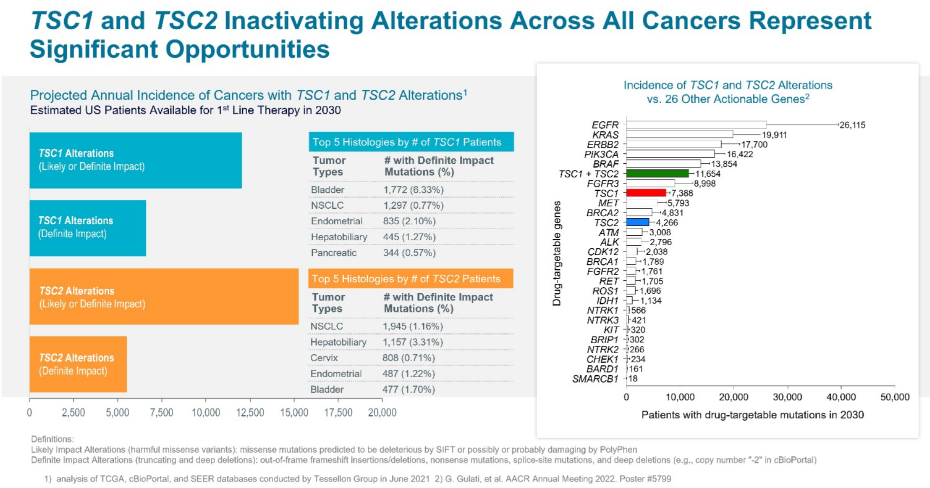
A post hoc electronic medical record review provided evidence of clinical benefit of *nab*-sirolimus in patients with malignant PEComa who had progressed or failed prior mTOR inhibitor treatment: 25% achieved a response (duration of response range: 1.3+–25.2+ months, 3 ongoing), and 50% had stable disease as best response as best response. Of patients with *TSC1 or TSC2* inactivating alterations, 44% had a response.

PRECISION 1 Clinical Trial.

PRECISION 1 is a registration-directed tumor-agnostic Phase 2 study of FYARRO in patients with *TSC1* and *TSC2* inactivating alterations that is based on evidence of activity seen in patients with *TSC1* and *TSC2* inactivating alterations from the completed AMPECT trial (presented at the Connective Tissue Oncology Society (CTOS) Annual Meeting in 2020) and the Expanded Access Program (presented at the ASCO Annual Meeting in 2021). We have completed a Type B meeting with the FDA in which we discussed the trial design with the FDA. The PRECISION 1 trial was opened for enrollment in the United States during the first quarter of 2022 and the first patient was dosed in March 2022. We anticipate having preliminary data on a meaningful number of patients in the PRECISION 1 trial during the second quarter of 2023.

The *TSC1* and *TSC2* genes encode for proteins that form a tumor suppressor complex that down regulates mTORC1 activity. Inactivating alterations in the *TSC1* or *TSC2* genes can result in activation of mTORC1. *TSC1* or *TSC2* alterations have been reported across a broad range of cancer types. Based on the SEER cancer statistics database and an analysis of mutation frequency by cancer type using the TCGA and cBioPortal databases, we believe there is a significant number of new patients with *TSC1* or *TSC2* inactivating alterations per year in the U.S (see chart titled "Projected Annual Incidence of Cancers with *TSC1* and *TSC2* Alterations" below). While there are no therapies approved specifically for *TSC1* or *TSC2* alterations, numerous case reports show durable responses to mTOR inhibition in patients with these alterations.

Figure 12



FYARRO in combination with KRAS^{G12C} inhibitors for KRAS^{G12C}-mutated cancer xenografts

In 2022, we conducted preclinical studies to investigate the antitumor activity of mTOR inhibitors, FYARRO or everolimus, in combination with KRAS^{G12C} inhibitors, sotorasib or adagrasib, in KRAS G12C-mutated cancer xenografts. KRAS is frequently mutated in non-small cell lung cancer (NSCLC) and other tumor types, with the KRAS^{G12C} present in approximately 9% of NSCLC patients. The mTOR pathway is often activated in patients with the KRAS mutation and contributes to adaptive resistance to KRAS inhibitors. We conducted these studies to determine the utility of a combination of the mTOR inhibitor nab-sirolimus and KRAS inhibitors, which could have synergistic potential in the treatment of

KRAS mutated cancers. Results of these studies showed that combining FYARRO with either of the $KRAS^{G12C}$ inhibitors significantly improved response against $KRAS^{G12C}$ mutant lung cancer and bladder cancer tumors in vivo and FYARRO also showed significantly greater potency in the combination compared to everolimus.

FYARRO for other indications

FYARRO is planned to be investigated in additional cancer indications as both single-agent or in combination with other drugs. We believe there is a significant opportunity to utilize FYARRO in other indications as a monotherapy, e.g., in other mTOR pathway mutations, as well as in combination with other targeted therapies, particularly in mTOR adjacent signaling pathways. For example, we currently are collaborating with Mirati to evaluate the combination of Mirati's adagrasib, a $KRAS^{G12C}$ selective inhibitor, and FYARRO in $KRAS^{G12C}$ mutant NSCLC and other solid tumors. These additional indications may be important drivers of commercial value and will continue to be evaluated.

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover formulations of FYARRO, its methods of use, related technologies, and other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, including our proprietary method of manufacturing FYARRO.

Our commercial success depends in part upon our ability to obtain and maintain patent and other proprietary protection for FYARRO and other commercially important technologies, inventions, and know-how related to our business, defend and enforce our intellectual property rights, in particular, our patent rights, preserve the confidentiality of our trade secrets, and operate without infringing valid and enforceable intellectual property rights of others.

The patent positions for biotechnology and pharmaceutical companies like us are generally uncertain and can involve complex legal, scientific, and factual issues. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that FYARRO will be protected or remain protectable by enforceable patents. Moreover, any patents that we hold may be challenged, circumvented, or invalidated by third parties. For more information regarding the risks related to our intellectual property please see "Risk Factors— Risks Related to Our Intellectual Property".

We own or exclusively license twelve (12) issued patents in the United States as well as issued patents in other countries. With respect to our licensed patents, we have exclusive, sublicensable rights to certain patents and patent applications relating to FYARRO under our license agreement with BMS. As of December 31, 2022, we licensed five (5) issued U.S. patents with composition of matter and method of use claims covering FYARRO. The first issued U.S. patent is expected to expire in 2029, and the other four are expected to expire in 2030, 2036, 2036 and 2040, respectively. In addition, we licensed related patents in Europe, Australia, North America, South America, and Asia that are expected to expire between 2023 and 2037. We also licensed many pending U.S. applications and related pending applications in Europe, Australia, North America, South America, Africa, and Asia.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application.

In the United States, the term of a patent covering an FDA approved drug may, in certain cases, be eligible for a patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, as compensation for the loss of patent term during FDA regulatory review process. The period of extension may be up to five years but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. In January 2022, we filed an application for patent term extension based on the approval of FYARRO. We also intend to seek patent term extensions in any jurisdictions where they are available, however, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

In addition to patent protection, we also rely on trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection, including, for example, certain aspects of our manufacturing processes for the nanoparticle compositions. However, trade secrets can be difficult to protect. Although we take steps to protect our proprietary information, including restricting access to our premises and our confidential information, as well as entering into agreements with our employees, consultants, advisors, and potential collaborators, such individuals may breach such agreements and disclose our proprietary information including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information. For more information regarding the risks related to our intellectual property please see "Risk Factors—Risks Related to Our Intellectual Property."

Commercial Operations

We have built a cross-functional commercial organization and infrastructure to support the commercialization of FYARRO for advanced malignant PEComa in the United States and will continue to evaluate potential partners in markets outside the United States. We have an experienced oncology commercial team including marketing, market access, commercial operations and sales personnel to educate physicians who are prescribers of treatments for advanced malignant PEComa. Our sales team is supported by marketing, commercial operations, and market access functions. We have assembled a network of specialty distributors and a specialty pharmacy to distribute FYARRO across multiple sites of care in the United States. Additionally, the sales and marketing teams manage relationships with key accounts such as managed care organizations, group purchasing organizations, hospital systems, physician group networks, and government accounts.

For future approvals of FYARRO in other oncology indications, if any, we intend to retain commercialization rights in the United States and leverage our commercial and marketing organization for FYARRO, with appropriate additions or modifications as necessitated by the specific indications pursued, assuming we obtain regulatory approval in the United States, and consider whether to build our own commercial and marketing organization in select markets outside the United States, or selectively establish partnerships. Accordingly, we will consider entering into relationships with strategic partners that enable the expansion of the ongoing clinical development and/or licenses for development and commercialization or distribution, while retaining significant value for our shareholders. These partnerships could focus on specific patient populations and their caregivers, on regional development, or on distribution and sales.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary drugs. While we believe that our technology, development experience, and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies, and public and private research institutions. Any drug candidates that we successfully develop and commercialize will compete with existing drugs and new drugs that may become available in the future. We compete in the segments of the pharmaceutical, biotechnology, and other related markets that address inhibition of kinases in cancer and other rare genetic diseases. There are other companies working to develop therapies in the field of kinase inhibition for cancer and other diseases. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes.

Many of the companies against which we are competing against or which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology, and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

Competition for FYARRO in Advanced Malignant PEComa

In advanced malignant PEComa, other than FYARRO, there are no existing FDA approved therapies or drugs that have been studied in prospective clinical trials. Following FDA approval, the National Comprehensive Cancer Network ("NCCN") Sarcoma panel included FYARRO as the only preferred regimen for treatment of malignant PEComa. FYARRO may face competition from available mTOR inhibitors including sirolimus, everolimus, and temsirolimus or other drug candidates in clinical trials. As of today, we are not aware of any other companies pursuing FDA approval for drugs to treat advanced malignant PEComa.

Competition for FYARRO in Truncating TSC1 and TSC2 Inactivating Alterations

For truncating *TSC1* or *TSC2* inactivating alterations, there are no existing FDA approved drugs. If FYARRO receives marketing approval, it may face competition from available mTOR inhibitors including sirolimus, everolimus, and temsirolimus or other drug candidates in clinical trials that target the mTOR pathway, such as dual mTORC1/2 inhibitors or other next-generation mTOR inhibitors.

Manufacturing

We do not own or operate, and have no plans to establish, any manufacturing facilities. We currently rely on third parties to manufacture FYARRO for preclinical and clinical testing, as well as for our commercial supply of FYARRO.

The Amended and Restated License Agreement for FYARRO with BMS, dated November 2019, transferred the responsibility for manufacturing of FYARRO to us. FYARRO was previously manufactured for us by BMS through their third-party manufacturer, Fresenius-Kabi, USA. As a result of the amendment to the License Agreement, we now obtain FYARRO directly from Fresenius-Kabi, USA.

To date, we have obtained drug substance and drug product from third-party manufacturers to support pre-clinical and clinical testing of FYARRO. On January 13, 2022, we entered into a Negotiated Purchase Order Terms and Conditions for Clinical and Commercial Product, as amended effective as of August 1, 2022 (the "Fresenius Agreement"), with Fresenius Kabi, LLC ("Fresenius Kabi") pursuant to which Fresenius Kabi will manufacture FYARRO for us, and we will purchase FYARRO as a finished drug product from Fresenius Kabi, on a purchase-order basis. Under the Fresenius Agreement, which is effective through March 31, 2024 (or such later date as may be agreed between the parties in writing), we may purchase FYARRO for either clinical or commercial purposes for use in the United States and Canada. We have a fully validated commercial manufacturing process in place for FYARRO at the Fresenius Kabi's Grand Island Manufacturing facility. We are evaluating options with Fresenius Kabi to create redundant supply of FYARRO. In addition to manufacturing, Fresenius Kabi will perform specified labeling, packaging and serialization activities in respect of FYARRO for our benefit. The price of FYARRO will be fixed, subject to the ability of Fresenius Kabi to increase pricing under specified circumstances. We have an obligation to purchase certain minimum quantities of FYARRO. Failure to purchase those minimum quantities will result in an additional payment from us to Fresenius Kabi.

We have supply agreements in place for key raw materials used in the manufacture of FYARRO such as the drug substance sirolimus and for human albumin, which are key ingredients in the drug product. We do not currently have arrangements in place for redundant supply of the key raw materials used in the manufacture of FYARRO. We expect to continue to evaluate options to cost-effectively produce FYARRO at contract manufacturing facilities.

We generally expect to rely on third parties for the manufacture or development of any companion diagnostics if we are required to do so in the future for FYARRO.

Government Regulation

Government authorities in the United States, including federal, state, and local authorities, and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling and packaging, storage, distribution, post-approval monitoring and reporting, advertising and promotion, and export and import of pharmaceutical and biological products, such as those we are developing. In addition, some government authorities regulate the pricing of such products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Government Regulation

Government authorities in the United States, at the federal, state, and local level, and other countries extensively regulate, among other things, the research, development, nonclinical and clinical testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, and export and import of products such as those we are developing.

Generally, before a new drug can be marketed, considerable data must be generated, which demonstrate the drug's quality, safety, and efficacy. Such data must then be organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

Drugs are also subject to other federal, state, and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable regulatory requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the regulatory authority's refusal to approve pending applications, withdrawal of an approval, clinical holds, untitled or warning letters, voluntary product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, debarment, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

U.S. Drug Development

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations. Drugs are also subject to other federal, state, and local statutes and regulations. Drugs must be approved by the FDA through the NDA process before they may be legally marketed in the U.S. The process required by the FDA before a drug may be marketed in the U.S. generally involves the following:

- completion of extensive preclinical, sometimes referred to as nonclinical, laboratory tests, animal studies, and formulation studies all performed in accordance with applicable regulations, including the FDA's good laboratory practice ("GLP") regulations;
- submission to the FDA of an investigational new drug application ("IND"), which must become effective before human clinical trials may begin and must be updated annually and amended in accordance with the regulations;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical trial-related regulations, sometimes referred to as good clinical practices ("GCPs"), to establish the safety and efficacy of the proposed drug for its proposed indication(s);
- submission to the FDA of an NDA for a new drug;
- 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 pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient ("API") and finished drug product are produced to assess compliance with the FDA's current good manufacturing practice requirements ("cGMP");
- potential FDA audit of the testing laboratories and clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the U.S.

Prior to beginning a clinical trial with a product candidate in the United States, companies 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. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic 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 new IND, or 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 review board ("IRB") for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the clinical 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 may review data and endpoints at designated check points, make recommendations and/or 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 of ongoing clinical studies and clinical study results to public registries.

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, 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, and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3: The 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.

A pivotal study is a clinical study that adequately meets regulatory agency requirements for the evaluation of a drug candidate’s efficacy and safety such that it can serve as the primary basis for approval of the drug. Generally, pivotal studies are also Phase 3 studies but may be Phase 2 studies if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need. Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse reactions, any finding from other clinical studies, tests in laboratory animals, or in vitro testing that suggests a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor’s initial receipt of the information. Phase 1, Phase 2, and Phase 3 trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB’s requirements or if the drug has been associated with unexpected serious harm to patients.

We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate. 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 as well as finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, cGMPs impose extensive procedural, substantive, and recordkeeping requirements to ensure and preserve the long-term stability and quality of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

A manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the earlier of the first initiation of a Phase 2 or Phase 3 trial of the investigational drug or, as applicable, 15 days after the drug receives a designation as a breakthrough therapy, fast track product, or regenerative advanced therapy.

If our clinical trials continue to be impacted by COVID-19, we may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus. For example, since the start of the pandemic, the FDA has issued various COVID-19 related guidance documents, including guidance on conducting clinical trials during the COVID-19 pandemic, good manufacturing practice considerations for responding to COVID-19 infection in employees in drug products manufacturing; manufacturing, supply chain, and drug and biological product inspections during COVID-19 public health emergency; and remote interactive evaluations of drug manufacturing and bioresearch monitoring facilities during the COVID-19 public health emergency. Changes in FDA's operations and policies, including delays in providing regulatory review or feedback to sponsors or delays in pre-approval inspections, as a result of the COVID-19 public health emergency can materially impact our clinical development plans and regulatory approval. Recently, President Biden announced that the administration intends to end the COVID-19 national and public health emergencies on May 11, 2023. The full impact of the termination of the public health emergencies on FDA and other regulatory policies and operations are unclear.

NDA and the FDA Review Process

Following trial completion, trial data are analyzed to assess safety and efficacy. The results of preclinical studies and clinical trials are then submitted to the FDA as part of a NDA, along with proposed labeling for the drug and information about the manufacturing process and facilities that will be used to ensure drug quality, results of analytical testing conducted on the chemistry of the drug, and other relevant information. The NDA is a request for approval to market the drug and must contain sufficient evidence of drug product quality, safety and efficacy, which is demonstrated by extensive analytical, preclinical and clinical testing. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a drug, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational drug product for a particular indication or indications to the satisfaction of the FDA. FDA approval of an NDA must be obtained before a drug may be offered for sale in the United States.

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 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 (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 12 months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after 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 does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification. In such event, the NDA must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed drug is safe and effective for its intended use, and whether the drug is being manufactured in accordance with cGMP to assure and preserve the drug's identity, strength, quality, and purity. The FDA may refer applications for novel drugs or drug candidates that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. In the course of its review, the FDA may re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. The review and evaluation of an NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

Before approving an NDA, the FDA typically conducts a pre-approval inspection of the manufacturing facilities for the new drug to determine whether they comply with cGMPs. The FDA will not approve the drug unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the drug within required specifications. In addition, before approving an NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process, and manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies, or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, challenge the determination set forth in the letter by requesting a hearing, or withdraw the application. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a drug product for marketing in the United States and we may encounter significant difficulties or costs during the review process. If a drug receives marketing approval, the approval may be significantly limited to specific diseases, dosages, or patient subgroups, or the indications for use may otherwise be limited, which could restrict the commercial value of the drug. Further, the FDA may require that certain contraindications, warnings, precautions, or adverse events be included in the drug labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing or clinical trials, and surveillance to monitor the effects of approved drugs.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail 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 (“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. It 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.

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. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA’s policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription, or dispensing of drugs. Drug approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

In November 2021, we received approval for the commercial sale of FYARRO from the FDA to treat patients with advanced (metastatic or locally advanced) PEComas. The NDA submission was based on results from our Phase 2 registrational study, AMPECT, in patients with advanced malignant PEComa, for whom there were no approved therapies in the U.S.

FDA Expedited Development and Review Programs

The FDA has various programs, including fast track designation, priority review, accelerated approval, and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs 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. With regard to a fast track product, 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.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis, or prevention of a disease 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 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 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 a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality, or other clinical endpoint and to submit promotional materials for preapproval and pre-use review, which could adversely impact the timing of the commercial launch of the product. In addition, the drug may be subject to accelerated withdrawal procedures. On December 29, 2022, the Consolidated Appropriations Act, 2023, including the Food and Drug Omnibus Reform Act (FDORA), was signed into law. FDORA made several changes to the FDA’s authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements.

The Food and Drug Administration Safety and Innovation Act established a category of drugs referred to as “breakthrough therapies” that may be eligible to receive breakthrough therapy designation. A sponsor may seek FDA designation of a product candidate as a “breakthrough therapy” if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, 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. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such drug.

In addition, the FDA may review new drug applications under the Oncology Center of Excellence Real-Time Oncology Review (“RTOR”), which, according to the FDA, aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality. Drugs considered for review under RTOR must be likely to demonstrate substantial improvements over available therapy, which may include drugs previously granted breakthrough therapy designation for the same or other indications, and must have straight-forward study designs and endpoints that can be easily interpreted. RTOR allows the FDA to review much of the data in an NDA earlier, before the applicant formally submits the complete application. This analysis of the pre-submission package gives the FDA and applicants an early opportunity to address data quality and potential review issues and allows the FDA to provide early feedback regarding the most effective way to analyze data to properly address key regulatory questions.

Fast track designation, priority review, accelerated approval, and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for FYARRO as appropriate.

Post-Marketing Requirements

Following approval of a new drug, a pharmaceutical company and the approved drug are subject to continuing regulation by the FDA, including, among other things, establishment registration and drug listing, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the drug, providing the regulatory authorities with updated safety and efficacy information, drug sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug’s approved labeling, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet.

In particular, 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. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling. Modifications or enhancements to the drug or its labeling or changes of the site or process of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process.

Prescription drug advertising is subject to federal, state, and foreign regulations. In the U.S., the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drugs and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act ("PDMA"), a part of the FDCA. The Drug Supply Chain Security Act ("DSCSA"), enacted in 2013, aims to build an electronic system to identify and trace certain prescription drugs distributed in the U.S. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that is expected to culminate in November 2023. The law's requirements include the quarantine and prompt investigation of a suspect product to determine if it is illegitimate and notifying trading partners and the FDA of any illegitimate product. Drug manufacturers and their collaborators are also required to place a unique product identifier on prescription drug packages. This identifier consists of the National Drug Code, serial number, lot number, and expiration date, in the form of a 2-dimensional data matrix barcode that can be read by humans and machines.

In the U.S., once a drug is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. FDA regulations require that drugs be manufactured in specific facilities per the NDA approval and in accordance with cGMP. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of its drugs in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural, and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute drugs manufactured, processed, or tested by them. Discovery of problems with a drug after approval may result in restrictions on a drug, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the drug from the market, and may require substantial resources to correct.

The FDA also may require post-approval testing, sometimes referred to as Phase 4 testing, risk minimization action plans, and post- marketing surveillance to monitor the effects of an approved drug or place conditions on an approval that could restrict the distribution or use of the drug. Discovery of previously unknown problems with a drug or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial, or administrative enforcement actions. 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 post-approval or Phase 4 clinical studies, if applicable;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license 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 may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Newly discovered or developed safety or effectiveness data may require changes to a drug's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures, including a REMS or the conduct of post-marketing studies to assess a newly discovered safety issue. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our drugs under development.

As a condition of the approval of the NDA for FYARRO, we are required to conduct certain post-marketing requirements ("PMR") and post-marketing commitments ("PMC"), which are ongoing. If we fail to comply with the PMR and PMC, the FDA may take enforcement actions, which may include, among other things, the issuance of a Warning Letter and assessing civil monetary penalties. The product may also be deemed misbranded.

Orphan Drug Designation

The FDA may grant orphan drug designation to drugs intended to treat a rare 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 marketing the drug for this type of disease or condition will be recovered from sales in the United States. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. After the grant of an orphan drug designation, FDA may revoke the designation if FDA finds that the request for designation contained an untrue statement of material fact, omitted required material information, or if FDA subsequently finds that the drug had not been eligible for the orphan drug designation at the time of the submission of the request.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity ("ODE"), which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. In January 2023, the FDA granted us ODE for FYARRO for the treatment of patients with advanced malignant PEComa.

In *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with the FDA's longstanding position that the ODE only applies to the approved use or indication within an eligible disease. This decision created uncertainty in the application of the ODE. On January 24, 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of ODE to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the ODE.

In the European Union, the European Commission, after receiving the opinion of the European Medicines Agency's ("EMA") Committee for Orphan Medicinal Products ("COMP"), grants orphan drug designation to also promote the development of products. The relevant European legislation provides that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention, or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Union when the application is made, or (2) a life-threatening, seriously debilitating, or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the product in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must also demonstrate that there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the product has to be of significant benefit compared to products available for the condition. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating, or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product.

In the European Union, orphan drug designation also entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following drug or biological product approval. During this market exclusivity period, neither the EMA nor the European Commission or the 27 member states that comprise the European Union can accept an application or grant a marketing authorization for the same therapeutic indication in respect of a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. This period may be reduced to six years if, after five years, the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration, and specifics of the FDA approval of our drug candidate, some of our United States patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. The U.S. Patent and Trademark Office ("USPTO"), in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Marketing exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications for competing products. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. 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 accept for review an abbreviated new drug application ("ANDA") or a 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 innovator drug or for another indication. 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 also 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) applications for drugs containing the active agent for the original indication or condition of use.

These five-year and three-year exclusivities will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

ODE, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances. Pediatric exclusivity is another type of regulatory market exclusivity in the U.S. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for a pediatric trial.

Other U.S. Regulatory Matters

Manufacturing, sales, promotion, and other activities following drug approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the U.S. Department of Health and Human Services ("HHS"), the Drug Enforcement Administration for controlled substances, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. In the United States, sales, marketing, and scientific/educational programs must also comply with state and federal fraud and abuse laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 (the "ACA"). If drugs are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Drugs must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion, and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

We are subject to numerous foreign, federal, state, and local 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. In addition, our leasing and operation of real property may subject us to liability pursuant to certain U.S. environmental laws and regulations, under which current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly, and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases.

The distribution of pharmaceutical drugs is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage, and security requirements intended to prevent the unauthorized sale of pharmaceutical drugs. The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines, or other penalties, injunctions, voluntary recall or seizure of drugs, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes, or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Coverage and Reimbursement

Sales of our drugs will depend, in part, on the extent to which our drugs will be covered by third-party payors, such as government health programs, commercial insurers, and managed healthcare organizations, as well as the level of reimbursement such third-party payors provide for our products. Patients and providers are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products in which our products are used. These third-party payors are increasingly reducing reimbursements for medical drugs and services.

In the U.S., no uniform policy of coverage and reimbursement for drugs or biological products exists, and one payor's determination to provide coverage and adequate reimbursement for a product does not assure that other payors will make a similar determination. In the U.S., the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within the HHS, as the CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private third-party payors tend to follow Medicare coverage and reimbursement limitations to a substantial degree, but also have their own methods and approval process apart from Medicare determinations. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for FYARRO will be made on a payor-by-payor basis. As a result, the coverage determination process may be a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high.

Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution of generic drugs. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for FYARRO or a decision by a third-party payor to not cover FYARRO could reduce physician usage of such drug and have a material adverse effect on our sales, results of operations and financial condition.

The Medicaid Drug Rebate Program ("MDRP") requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the MDRP, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate percentage on most branded prescription drugs of average manufacturer price ("AMP") and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, creating a new methodology by which rebates owed are calculated for drugs that are inhaled, infused, instilled, implanted, or injected, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufactures pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, while all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. These Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for drugs for which we may obtain marketing approval. However, any negotiated prices for our drugs covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the HHS, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures are made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of FYARRO, if any such drug or the condition that such drug is intended to treat are the subject of a trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's drug could adversely affect the sales of our drug candidate. If third-party payors do not consider our drugs to be cost-effective compared to other available therapies, they may not cover our drugs as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our drugs on a profitable basis.

In recent years, additional laws have resulted in direct or indirect reimbursement reductions for certain Medicare providers. For example, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2022, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments can vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws, and future state and federal healthcare reform measures, as discussed further below, may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any indication of FYARRO for which it may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and other third-party payors fail to provide adequate coverage and reimbursement. We expect that an increasing emphasis on cost containment measures in the U.S. will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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

U.S. Healthcare Reform

The ACA has had a significant impact on the healthcare industry. The ACA expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, the ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the MDRP are calculated for drugs that are inhaled, infused, instilled, implanted, or injected, increased the minimum Medicaid rebates owed by manufacturers under the MDRP and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) 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. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than they receive on the sale of products, which could have a material impact on our business.

The ACA requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each such manufacturer is required to pay a prorated share of the branded prescription drug fee based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. The ACA also expanded the 340B program to include additional types of covered entities. Federal law requires that any company that participates in the Medicaid rebate program also participate in the 340B program in order for federal funds to be available for the manufacturer’s drugs under Medicaid. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B “ceiling price” for the manufacturer’s covered outpatient drugs. In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid programs and purchased by certain federal grantees and agencies, a manufacturer also must participate in the Department of Veterans Affairs Federal Supply Schedule (“FSS”) pricing program, established by Section 603 of the Veterans Health Care Act of 1992. Under this program, the manufacturer is obligated to make products available for procurement on an FSS contract and charge a price to four federal agencies—the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the Coast Guard—that is at least 24% less than the Non-Federal Average Manufacturing Price for the prior fiscal year.

Since the enactment of the ACA, there have been judicial and Congressional challenges to certain aspects of the ACA. In June 2021, the Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, upholding the ACA. In January 2021, President Biden also issued an executive order to initiate a special enrollment period to allow people to obtain health insurance coverage through the ACA marketplace and instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, among others. We cannot predict how future litigation, healthcare reform measures of the Biden administration, or what other regulations will ultimately be implemented at the federal or state level, or the effect of any future legislation or regulation may have on our business.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, for example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019. Additionally, CMS issued a final rule, effective on July 9, 2019, that requires direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product if it is equal to or greater than $35 for a monthly supply or usual course of treatment. Prescription drugs and biological products that are in violation of these requirements will be included on a public list.

In July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at increasing competition for prescription drugs. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. There are important exemptions to Maximum Fair Price including medications that are orphan drug designated and approved, for only one rare disease, and drugs with low Medicare spend as defined by CMS. In an effort to curb Medicare patients’ out-of-pocket costs for prescription drugs, the Part D redesign legislation requires manufacturers to contribute to the catastrophic coverage phase for Part D Drugs, as discounts through a manufacturer discount program. Furthermore, any reduction in reimbursement from Medicare and 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 any of the product candidates for which we receive approval. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare drugs and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability and may increase our regulatory burdens and operating costs.

Moreover, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

Other Healthcare Laws

For our product and any product candidates that obtain regulatory approval and are marketed in the United States, our arrangements, directly or indirectly, with third-party payors, healthcare providers, 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 any products for which we obtain marketing approval. Our employees, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements. Federal and state healthcare laws and regulations that may affect our ability to conduct business, include, without limitation:

- FDA, Department of Justice, and other government authority prohibitions against the advertisement, promotion and labeling of our products for off-label uses, or uses outside the specific indications approved by the FDA;

- the federal Anti-Kickback Statute, which broadly prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce 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 federal healthcare programs, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government. These laws have been interpreted to apply to arrangements between manufacturers, on the one hand, and prescribers, purchasers, and other healthcare-related professionals on the other. They can apply to manufacturers who provide inaccurate information on coverage, coding, and reimbursement of their products to persons who bill third-party payers. In addition, manufacturers have been prosecuted or faced civil and criminal liability under these laws for a variety of alleged promotional and marketing activities, including violations of the federal Anti-Kickback Statute and engaging in off-label promotion that caused claims to be submitted for non-covered off-label uses. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement;
- the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended, which among other things, also created criminal liability for knowingly and willfully falsifying or concealing a material fact or making a materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. 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;
- Federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making, or causing to be made, false statements relating to healthcare matters;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the Foreign Corrupt Practices Act, the U.K. Bribery Act of 2010, and other local anti-corruption laws that apply to our international activities;
- the federal Physician Payment Sunshine Act (“Open Payments”), and implementing regulations, which require applicable group purchasing organizations and manufacturers of covered drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value made to covered recipients, including licensed physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, and information regarding ownership and investment interests held by physicians and their immediate family members;
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require pharmaceutical manufacturers to comply with the industry’s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers, foreign and state laws, including the E.U. General Data Protection Regulation (“GDPR”), governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

The scope and enforcement of each of these laws are uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices 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, including those of our contractors or agents who conduct business for or on our behalf, are found to be in violation of any of these laws or any other related governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight, and reporting obligations if we becomes subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. 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 similar actions, penalties, and sanctions, which may also adversely affect our business. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Privacy and Data Protection Laws

We are subject to laws and regulations covering data privacy and the protection of health-related and other personal information. Federal, state, and foreign laws also govern the privacy and security of health information in some circumstances. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations also impose obligations on covered entities such as health insurance plans, healthcare clearinghouses, and certain health care providers and their respective business associates and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, State data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts in states or jurisdictions we conduct business. For example, California recently enacted the California Consumer Privacy Act ("CCPA"), which creates new individual privacy rights for California consumers, as defined in the law, and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020 and became enforceable by the California Attorney General on July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. California also passed the California Privacy Rights Act, which imposes additional data protection obligations on companies doing business in California. These and other applicable state and foreign privacy laws, as well as uncertain changes in future regulation and legislation, could impact our business strategies, increase our potential liability, increase our compliance costs, and adversely affect our business.

The collection and use of personal health data in the European Union are governed by the provisions of the Data Protection Directive, and as of May 2018, the General Data Protection Regulation ("GDPR"). This directive imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities, and the security and confidentiality of the personal data. The Data Protection Directive and GDPR also impose strict rules on the transfer of personal data out of the European Union to the U.S. Failure to comply with the requirements of the Data Protection Directive, the GDPR, and the related national data protection laws of the European Union member states may result in fines and other administrative penalties. The GDPR introduces new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations, and prospects.

Foreign Regulatory Matters

European Drug Development

In Europe, any future drug products for which we receive marketing authorization will also be subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the United States, the various phases of preclinical and clinical research in Europe are subject to significant regulatory controls. Although the European Union Clinical Trials Directive 2001/20/EC ("Clinical Trials Directive") has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU member states have transposed and applied the provisions of the Clinical Trials Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated, it must be approved in each of the EU member states where the trial is to be conducted by two distinct bodies: the National Competent Authority ("NCA") and one or more Ethics Committees ("ECs"). Under the current regime, all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the member state where they occurred.

In 2014, a new Clinical Trials Regulation 536/2014 (“Clinical Trials Regulation”), replacing the current Directive, was adopted. The Clinical Trials Regulation will become directly applicable in all EU member states (without national implementation) once the EU Portal and Database are fully functional. The implementation of the Clinical Trials Regulation depends on confirmation of full functionality of the Clinical Trials Information System through an independent audit, which commenced in September 2020. This system went into application in first quarter of 2022. The Clinical Trials Regulation seeks to simplify and streamline the approval of clinical trials in the European Union. For example, the sponsor can submit a single application for approval of a clinical trial via the EU Portal. As part of the application process, the sponsor will propose a reporting member state, which will coordinate the validation and evaluation of the application. The reporting member state shall consult and coordinate with the other member states in which the clinical trial will take place, also referred to as the Member States Concerned. If an application is rejected, it can be amended and resubmitted through the EU Portal. If an approval is issued, the sponsor can start the clinical trial in all Member States Concerned. However, a Member State Concerned can in limited circumstances declare an “opt-out” from an approval. In such a case, the clinical trial cannot be conducted in that member state. The Clinical Trials Regulation also aims to streamline and simplify the rules on safety reporting and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU Database.

European Drug Review and Approval

In the European Economic Area (“EEA”), which is comprised of the 27 EU member states plus Norway, Iceland, and Liechtenstein, medicinal products can only be commercialized after obtaining approval of an EU marketing authorization application (“MAA”). There are two types of marketing authorizations. The first is the community or centralized EU MAA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (“CHMP”) of the European Medicines Agency and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of drugs, such as biotechnology medicinal drugs, orphan medicinal drugs, and medicinal drugs containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune, and viral diseases. The Centralized Procedure is optional for drugs containing a new active substance not yet authorized in the EEA, or for drugs that constitute a significant therapeutic, scientific, or technical innovation or which are in the interest of public health in the EU.

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

Under the above-described procedures, before granting the EU MAA, the EMA or the competent authorities of the member states of the EEA make an assessment of the risk-benefit balance of the drug on the basis of scientific criteria concerning its quality, safety, and efficacy.

European Chemical Entity Exclusivity

In Europe, new chemical entities, sometimes referred to as new active substances, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator’s data to assess a generic application for eight years, after which generic marketing authorization can be submitted, and the innovator’s data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the EU, commonly referred to as Brexit. Thereafter, on March 29, 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The United Kingdom formally left the EU on January 31, 2020. A transition period began on February 1, 2020, during which EU pharmaceutical law remains applicable to the United Kingdom and ended on December 31, 2020. Although the United Kingdom is no longer a member of the EU, EU law remains applicable in Northern Ireland. There are a number of new marketing authorization routes available in the United Kingdom, Great Britain (England, Scotland and Wales) or Northern Ireland, in addition to the national procedure. As with the EU position, a company can only start to market a medicine in the United Kingdom once it has received a marketing authorization. The main legislation that applies to clinical trials in the United Kingdom is the United Kingdom Medicines for Human Use (Clinical Trials) Regulations 2004, which transposes the Clinical Trials Directive into domestic law. Consequently, the requirements and obligations that relate to the conduct of clinical trials in the UK currently remain largely aligned with the EU position. It is unclear how future regulatory regime in the United Kingdom will impact regulations of products, manufacturers, and approval of product candidates in the United Kingdom.

Other Foreign Countries

For other countries outside of the United States and the European Union, the requirements governing the conduct of clinical trials, drug approval or marketing authorization, pricing, and reimbursement vary from country to country. In all cases, clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki, which is a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data, developed by the World Medical Association.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Employees and Human Capital

We have operated by leveraging skilled experts, consultants, contract research organizations, and contractors to manage our clinical operations, manufacturing, research and development, and other functions under the leadership and direction of our management. We will continue to expand our infrastructure to manage our operations, including commercial with additional full-time employees.

As of December 31, 2022, we had 79 full-time or part-time employees. Of these employees, 47 employees are engaged in research and development activities and 32 employees are engaged in general and administrative activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider the relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees, advisors and consultants, while being committed to a diverse and dynamic workplace. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of equity-based compensation awards in order to increase shareholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Our Corporate Information

We were originally incorporated in the State of Delaware in November 2007 under the name “Zeta Acquisition Corp. II.” Zeta Acquisition Corp. II was a “shell” company registered under the Exchange Act with no specific business plan or purpose until it began operating the business of Aerpio Pharmaceuticals, Inc. through a merger in March 2017. In August 2021, we effected a reverse merger pursuant to which a wholly owned subsidiary of ours, merged with and into Aadi Subsidiary, Inc. (formerly Aadi Bioscience, Inc.) (“Private Aadi”), with Private Aadi surviving as a wholly owned subsidiary of ours (the "Merger"). Upon the closing of the Merger, we changed our name from “Aerpio Pharmaceuticals, Inc.” to “Aadi Bioscience, Inc.” and the name of Private Aadi was changed from “Aadi Bioscience, Inc.” to “Aadi Subsidiary, Inc.”

Our principal executive offices are located at 17383 Sunset Boulevard, Suite A250, Pacific Palisades, California 90272. We maintain a website at www.aadibio.com, to which we regularly post copies of our press releases as well as additional information about us. Our filings with the Securities and Exchange Commission (the “SEC”) will be available free of charge through the website as soon as reasonably practicable after being electronically filed with or furnished to the SEC. Information contained in our website does not constitute a part of this Annual Report on Form 10-K or any of our other filings with the SEC unless specifically incorporated herein by reference. In addition, our filings with the SEC may be accessed through the SEC's Electronic Data Gathering, Analysis, and Retrieval system at http://www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. Risk Factors

Investing in our common stock involves significant risks, some of which are described below. In evaluating our business, investors should carefully consider the following risk factors. These risks and uncertainties summarized above and described below are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem immaterial may also impair our business operations. Please see page 2 of this Annual Report for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risk Factors Summary

Our business is subject to numerous risks and uncertainties that you should be aware of in evaluating our business, including those described in Part I, Item 1A. “Risk Factors” in this Annual Report on Form 10-K. These risks include, but are not limited to, the following:

- We are a commercial-stage biopharmaceutical company, have a limited operating history and have a single product approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.
- We have incurred significant net losses since our inception, and we expect to continue to incur significant net losses for the foreseeable future.
- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of FYARRO and any future product candidates.
- We may be unable to obtain United States approval for FYARRO for additional indications or other product candidates that we may develop in the future or foreign regulatory approval for FYARRO or other product candidates that we may develop in the future and, as a result, may be unable to commercialize FYARRO or any future product candidates and our business will be substantially harmed.
- Even following approval and commercialization of FYARRO for the advanced malignant PEComa indication, we will require 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.
- We are substantially dependent on the success of our lead product candidate, FYARRO. If we are unable to successfully commercialize FYARRO for the advanced malignant PEComa indication or complete development of, obtain approval for and commercialize FYARRO for one or more other indications in a timely manner, our business will be harmed.
- If any of our third-party manufacturers encounter difficulties in production, our ability to provide adequate supply of FYARRO for patients or for clinical trials or any other product candidate that we may develop in the future, if approved, could be delayed or prevented.
- We are dependent on a single-source supplier for the drug product FYARRO, and the loss of such supplier could harm our business.
- If we cannot replicate the results from our earlier preclinical studies and clinical trials of our product candidates in our later preclinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.
- If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our regulatory submissions or receipt of necessary regulatory approvals could be delayed or prevented.
- We have limited resources and are currently focusing our efforts on developing and commercializing FYARRO for particular indications. As a result, we may fail to capitalize on other indications or product candidates that may ultimately prove to be more profitable or to have a greater likelihood of success.
- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or achieve regulatory approval before we do or that are more effective, safer or less expensive than the products we develop, our commercial opportunities will be negatively impacted.
- The market opportunities for FYARRO and any other product candidates we may develop in the future, if approved, may be limited to certain smaller patient subsets.

- We may be unable to obtain United States approval for FYARRO for additional indications or other product candidates that we may develop in the future or foreign regulatory approval for FYARRO or other product candidates that we may develop in the future and, as a result, may be unable to commercialize FYARRO or any future product candidates and our business will be substantially harmed.
- FYARRO is, and any other product candidate we may develop in the future for which we obtain marketing approval for could be, subject to post-marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we or our collaborators fail to comply with regulatory requirements or if we or our collaborators experience unanticipated problems with FYARRO, or any other product candidate we may develop in the future when and if any of them are approved.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers, key scientific personnel and employees. If we fail to attract and retain such personnel, we may be unable to continue to successfully develop or commercialize our product or any future product candidates or otherwise implement our business plan.
- If we are unable to establish or appropriately scale up our 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 or any future product candidates that obtain regulatory approval.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.
- If we do not obtain patent term extension for our product or any future product candidates, our business may be materially harmed.
- We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
- We contract with qualified third parties for the production of FYARRO for commercialization and expect to continue to do so for additional clinical trials. This reliance on third parties, some of which are sole source suppliers, increases the risk that we will not have sufficient quality and quantities of FYARRO or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials and those third parties may not perform satisfactorily.
- Litigation and legal proceedings, including the EOC dispute, may substantially increase our costs and harm our business, irrespective of outcome.

Risks Related to Our Business, Financial Condition and Capital Requirements

We are a commercial-stage biopharmaceutical company, have a limited operating history and have a single product approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.

We are a commercial-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We have a single product, FYARRO, approved for commercial sale by the FDA in November 2021 and launched commercially in the United States for treatment of advanced malignant perivascular epithelioid cell tumor (“PEComa”) in February 2022. We generated net product sales for FYARRO of $15.2 million for the year ended December 31, 2022. We continue to incur significant research and development and other expenses related to our ongoing operations. We have not yet demonstrated an ability to overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Consequently, any predictions about our future performance may not be as accurate as they would be if we had a history of successfully developing and commercializing biopharmaceutical products.

To date, we have devoted substantially all of our resources to research and development activities, business planning, establishing and maintaining our intellectual property portfolio, preparing for commercialization of FYARRO, hiring personnel, raising capital and providing general and administrative support for these operations. We conducted a Phase 2 registrational study of FYARRO (the “AMPECT" trial) for PEComa and completed a rolling New Drug Application (an “NDA”) submission for FYARRO in May 2021. The U.S. Food and Drug Administration (the “FDA”) accepted our NDA in July 2021 and approved FYARRO for the treatment of advanced malignant PEComa in November 2021.

Based on the AMPECT trial and emerging data for FYARRO in other solid tumors with truncating Tuberous Sclerosis Complex 1 and 2 (“*TSC1 & TSC2”)* alterations, and following discussions with the FDA, we opened enrollment for our registration-directed tumor-agnostic Phase 2 trial ("PRECISION 1") in malignant solid tumors harboring *TSC1 & TSC2* inactivating alterations in the first quarter of 2022. In addition, in October 2022 we entered into a collaboration and supply agreement with Mirati Therapeutics, Inc. ("Mirati") to evaluate the combination of Mirati's adagrasib (KRAZATI™), a KRASG12C selective inhibitor, and FYARRO in KRAS G12C mutant non-small cell lung cancer (NSCLC) and other solid tumors. Under the terms of the agreement, Mirati will be responsible for sponsoring and operating the Phase 1/2 study and we will supply study drug and jointly share the cost of the study. Our other programs are in early preclinical research stages.

We have limited experience managing the manufacture of commercial-scale product through a third party and conducting the sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our likelihood of success and viability than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early commercial-stage biopharmaceutical companies in rapidly evolving fields. We also are transitioning to a company capable of supporting commercial activities.

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

We have incurred significant net losses since our inception, have only recently begun to generate revenue from product sales and have financed our operations principally through private placements and public offerings of our securities, federal grants and proceeds from licenses. Our net losses were $60.5 million and $110.1 million for the years ended December 31, 2022 and 2021, respectively. We had an accumulated deficit of $203.2 million and $142.7 million as of December 31, 2022 and 2021, respectively. These losses have resulted primarily from costs incurred in connection with research and development activities, costs incurred in connection with commercializing FYARRO and general and administrative costs associated with our operations. We have only one product approved for commercial sale which generated net product sales of $15.2 million for the year ended December 31, 2022, and we continue to incur significant selling, general and administrative expenses as well as research and development expenses related to our ongoing operations. As a result, we expect to continue to incur significant operating expenses for the foreseeable future due to the cost of commercializing FYARRO, research and development, including identifying and designing additional product candidates and conducting preclinical studies and clinical trials, and the regulatory approval process for FYARRO and any future product candidates. We expect our expenses, and the potential for losses, to increase substantially as we commercialize FYARRO, continue to conduct clinical trials of FYARRO and seek to expand our pipeline. The amount of our future expenses and potential losses is uncertain.

Even if we succeed in commercializing FYARRO for its approved advanced malignant PEComa indication, and if we succeed in receiving regulatory approval for and commercializing FYARRO in additional indications and any future product candidates, we expect to continue to incur significant expenses and increasing operating losses over the next several years and for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. 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, our ability to fund the commercialization of FYARRO, the development of FYARRO for additional indications and any future product candidates, our ability to achieve and maintain profitability and the performance of our stock.

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

We have one product approved for commercialization in the United States, FYARRO, for the treatment of advanced malignant PEComa, which was approved by the FDA in November 2021 and launched commercially in the United States in February 2022. Our ability to generate substantial product sales sufficient to achieve profitability depends on our ability, alone or with strategic collaboration partners, to obtain the regulatory and marketing approvals necessary to successfully complete discovery, development and eventual commercialization of additional indications (such as *TSC1* & *TSC2*), commercialize FYARRO in foreign jurisdictions or any future product candidates. We do not anticipate generating revenue from product sales significant enough to achieve profitability for the foreseeable future. Our ability to generate future revenue and achieve profitability depends significantly on our ability, or any current or future collaborator's ability, to achieve several objectives, including, but not limited to:

- demonstrating the safety and efficacy of FYARRO to the satisfaction of the FDA and obtaining regulatory approval for FYARRO for other indications and for any future product candidates, if any, for which there is a commercial market;

- launching and successfully commercializing FYARRO or any product candidates following any regulatory approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for FYARRO or any other product candidates we may develop, if approved;
- completing development activities, including clinical trials for FYARRO for *TSC1 & TSC2*, successfully and on a timely basis;
- obtaining additional regulatory and marketing approvals for FYARRO for additional indications;
- our ability to complete investigational new drug application (an “IND”) enabling studies and successfully submit INDs or IND supplements or comparable applications, which become effective without any objections by the FDA or comparable regulatory authorities before commencing a clinical trial for any future product candidates;
- establishing and maintaining relationships with contract research organizations (“CROs”) and clinical sites for the clinical development of FYARRO in other indications and any other future product candidates that we may develop;
- timely receipt of regulatory approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- developing or contracting for an efficient and scalable manufacturing process for future product candidates, including obtaining finished products that are appropriately packaged for sale;
- negotiating and maintaining an adequate price for our product or any future product candidates, both in the United States and in foreign countries where our products are commercialized;
- a continued acceptable safety profile following any regulatory approval of product candidates;
- commercial acceptance of product candidates by patients, the medical community and third-party payors;
- obtaining coverage and adequate reimbursement by third-party payors for product candidates;
- satisfying any required post-regulatory approval commitments to applicable regulatory authorities;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- entering into and maintaining, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product and any future product candidates; and
- addressing any competing therapies and technological and market developments; and attracting, hiring and retaining qualified personnel.

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

We will require 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 and planned activities, particularly as we seek additional regulatory approval of FYARRO for additional indications, and the commercialization of FYARRO for its approved indication (PEComa). Our expenses could increase beyond our current expectations if we are required by the FDA, the European Medicines Agency (the "EMA") or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate, or if there are any delays in any of our clinical trials or the development of any future product candidates. Other unanticipated costs may also arise. In addition, even if we obtain regulatory approval for any of other product candidates, including additional indications for FYARRO, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution activities and ongoing compliance activities. We cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully commercialize FYARRO for the advanced malignant PEComa indication or complete the development and, if approved, commercialize FYARRO for any other additional indications, or any other product candidates or other indications we may develop. Upon receiving regulatory approval for FYARRO from the FDA in November 2021, we are only permitted to market or promote FYARRO for the advanced malignant PEComa indication, and not for any other indication, or any other product candidate, in the United States. In addition, we will incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of December 31, 2022, we had $172.6 million in cash, cash equivalents and short-term investments. Based on our current operating plan, we believe that our cash, cash equivalents and short-term investments will enable us to fund our planned operating expenses and capital expenditures into 2025. Our estimate as to how long we expect our cash, cash equivalents and short-term investments to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We plan to use our cash, cash equivalents and short-term investments to fund the commercialization of FYARRO for the advanced malignant PEComa indication, ongoing and planned clinical trials of FYARRO for other indications such as the *TSC1 & TSC2* indications, for manufacturing operations and to fund our other research for other product candidates and development activities, as well as for working capital and other general corporate purposes. Advancing the development of FYARRO and any future product candidate will require a significant amount of capital. Our existing cash, cash equivalents and short-term investments will not be sufficient to fund all of the activities that are necessary to complete the development of FYARRO and any future product candidates.

We will be required to obtain further funding to support our continuing operations through public or private equity offerings, debt financings, third-party funding, marketing and distribution arrangements, collaborations with third parties and licensing arrangements or other sources or a combination of these approaches, which may dilute our stockholders or restrict our operating activities. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize FYARRO or any other product candidates we may develop in the future, if approved. Adequate additional financing may not be available to us in sufficient amounts or on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder and the possibility of such issuance may cause the market price of our shares to decline. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect the conduct of 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 certain of our technologies or our product candidates, or grant licenses on terms that are not favorable to us, which may have a material adverse effect on our business, operating results and prospects. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic, the conflicts in Eastern Europe, and otherwise. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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

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

We have only one product, FYARRO, which has completed development and obtained regulatory approval by the FDA for a single indication. We are substantially dependent on the success of FYARRO. If we are unable to successfully

commercialize FYARRO for the advanced malignant PEComa indication or complete development of, obtain approval for and commercialize FYARRO for one or more other indications in a timely manner, our business will be harmed.

We have only one commercial product that has launched, completed development and been approved by the FDA, FYARRO, our lead product. Our future success is dependent on our ability to successfully commercialize FYARRO, and to timely and successfully obtain regulatory approval for additional indications for FYARRO. We are investing the majority of our efforts and financial resources to commercialize FYARRO for the advanced malignant PEComa indication and in the research and development of FYARRO for multiple additional indications.

In May 2021, we completed the filing of a rolling NDA for FYARRO to the FDA for approval to treat patients with advanced malignant PEComa, and the FDA accepted our NDA in July 2021 and approved FYARRO for advanced malignant PEComa in November 2021. Our NDA was based on results from our AMPECT trial, involving patients for whom there were no approved therapies in the United States. FYARRO will require additional clinical development, expansion of manufacturing capabilities, regulatory approval from foreign regulatory authorities in jurisdictions outside of the United States where we plan to market FYARRO for advanced malignant PEComa and potentially in additional indications, if approved, substantial investment and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote FYARRO for non-PEComa indications, before we receive regulatory approval from the FDA and comparable foreign regulatory authorities, and we may never receive such regulatory approvals.

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

- the efficacy and safety of FYARRO in a larger number of patients in a non-clinical trial setting that those demonstrated in our clinical trials;
- the effectiveness of our sales, marketing and distribution efforts;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers for sufficient commercial supplies and additional clinical development of FYARRO;
- the success of our commercial sales, including the ongoing development of a commercial infrastructure, whether in-house or with one or more collaborators;
- the timely receipt of regulatory approval for FYARRO from applicable foreign regulatory authorities for advanced malignant PEComa;
- the successful completion of any clinical trials, regulatory approval and commercialization of FYARRO for one or more label expansion indications;
- the extent of any required post-regulatory approval commitments to applicable regulatory authorities;
- the willingness of medical professionals to prescribe and patients to use FYARRO and continue to use FYARRO;
- the availability of coverage and adequate reimbursement and pricing by private and government payors;
- the prevalence and severity of adverse side effects;
- the convenience of prescribing, administrating and initiating patients on FYARRO;
- the potential and perceived value and relative cost of FYARRO;
- the successful and timely completion of the required preclinical studies and clinical trials of FYARRO for current and future indications;
- INDs going into effect with the FDA for our planned and future clinical trials;
- the initiation and successful patient enrollment and completion of additional clinical trials of FYARRO on a timely basis, including our PRECISION 1 trial, a registration-directed tumor-agnostic Phase 2 study of FYARRO in patients with truncating *TSC1 & TSC2* alterations;
- maintaining and establishing relationships with CROs and clinical sites for the development of FYARRO both in the United States and internationally;
- the type, frequency and severity of adverse events in clinical trials;

- demonstrating efficacy and safety profiles that are satisfactory to the FDA and any comparable foreign regulatory authority for regulatory approval obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- a continued acceptable safety profile following our current and future regulatory approval; and
- our ability to compete with other therapies.

In addition to advanced malignant PEComa, based on exploratory data from the completed AMPECT and our Expanded Access Program, we have initiated a registration-directed tumor-agnostic Phase 2 study, PRECISION 1, of FYARRO in patients with malignant solid tumors harboring *TSC1 & TSC2* alterations. We completed a Type B meeting with the FDA in which we discussed the trial design. The PRECISION 1 trial is now open for enrollment in the United States and the first patient in the trial was dosed in March 2022. Our product development costs could increase if we experience delays. Significant trial delays also could shorten any periods during which we may have the exclusive right to commercialize FYARRO or allow our competitors to bring products to market before we do, which would impair our ability to successfully capitalize on FYARRO and may harm our business, results of operations and prospects. Events that may result in a delay or unsuccessful completion of additional clinical development of FYARRO include, among other things:

- unexpectedly high rate of patients withdrawing consent or being lost to follow-up;
- feedback from the FDA and foreign regulatory authorities, institutional review boards ("IRBs"), or a data safety monitoring board, or results from clinical trials that might require modification to a clinical trial protocol;
- imposition of a clinical hold by the FDA or other regulatory authorities, a decision by the FDA, other regulatory authorities, IRBs or us, or a recommendation by a data safety monitoring board to suspend or terminate trials at any time for safety issues or for any other reason;
- deviations from the trial protocol by clinical trial sites and investigators or failure to conduct the trial in accordance with regulatory requirements;
- failure of third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;
- delays in the testing, validation, manufacturing and delivery of FYARRO to customers or the clinical trial sites;
- delays caused by patients dropping out of a trial due to side effects, disease progression or other reasons;
- unacceptable risk-benefit profile or unforeseen safety issues or adverse drug reactions;
- failure to demonstrate the efficacy of FYARRO in this clinical trial;
- changes in government regulations or administrative actions or lack of adequate funding to continue the trials; or
- business interruptions resulting from geo-political actions, including war and terrorism, such as the Russia-Ukraine conflict, or natural disasters and public health epidemics, such as the COVID-19 pandemic.

An inability by us to timely complete clinical development could result in additional costs to us or impair our ability to generate substantial product sales or development, regulatory, commercialization and sales milestone payments and royalties on product sales.

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 our current or any future collaborators. 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 FYARRO for multiple indications, which would materially harm our business. If we do not receive regulatory approvals for FYARRO in additional indications or for other product candidates, we may not be able to continue our operations.

In addition to FYARRO, our prospects depend in part upon discovering, developing and commercializing additional product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.

Our future operating results are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates other than FYARRO. Prior to initiating clinical trials with product candidates, we will need to file an IND or similar application to the FDA or regulatory authorities in other jurisdictions. We may not be able to file future INDs for product candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that result in the suspension or termination of 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 clearance for our trials may prevent us from developing product candidates on a timely basis, if at all. 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 other product candidates we may develop will depend on many factors, including the following:

- generating sufficient preclinical data to support the initiation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct preclinical studies and clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of a product candidate for use in clinical trials; and
- generating sufficient safety and efficacy data to warrant continued development and which are satisfactory to the FDA or any other regulatory authority for marketing approval.

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 any additional product candidates beyond FYARRO for advanced malignant PEComa.

FYARRO or any other product candidates we may develop in the future may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success, which would limit the revenue that we generate from our sales.

Even though FYARRO has been approved for advanced malignant PEComa, and even if any other product candidates that we may develop in the future receive regulatory approval, such approved product candidates may not gain adequate market acceptance among physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including, among others:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which a product candidate is approved;
- restrictions on the use of product candidates in the labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or a risk evaluation and mitigation strategy, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities or the willingness of patients to pay out-of-pocket in the absence of third-party payor coverage;
- the availability of an approved product candidate for use as a combination therapy;
- the prevalence and severity of any adverse effects associated with any approved product candidate;
- any restrictions on the use of our product candidates together with other medications;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and undergo required diagnostic screening to determine treatment eligibility and of physicians to prescribe these therapies and diagnostic tests;
- the effectiveness of sales and marketing efforts;

- unfavorable publicity relating to our product candidates; and
- the approval of other new therapies for the same indications.

Even though FYARRO is approved for advanced malignant PEComa, it may never achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, and we may not generate or derive sufficient revenue from that product and our financial results could be negatively impacted. Before granting reimbursement approval, healthcare payors may require us to demonstrate that our product candidates, in addition to treating target indications, also provide incremental health benefits to patients. Our efforts to educate the medical community and third-party payors about the benefits of our product candidates may require significant resources and may never be successful.

The market opportunities for FYARRO and any other product candidates we may develop in the future, if approved, may be limited to certain smaller patient subsets.

Cancer therapies are sometimes characterized by line of therapy (first-line, second-line, third-line, etc.) and the FDA often approves new therapies initially only for a particular line or lines of use. When cancer is detected early enough, first-line therapy, such as chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. FYARRO for advanced malignant PEComa has been approved as a first-line therapy. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor- targeted therapies, more invasive forms of surgery and new technologies. Our completed and planned clinical trials for FYARRO are with patients who may have received one or more prior treatments. There is no guarantee that product candidates that we develop, even if approved, would be approved for first-line or second-line therapy and, prior to any such approvals, we may have to conduct additional clinical trials that may be costly, time-consuming and subject to risk.

The number of patients who have the cancers we are targeting may turn out to be lower than expected. Our projections of addressable patient populations that may benefit from treatment with our product or any future product candidates are based on our estimates, which may prove to be incorrect. Additionally, the potentially addressable patient population for FYARRO and any future product candidates may be limited or may not be amenable to treatment with such product. Regulatory approval may limit the market of a product candidate to target patient populations when such biomarker-driven identification and/or highly specific criteria related to the stage of disease progression are utilized. 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.

Even if we obtain significant market share for any approved product, if the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

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

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of FYARRO or any other product candidate we may develop in the future that receives regulatory approval will depend substantially, both in the United States and internationally, on the extent to which the costs of such product candidate 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 FYARRO or any other product candidates that we may develop in the future. 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, FYARRO or any other product candidate that we may develop in the future for which we obtain regulatory approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize FYARRO or any other product candidate that we may develop in the future for which we obtain regulatory approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products, which would include FYARRO and any other product candidate we may develop in the future for which we may obtain regulatory approval. Market acceptance and sales of FYARRO or any other product candidates we may develop in the future for which we obtain regulatory approval will depend on reimbursement policies and may be affected by healthcare reform measures. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance. Third-party payors decide which drugs they will pay for and establish reimbursement levels. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("HHS"). CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. Factors that payors consider in determining reimbursement are based on whether the product is: (i) a covered benefit under the health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational. 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 such as FYARRO. 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. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price (an "ASP") and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Moreover, FYARRO or any other product candidate we may develop in the future may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for FYARRO or any other product that we may commercialize and, if reimbursement is available, what the level of reimbursement will be.

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 prescription drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, under the American Rescue Plan Act of 2021, effective January 1, 2024 (the "American Rescue Plan"), the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at increasing competition for prescription drugs. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such laws once we begin commercialization for FYARRO or, after obtaining regulatory approval, any of our other product candidates that we may develop in the future. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize FYARRO or any other product candidates that we may develop in the future if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

Outside the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as FYARRO or any other product candidates that we may develop in the future if approved. 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 regulatory approval. To obtain favorable reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of FYARRO or any other product candidate that we may develop in the future if approved 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 FYARRO or any other product candidates that we may develop in the future if approved. Accordingly, in markets outside the United States, the reimbursement for FYARRO or any other products that we may develop in the future and receive regulatory approval for may be unavailable or reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. If reimbursement is conditioned upon our completion of additional clinical trials, or if pricing is set at unsatisfactory levels, our operating results could be materially adversely affected.

If we are unable to establish or sustain coverage and adequate reimbursement for FYARRO or any other product candidates that we may develop in the future if approved from third-party payors, the adoption of FYARRO or those other products if approved, the prices of FYARRO or those other products if approved and sales revenue from FYARRO or those other products if approved will be adversely affected, which, in turn, could adversely affect the ability to market or sell FYARRO or any other product candidates that we may develop in the future, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. It is unclear what effect these legislative, executive, and administrative actions and any, future healthcare measures and agency rules will have on the number of covered individuals. Even if favorable coverage and reimbursement status is attained for FYARRO or one or more product candidates that we may develop in the future for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

We may not be able to obtain FDA approval of any future NDA for FYARRO or any other product candidates we may develop in the future.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing and distribution and other possible activities relating to FYARRO and any other product candidate that we may develop in the future are subject to extensive regulation in the United States. Prior to the recent approval of our NDA for FYARRO for advanced malignant PEComa, we had not submitted an application for approval or obtained FDA approval for any product.

Approval of an NDA is not guaranteed. The approval process is expensive and uncertain and may take several years. The FDA and foreign regulatory entities also have substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Data are subject to varying interpretation and the FDA may not agree that our clinical data support that any of our product candidates are safe and effective for the proposed therapeutic use. FDA’s Oncology Center of Excellence initiated Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development and Project FrontRunner to help develop and implement strategies to support approvals in the early clinical setting, among other goals. How the FDA plans to implement those goals and their impact on specific clinical programs and the industry are unclear. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage, and we could encounter problems that require us to repeat or perform additional preclinical studies or clinical trials or generate additional chemistry, manufacturing and controls data, including drug product stability data. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate, and may ultimately approve the product for narrower indications or with unfavorable labeling that would impede our commercialization of the drug.

Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, including obtaining reimbursement and pricing approval in select markets. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others, including the risk that our product candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the product may be marketed.

Failure to obtain marketing approval in international jurisdictions would prevent FYARRO and any other product candidates we may develop in the future from being marketed abroad.

In order to market and sell our products in the European Union and any other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

A variety of risks associated with marketing FYARRO and any other product candidates we may develop in the future internationally could affect our business.

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

- differing regulatory requirements in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the United States Foreign Corrupt Practices Act (“FCPA”) or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

In addition, the conflict between Russia and Ukraine has led to, and could continue to lead to, disruption, instability and volatility in global markets and industries that could negatively impact our operations. The U.S. government and other governments in jurisdictions in which we may operate in the future have imposed severe sanctions and export controls against Russia and Russian interests and threatened additional sanctions and controls. The impact of these measures, as well as potential responses to them by Russia, is currently unknown and they could adversely affect our business, supply chain, business partners or customers.

These and other risks associated with our international operations may compromise our ability to achieve or maintain profitability.

The preclinical studies and clinical trials for FYARRO or any other product candidates that we may develop in the future may not demonstrate safety and efficacy to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities or otherwise produce positive results, which would prevent, delay, or limit the scope of development, regulatory approval and commercialization.

Before obtaining regulatory approval from the EMA or other foreign regulatory authorities for the sale of FYARRO for advanced malignant PEComa or any additional indications that we may seek approval for, or other product candidates when approved, we, among other requirements, must complete preclinical development and extensive clinical trials to demonstrate with substantial evidence the safety and efficacy of such product or other product candidates. Each product or product candidate must demonstrate an adequate risk versus benefit profile in our intended patient population and for our intended use. Drug product must also be manufactured and tested in accordance with regional regulatory requirements which may differ from region to region. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is inherently uncertain. A failure of one or more preclinical studies or 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. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies in the biopharmaceutical industry that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their products. Our current or future clinical trials may not ultimately be successful or support further clinical development of FYARRO or any other product candidates we may develop in the future.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or our ability to commercialize FYARRO for additional indications or for any other product candidates we may develop in the future, including:

- receipt of feedback from regulatory authorities that require us to modify the design of our clinical trials;
- negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain drug development programs;
- the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated or participants dropping out of these clinical trials at a higher rate than anticipated;
- clinical trial sites or our CRO failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements or a finding that our product candidates have undesirable side effects or other unexpected characteristics;
- the cost of clinical trials of our product candidates being greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate; and
- delays due to health epidemics, such as the COVID-19 pandemic, including starting any clinical trials for other indications or programs.

For instance, we do not know whether FYARRO will perform in current or future clinical trials for additional indications as it has performed in preclinical studies or prior clinical trials. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA, and other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. Additionally, while we are aware of several other approved and clinical-stage mTOR inhibitors being developed by multiple other companies, to our knowledge, there are no mTOR inhibitors approved specifically for the treatment of advanced malignant PEComa other than FYARRO. As such, the development of FYARRO and our stock price may be impacted by inferences, whether correct or not, that are drawn between the success of our product and those of other companies' mTOR inhibitors. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety and efficacy results, which could delay regulatory approval, limit the size of the patient population to which we may market our product candidates, or prevent regulatory approval.

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 dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our products in clinical trials may have received surgical, radiation and chemotherapy treatments and/or may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our products. 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 approval to market FYARRO for additional indications or for any other product candidates we may develop in the future. If we are required to conduct additional clinical trials or other testing of our product beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product or other testing in a timely manner, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may (i) incur unplanned costs, (ii) be delayed in seeking and obtaining regulatory approval for respective indications, if we receive such approval at all, (iii) receive more limited or restrictive regulatory approval for respective indications, (iv) be subject to additional post-marketing testing requirements or (v) have the drug removed from the market after obtaining regulatory approval. 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 candidates, which may also limit their commercial potential.

FYARRO or any other product candidates that we may develop in the future may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that could delay or prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

If FYARRO or any other product candidates that we may develop in the future is associated with serious adverse events or other undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs, we may need to conduct additional studies to further evaluate the product candidates' safety, interrupt, delay or abandon their development or halt clinical trials 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 a more restrictive label, delay or denial of regulatory approval or potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate, could substantially increase the costs of commercializing our product(s) and significantly impact our ability to successfully commercialize our product(s) and generate revenues, and may harm our business, financial condition and prospects significantly. For example, in our AMPECT trial of FYARRO, most treatment-related adverse events were mild or moderate, with the most commonly reported adverse events being anemia, edema, infections, mucositis, pain, nail changes, vomiting, thrombocytopenia, hypertension and nausea. Treatment-related adverse events in our other oncology and PAH trials of FYARRO included thrombocytopenia, diarrhea, fatigue, mucosal inflammation, nausea, anemia, and rash. Additionally, in our first- in-human study of FYARRO in solid tumors, one patient died of dyspnea which was deemed possibly related to FYARRO.

Patients in our completed and planned clinical trials may in the future suffer other significant adverse events or other side effects not observed or anticipated based on our preclinical studies or previous clinical trials. FYARRO or other product candidates may be used in populations for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, FYARRO is being studied in combination with other therapies, which may exacerbate adverse events associated with the therapy. Patients treated with FYARRO or our other product candidates that we may develop in the future may also be undergoing surgical, radiation and/or chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, it is expected that some of the patients enrolled in our FYARRO clinical trials will die or experience major adverse clinical events either during the course of our clinical trials or after such trials, which has occurred in the past.

If further significant adverse events or other side effects are observed in any of our current or 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, EMA, other comparable regulatory authorities or an institutional review board may suspend or terminate clinical research at any time for various reasons, including noncompliance with regulatory requirements or a finding that the participants 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 regulatory 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.

Further, for FYARRO for advanced malignant PEComa, or if FYARRO receives regulatory approval for any other indication, or if any other product candidate that we may develop in the future if any of our product candidates obtains regulatory approval, toxicities associated with such product candidates and not seen during clinical testing may also develop after such approval and lead to a requirement to (i) conduct additional clinical safety trials, (ii) add additional contraindications, warnings and precautions to the drug label, (iii) significantly restrict the use of the product, (iv) change the way the product is distributed or administered, (v) implement a risk evaluation and mitigation strategy, or create a medication guide outlining the risks of such side effects for distribution to patients, or (vi) suspend or withdraw the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

Results from early preclinical studies and clinical trials of FYARRO or other product candidates that we may develop in the future are not necessarily predictive of the results of later preclinical studies and clinical trials of FYARRO or such

other product candidates. If we cannot replicate the results from our earlier preclinical studies and clinical trials in our later preclinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize FYARRO in additional indications or any future product candidates.

Any results from early preclinical studies and clinical trials of FYARRO or other product candidates that we may develop in the future may not necessarily be predictive of the results from later preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies and clinical trials according to our current development timeline, the results from such preclinical studies and clinical trials may not be replicated in subsequent preclinical studies or clinical trial results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical and other nonclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical, nonclinical 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 EMA approval.

We are subject to risks relating to open-label clinical trials.

Some of our ongoing, planned and future clinical trials may utilize an open-label study design and may be conducted at a limited number of clinical sites on a limited number of patients. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to biases, including a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open- label trial may not be predictive of future clinical trial results with any of our product candidates when studied in a controlled environment with a placebo or active control.

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

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

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

Adverse results of clinical trials conducted by third parties investigating the same product candidates as us in different territories could adversely affect our development of such product candidate.

Lack of efficacy, adverse events, undesirable side effects or other adverse results may emerge in clinical trials conducted by third parties investigating our approved product or the same product candidates as us in different territories for the same or different indications. For example, we may in the future enter into collaborations for the development and commercialization of FYARRO in certain foreign jurisdictions. As part of these collaborations, we may grant such collaboration partners with the right to develop and commercialize the same compounds licensed to us, including FYARRO, in such foreign jurisdictions. As a result, we may not have control over clinical trials or development programs of such third parties that we may collaborate with in the future, and any adverse findings or unexpected side effects from such third party's conduct of clinical trials could adversely affect our development and commercialization of FYARRO or the viability of FYARRO as a product candidate. We may be required to report these adverse events or unexpected side effects to the FDA or comparable foreign regulatory authorities, which could, among other things, order us to cease further development of FYARRO.

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

We may not be able to initiate or continue clinical trials for FYARRO or any future 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, EMA or other comparable foreign regulatory authorities. Orphan indications, in particular, have small populations, and it may be difficult for us to locate and enroll sufficient patients in trials for orphan-designated indications. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to identify and enroll eligible patients for clinical trials may be limited or may result in slower enrollment than we anticipate. For instance, patients for our trials for the *TSC1 & TSC2* study are screened using genomic information to identify alterations in the *TSC1 & TSC2* genes and utilizing such criteria and/or certain highly specific criteria related to the cancer sub-types may limit patient populations eligible for our clinical trials. In particular, because we are focused on patients with specific genetic alterations for certain of our development programs, our ability to enroll eligible patients may be limited or may result in slower enrollment than anticipated. For example, with respect to FYARRO, we cannot be certain how many patients will harbor the *TSC1 & TSC2* alterations that FYARRO is designed to target or that the number of patients enrolled for each alteration will suffice for regulatory approval and inclusion of each such alteration in the approved label. We may also engage third parties to develop companion diagnostics for use in our clinical trials, but such third parties may not be successful in developing such companion diagnostics, furthering the difficulty in identifying patients with the targeted genetic alterations for our clinical trials. If our strategies for patient identification prove unsuccessful, we may have difficulty enrolling or maintaining patients appropriate for FYARRO.

Patient enrollment may 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.

Also, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment for one or more of our trials. Patient enrollment and retention for our current or any future clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol or as mandated by regulatory agencies;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies and product candidates, including any new products that may be approved or other product candidates being investigated for the indications we are investigating;
- the ability to recruit clinical study investigators with the appropriate competencies and experience;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;
- patient referral practices of physicians;

- the ability to obtain and maintain patient consents;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- factors we may not be able to control, such as current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability (e.g., the COVID-19 pandemic).

Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays or may require us to abandon one or more clinical trials altogether. Furthermore, any negative results we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials we are conducting. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain regulatory 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, there is a 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. As a result, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods. In addition, we rely on clinical trial sites to ensure timely conduct of our clinical trials and, while we have entered into agreements governing their services, we are limited in our ability to compel their actual performance.

We expect to develop FYARRO and potentially other product candidates in combination with other therapies, which exposes us to additional risks.

We intend to develop FYARRO and potentially other product candidates, in combination with one or more currently approved or unapproved therapies to treat cancer or other diseases. For example, in October 2022 we entered into a collaboration and supply agreement with Mirati to evaluate the combination of Mirati's adagrasib (KRAZATI™), a KRASG12C selective inhibitor, and FYARRO in KRAS G12C mutant non-small cell lung cancer (NSCLC) and other solid tumors. Patients may not be able to tolerate FYARRO or any of our future product candidates in combination with other therapies or dosing of FYARRO in combination with other therapies may have unexpected consequences. Even though FYARRO has received FDA approval for advanced malignant PEComa, and even if FYARRO receives regulatory approval for additional indications, if any of our product candidates that we develop in the future were to receive regulatory approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with such product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates, the FDA, EMA or comparable foreign regulatory authorities in other jurisdictions requiring additional clinical trials, or our own products being removed from the market or being less successful commercially.

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

If the FDA, EMA or other comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with FYARRO or any future product candidate, we may be unable to obtain approval of or successfully market any one or all of the product candidates we develop. These unapproved therapies face the same risks described with respect to product candidates currently in development, including serious adverse effects and delays in their clinical trials. In addition, other companies may also develop their products or product candidates in combination with the unapproved therapies with which we are developing our product candidates for use in combination. Any setbacks in these companies' clinical trials, including the emergence of serious adverse effects, may delay or prevent the development and approval of our product candidates.

Additionally, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We have limited resources and are currently focusing our efforts on developing and commercializing FYARRO for particular indications. As a result, we may fail to capitalize on other indications or product candidates that may ultimately prove to be more profitable or to have a greater likelihood of success.

We are currently focusing our resources and efforts on developing and commercializing FYARRO for particular indications. As a result, because we have limited financial and managerial resources, we may forgo or delay pursuit of opportunities for other indications or with other product candidates that may later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Failure to properly assess potential product candidates could result in our focus on product candidates with low market potential, which would harm our business, financial condition, results of operations and prospects. Our spending on current and future research and development activities for FYARRO and other programs may not yield any commercially viable drugs. If we do not accurately evaluate the completed clinical trial data, likelihood of future clinical trial success, commercial potential or target markets for FYARRO or any of our other product candidates that we may develop in the future, we may relinquish valuable rights to that product candidate or program through collaboration, licensing or other strategic or royalty arrangements in cases in which we would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or program.

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

The biotechnology and pharmaceutical 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 FYARRO for advanced malignant PEComa or for any additional indications we may seek approval for, and for any other product candidates that we may develop in the future, if approved. 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 drugs that physicians currently use 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 field of oncology. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, emerging and start-up companies, government agencies, universities and other research institutions. We also compete with these organizations to recruit and retain 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.

Other than FYARRO, we are not aware of any FDA or EMA approved products indicated specifically for the treatment of advanced malignant PEComa. Patients with malignant PEComa commonly receive chemotherapy regimens and currently mTOR inhibitors including sirolimus, everolimus, and temsirolimus are recommended in the National Comprehensive Cancer Network (the “NCCN”) guidelines for treatment of malignant PEComa based on published retrospective data. Following FDA approval, FYARRO was added to the NCCN guidelines as the only preferred regimen for treatment of malignant PEComa. For truncating *TSC1 & TSC2* inactivating alterations, there are no existing FDA or EMA approved products indicated for such use. If FYARRO receives additional regulatory approval for these *TSC1 & TSC2* indications, it may face competition from other drug candidates in clinical trials that target the mTOR pathway. These may include dual mTORC1/2 inhibitors in clinical trials or next generation mTOR inhibitors in development. Any potential competitors may have significantly greater financial, manufacturing, marketing, drug development, technical and human resources, and commercial expertise than us. 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 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. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA, EMA or other comparable foreign regulatory authorities or in discovering, developing and commercializing products in the field before us.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, have a broader label, are marketed more effectively, are more widely reimbursed or are less expensive than any products that we may develop and commercialize. Our competitors also may obtain regulatory approval from the FDA, EMA or other comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market. Our approved product, or product candidates we may develop in the future which achieve regulatory approval, 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 FYARRO or any product candidates we may develop in the future, if approved, could be adversely affected.

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

As product candidates progress through preclinical studies and clinical trials to regulatory approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. For example, we may introduce alternative formulations or dosage forms of FYARRO in additional clinical trials for other indications. Such material changes will require regulatory approval before implementation and carry the risk that they will not achieve these intended objectives. Any of these changes could cause FYARRO and any other product candidate that we may develop in the future 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 FYARRO or any other product candidates that we may develop in the future, if approved, and generate revenue.

We may not be successful in growing our product pipeline through acquisitions and in-licenses.

We believe that accessing external innovation and expertise is important to our success; and while we plan to leverage our leadership team's prior business development experience as we evaluate potential in-licensing and acquisition opportunities to further expand our portfolio, we may not be able to identify suitable licensing or acquisition opportunities, and even if we do, we may not be able to successfully secure such licensing and acquisition opportunities. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We may also be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully license or acquire additional product candidates to expand our portfolio, our pipeline, competitive position, business, financial condition, results of operations, and prospects may be materially harmed.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have a material 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 might be brought against us by patients, healthcare providers, or others selling or otherwise coming into contact with FYARRO or any other product candidates that we may develop in the future. For example, we may be sued if FYARRO or any other product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we become subject to product liability claims and cannot successfully defend against them, we could incur substantial liabilities. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of our products, our (or third-party) manufacturing processes and facilities or our marketing programs. FDA, EMA or other regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. Although we have obtained product liability insurance coverage, our insurance coverage 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 or maintain 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. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial, particularly in light of the size of our business and financial resources. A product liability claim or series of claims brought against us could also cause our stock price to decline.

The recent global COVID-19 outbreak has affected and is expected to continue to affect our business and operations.

Broad-based business or economic disruptions could adversely affect our ongoing or planned research and development activities. To date, the COVID-19 pandemic has caused significant disruptions to the United States and global economy. Further, infections and deaths related to COVID-19 are disrupting certain healthcare and healthcare regulatory systems globally. Such disruptions could divert healthcare resources away from, or materially delay review by, the FDA and comparable foreign regulatory agencies. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially adversely affect the development and study of our product candidates. For example, we have experienced, and continue to experience, some clinical development disruptions due to the pandemic, including closures at certain lab facilities, which have led, and continue to lead, to longer than anticipated clinical development times. In addition, our clinical trials have been, and may continue to be, affected by the closure of offices, or country borders. Constraints surrounding hospital resources, infrastructure, staff and other resources, can also make it more difficult to enroll new patients in ongoing or planned clinical trials.

As a result of the evolving COVID-19 pandemic, we have experienced and expect to continue to experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- continued delays or difficulties in enrolling and retaining and adequate number of patients in our clinical trials;
- continued delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in receiving authorizations from regulatory authorities to initiate our planned clinical trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data 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, which may impact the integrity of subject data and clinical study endpoints;
- risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations ("CMOs") due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, including as a result of the COVID-19 pandemic;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- changes in local regulations as part of a response to the COVID-19 pandemic, which may require changes in the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether;
- interruption or delays to our sourced discovery and clinical activities; and

- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

The extent of the impact of the COVID-19 pandemic on our future liquidity and operational performance will depend on certain developments, including the duration and spread of further outbreaks, the availability, acceptance and effectiveness of vaccines, the impact on our clinical trials, patients, and collaboration partners, and the effect on our suppliers.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

If the FDA does not conclude that a product candidate and/or new indications satisfy the requirements under the 505(b)(2) regulatory pathway, or if the requirements for such product candidate and/or new indications under Section 505(b)(2) are not as we expect, the approval pathway for such product candidates and/or new indications may take longer, cost more or entail greater complications and risks than anticipated, which may delay or prevent the approval of a product candidate and/or new indications for commercial use.

We submitted a Section 505(b)(2) NDA to the FDA in May 2021 for FYARRO for the treatment of advanced malignant PEComa, and the FDA approved the NDA on November 22, 2021. We may not be successful in obtaining FDA approval under 505(b)(2) regulatory pathway for other indications or product candidates that we may develop.

Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the "FDCA") was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments") and permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and efficacy for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and efficacy. The FDA is not required to meet the PDUFA goal date, and the FDA could require additional information to sufficiently demonstrate safety and efficacy to support approval. Moreover, even if any new indication or product candidate is approved under the Section 505(b)(2) regulatory pathway, the approval may be subject to limitations on the indicated uses for which we may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

We may be unable to obtain United States approval for FYARRO for additional indications or other product candidates that we may develop in the future or foreign regulatory approval for FYARRO or such product candidates that we may develop in the future and, as a result, may be unable to commercialize FYARRO or other product candidates and our business will be substantially harmed.

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

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 numerous factors, including the type, complexity and novelty of the product candidate. The standards that the FDA and our foreign counterparts use when evaluating clinical trial data can, and often does, change during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA policy during the period of drug development, clinical trials and FDA regulatory review. 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 studies. 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.

Disruptions at the FDA and other agencies, including delays or disruptions due to the COVID-19 pandemic, travel restrictions, and staffing shortages, may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In response to the COVID-19 pandemic, after foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. While the FDA has largely caught up with domestic preapproval inspections, it continues to work through its backlog of foreign inspections. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions the FDA is unable to complete such required inspections during the review period.

Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from any particular product candidates we are developing and for which we are seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market, promote and advertise the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy ("REMS") plan as part of approving an 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.

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

Obtaining approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Even though FYARRO has been approved by the FDA, and even if we eventually complete clinical testing and receive approval for FYARRO in additional indications or for any other product candidates that we may develop in the future, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested or may impose other prescribing limitations or warnings that limit the product's commercial potential. Other than FYARRO, we have not obtained regulatory approval for any product candidate, and it is possible that none of our additional product candidates will ever obtain regulatory approval.

Further, regulatory approval may be delayed for reasons beyond our control. For example, a United States federal government shutdown or budget sequestration, such as ones that occurred during 2013, 2018 and 2019, or the current diversion of resources to handle the COVID-19 public health emergency and pandemic may result in significant reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to obtain regulatory approval for our product candidates. In addition, the impact of COVID-19 may cause the FDA to allocate additional resources to product candidates focused on treating related illnesses, which could lead to longer approval processes for our product candidates. Finally, our competitors may file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical trials that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any of our NDAs.

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

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe or effective, are only moderately effective or have undesirable or unintended side effects,

toxicities or other characteristics that preclude us from obtaining regulatory approval or prevent or limit commercial use;

- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that our product candidate's risk-benefit ratio for our proposed indication is acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA, EMA or other comparable regulatory authorities may fail to approve companion diagnostic tests for our product candidates, if required; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

Our clinical trials have been and may in the future be undertaken in the United States. We may choose to conduct additional clinical trials internationally as well. For example, we are currently conducting our PRECISION 1 trial of FYARRO in the United States, but we may conduct the trial in other countries in the future. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from United States clinical trials are intended to serve as the basis for regulatory approval in foreign countries outside the United States, the standards for clinical trials and approval may be different. There can be no assurance that any United States or foreign regulatory authority would accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

We are subject to risks relating to regulatory uncertainty in foreign jurisdictions.

Brexit and uncertainty in the regulatory framework as well as future legislation in the United Kingdom, European Union, and other jurisdictions can lead to disruption in the execution of international multi-center clinical trials, the monitoring of adverse events through pharmacovigilance programs, the evaluation of the benefit-risk profiles of new medicinal products, and determination of marketing authorization across different jurisdictions. Uncertainty in the regulatory framework could also result in disruption to the supply and distribution as well as the import/export both of active pharmaceutical ingredients and finished product. Such a disruption could create supply difficulties for ongoing clinical trials. The cumulative effects of the disruption to the regulatory framework, uncertainty in future regulation, and changes to existing regulations may increase our development lead time to marketing authorization and commercialization of products in the European Union and/or the United Kingdom and increase our costs. We cannot predict the impact of such changes and future regulation on our business or the results of our operations.

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA or EMA grants regulatory 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. The regulatory approval processes in other countries may implicate all of the risks detailed above regarding FDA approval in the United States, as well as other risks. 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 regulatory approvals, our target market will be reduced and our ability to realize the full market potential of a product candidate will be harmed.

Following Brexit, to the extent we conduct any operations in the United Kingdom, we will be subject to applicable regulatory requirements in the United Kingdom. Although the United Kingdom is no longer a member of the European Union, European Union law remains applicable in Northern Ireland. There are a number of new marketing authorization routes available in the United Kingdom, Great Britain (England, Scotland and Wales) or Northern Ireland, in addition to the national procedure. As with the European Union position, a company can only start to market a medicine in the United Kingdom once it has received a marketing authorization. The main legislation that applies to clinical trials in the United Kingdom is the UK Medicines for Human Use (Clinical Trials) Regulations 2004, which transposes the Clinical Trials Directive into domestic law. Consequently, the requirements and obligations that relate to the conduct of clinical trials in the United Kingdom currently remain largely aligned with the European Union position. It is unclear how future regulatory regime in the United Kingdom will impact regulations of products, manufacturers, and approval of product candidates in the United Kingdom. In the immediately foreseeable future, the United Kingdom regulatory approval process is likely to remain similar to that applicable in the European Union, albeit that the processes for applications will be separate. Longer term, the United Kingdom is likely to develop its own legislation that diverges from that in the European Union.

FYARRO is, and any other product candidate we may develop in the future for which we obtain marketing approval for could be, subject to post-marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we or our collaborators fail to comply with regulatory requirements or if we or our collaborators experience unanticipated problems with FYARRO, or any other product candidate we may develop in the future when and if any of them are approved.

FYARRO is, and any other product candidate we may develop in the future for which we obtain marketing approval could be, subject to a comprehensive regulatory scheme, which includes the regulation of manufacturing processes, post-approval clinical data, labeling, advertising, marketing, distribution and promotional activities for such product, by the FDA and other regulatory authorities. The FDA has significant post-marketing authority, including, for example, the authority to require labeling changes based on new safety information and to require post-marketing studies or clinical trials to evaluate serious safety risks related to the use of a drug. For example, the FDA may require the submission of 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. Any REMS required by the FDA may lead to increased costs to assure compliance with new post-approval regulatory requirements and potential requirements or restrictions on the sale of approved products, all of which could lead to lower sales volume and revenue. 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 current good manufacturing practices (“cGMPs”), good laboratory practices (“GLPs”) and good clinical practices (“GCPs”) for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

FYARRO is, and if marketing approval of any other product candidate we may develop in the future is granted may be, subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REMS, which could involve requirements for, among other things, a medication guide, special training for prescribers and dispensers, and patient registries. As a condition of the approval of the NDA for FYARRO, we are required to conduct certain post-marketing requirements (“PMR”) and/or post-marketing commitments (“PMC”). If we fail to comply with the PMR and/or PMC, the FDA may take enforcement actions, which may include, among other things, the issuance of a Warning Letter and assessing civil monetary penalties. The product may also be deemed misbranded.

FYARRO does, and if any other product candidate that we may develop in the future receives marketing approval they may, have a label that limits their approved uses, including more limited subject populations, than we request, and regulatory authorities may require that contraindications, warnings or precautions be included in the product labeling, including a boxed warning, 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, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of products to ensure products are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our prodrug products, if any, for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug and Cosmetic Act relating to the promotion of prescription drugs may lead to a number of actions and penalties, including warning letters, cyber letters, or untitled letters, adverse publicity, the requirement for dear-health-care-provider letters or other corrective information, fines and other monetary penalties, civil or criminal prosecution, including False Claims Act liability, restrictions on our operations and other operating requirements through consent decrees or corporate integrity agreements, debarment, exclusion from participation in federal health care programs and refusal of government contracts or future orders under existing contracts, among other consequences.

We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. 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. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory requirements may have negative consequences, including:

- adverse inspection findings;
- additional warnings or otherwise restrict the product's indicated use, label, or marketing;
- restrictions on our FYARRO products, distribution, manufacturers or manufacturing processes;
- issuance of warning letters, safety alerts, dear-healthcare-provider letters, press releases or other communications containing warnings regarding the product that would result in adverse publicity;
- voluntary or mandatory product recalls and publicity requirements or withdrawal of FYARRO from the market;
- suspension or withdrawal of marketing or regulatory approvals or other permits or voluntary;
- product seizures, detentions or import bans;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements;
- requirement to establish or modify a REMS;
- requirement to conduct post-marketing studies or surveillance;
- restrictions on drug distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- refusal to approve pending applications or supplements to approved applications that we submit and other delays;
- delays in or the rejection of approvals of additional indications for FYARRO;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on, or the suspension or termination of, ongoing or planned trials;
- fines, restitution or disgorgement of profits or revenue;
- reputational harm;

- refusal of government contracts or future orders under existing contracts, exclusion from participation in federal health care programs; or
- injunctions or the imposition of civil or criminal penalties, including False Claims Act liability.

The holder of an approved NDA or comparable regulatory approval must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process and the FDA or comparable foreign regulatory authority may refuse to approve pending applications or supplements to approved applications filed by us.

The occurrence of any event or penalty described above may inhibit our ability to commercialize FYARRO and any other product candidates that we may develop in the future, if approved, and generate revenue. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of the 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 we are found to have improperly promoted off-label uses of FYARRO or any other product candidate that we may develop in the future, if approved, we may become subject to significant liability. The FDA and other regulatory agencies, including the U.S. Department of Justice, strictly regulate the post-approval marketing and promotional claims that may be made about prescription products, such as for FYARRO. 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. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties. As such, we may not promote our products for indications or uses for which they do not have approval. For example, physicians may, in their practice of medicine, use drug products for their patients in a manner that is inconsistent with the approved label. If we, or any of our contractors or agents acting on behalf of us, are found to have promoted such off-label uses, we may become subject to significant liability. The United States federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of FYARRO and any other product candidate that we may develop in the future, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

If we are required by the FDA to obtain approval of a companion diagnostic product in connection with approval of any future product candidates or new indication that we may develop, and if we fail to obtain or face delays in obtaining FDA approval of such companion diagnostic product, we will not be able to commercialize such product candidate intended for use with such companion diagnostic product and our ability to generate revenue from such product candidate will be materially impaired.

In connection with the development of any future product candidates or new indications we may develop or work with collaborators to develop or obtain access to companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our programs. Such companion diagnostics would be used during our clinical trials as well as in connection with the commercialization of any future product candidates or new indication we may develop. To be successful in developing and commercializing such product candidate in combination with these companion diagnostics, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared at the same time the product candidate is approved. To date, the FDA has required marketing approval of all companion diagnostic tests for cancer therapies. Various foreign regulatory authorities also regulate in vitro companion diagnostics as medical devices and, under those regulatory frameworks, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of our current diagnostics and any future diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization.

The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express certain biomarkers or the specific genetic alteration that the companion diagnostic was developed to detect. If the FDA, EMA or a comparable regulatory authority requires approval of a companion diagnostic for any future product candidate or new indication that we may develop, whether before or concurrently with approval of such product candidate, we, and/or future collaborators, may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of such product candidate. Further, in April 2020, the FDA issued new guidance on developing and labeling companion diagnostics for a specific group of oncology therapeutic products, including recommendations to support a broader labeling claim rather than individual therapeutic products. We will continue to evaluate the impact of this guidance on our companion diagnostic development and strategy. This guidance and future issuances from the FDA and other regulatory authorities may impact our development of a companion diagnostic for our product candidates and result in delays in regulatory approval. We may be required to conduct additional studies to support a broader claim. Also, to the extent other approved diagnostics are able to broaden their labeling claims to include our approved drug products, we may be forced to abandon our companion diagnostic development plans or we may not be able to compete effectively upon approval, which could adversely impact our ability to generate revenue from the sale of our approved products and our business operations.

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

A Fast Track or Breakthrough Therapy designation for FYARRO may not lead to a faster development or review process, or we may be unable to maintain or effectively utilize such a designation. We may also seek additional Fast Track designations from the FDA for FYARRO or any of our other product candidates. Even if one or more of our product candidates receive Fast Track designation, we may be unable to obtain or maintain the benefits associated with the Fast Track designation.

In March 2022 and October 2018, we announced that the FDA granted Fast Track designation for FYARRO for the investigation of the treatment of adult and adolescent patients with malignant solid tumors harboring *TSC1 & TSC2* alterations and of patients with advanced malignant PEComa, respectively. While the FDA granted us Priority Review of our NDA for FYARRO in patients with advanced malignant PEComa, there is no guarantee that this Fast Track designation for the *TSC1 & TSC2* alterations will qualify for or that we will be able to take advantage of the expedited review procedures or that we will ultimately obtain regulatory approval of FYARRO in other indications. Even though we received this Fast Track designation in the past, we may not experience a faster development process, review or approval compared to conventional FDA procedures for other indications for FYARRO. We may also seek Fast Track designation for additional cancer indications or other diseases, and we may not be successful in securing such additional designation or in expediting development if such designations were received. Even if we receive Fast Track designation for additional cancer indications, the FDA may withdraw such Fast Track designation if it believes that the Fast Track designation is no longer supported by data from our clinical development program.

Fast Track designation is designed to facilitate the development and expedite the review of therapies intended for the treatment of a serious or life-threatening condition which demonstrate the potential to address unmet medical needs for the condition. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is being studied. If FYARRO for the investigation for the treatment of patients with malignant solid tumors harboring *TSC1 & TSC2* alterations, or FYARRO for any other indication or any other product candidates that we may develop in the future that receives Fast Track designation, does not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. The FDA may withdraw any Fast Track Designation at any time. Furthermore, Fast Track designation does not change the standards for approval. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures and we may not experience a faster development process, review or approval compared to conventional FDA procedures.

In December 2018, we announced that the FDA granted Breakthrough Therapy designation for FYARRO for the treatment of patients with advanced malignant PEComa. We may also seek a Breakthrough Therapy designation for FYARRO for various cancer indications or other diseases. Breakthrough Therapy designation is for a product candidate that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request the FDA to designate our product candidate as a Breakthrough Therapy at the time of, or any time after, the submission of an IND for the product candidate. For product candidates that have been designated as a Breakthrough Therapy, the FDA may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the product candidate; providing timely advice to, and interactive communication with, the sponsor regarding the development of the product candidate to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.

The FDA has broad discretion in determining whether to grant a Fast Track or Breakthrough Therapy designation for a drug. Obtaining a Fast Track or Breakthrough Therapy designation does not change the standards for product approval but may expedite the development or approval process. There is no assurance that the FDA will grant either such designation for any other indication or product candidate that we may pursue. Even if the FDA does grant either such designation, it may not actually result in faster clinical development or regulatory review or approval. Furthermore, such a designation does not increase the likelihood that FYARRO will receive regulatory approval in the United States in other indications.

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

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

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

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

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

We received orphan drug designation and orphan drug exclusivity from the FDA for FYARRO for the treatment of advanced malignant PEComa. We may be unable to obtain orphan drug designation or orphan drug exclusivity for any other indication or regulatory approval for FYARRO for any other orphan population, or we may be unable to successfully commercialize FYARRO for such orphan population due to risks that include:

- the orphan patient populations may change in size;
- there may be changes in the treatment options for patients that may provide alternative treatments to FYARRO;
- the development costs may be greater than projected revenue of drug sales for the orphan indications;
- the regulatory agencies may disagree with the design or implementation of our clinical trials;
- there may be difficulties in enrolling patients for clinical trials;
- FYARRO may not prove to be efficacious in the respective orphan patient populations;
- clinical trial results may not meet the level of statistical significance required by the regulatory agencies; and
- FYARRO may not have a favorable risk/benefit assessment in the respective orphan indication.

If we are unable to obtain regulatory approval for FYARRO in any other orphan population for which we obtain orphan drug designation or we are unable to successfully commercialize FYARRO for such orphan population, it could harm our business prospects, financial condition and results of operations.

Where appropriate, we plan to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated registration pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary regulatory 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 PMRs, the FDA may seek to withdraw accelerated approval.

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for future product candidates. Under the accelerated approval provisions in the FDA, and the FDA's implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that generally provides a 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. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. On December 29, 2022, the Consolidated Appropriations Act, 2023, including the Food and Drug Omnibus Reform Act (FDORA), was signed into law. FDORA made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements.

Prior to seeking such accelerated approval, we will seek feedback from the FDA and will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent 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 under another expedited regulatory designation (e.g., breakthrough therapy designation), there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA 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 a 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 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 FYARRO for advanced malignant PEComa outside the United States and for any additional indications that we may seek approval for, or any product candidates that we may develop in the future. 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 regulatory approval that we may have obtained, and we may not achieve or sustain profitability.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the "ACA"), was passed, which substantially changes the way healthcare is financed by both the government and private insurers, and significantly impacts the United States pharmaceutical industry. In December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of the federal district court litigation regarding the method CMS uses to determine this risk adjustment. Since then, the ACA risk adjustment program payment parameters have been updated annually. Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the former Trump administration to repeal or replace certain aspects of the ACA. In June 2021, the Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is unclear how this decision and other healthcare reforms will impact our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2022, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In January 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for FYARRO or any other product candidates that we may develop if the future, if approved, and accordingly, our financial operations.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require a pharmaceutical manufacturer to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. Further, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at increasing competition for prescription drugs. In response to this executive order, the HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and potential legislative policies that Congress could pursue to advance these principles. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. The impact of these legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the Biden administration on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, a number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. Implementation of cost containment measures or other healthcare reforms that affect the pricing and/or availability of drug products may impact our ability to generate revenue, attain or maintain profitability, or commercialize products for which we may receive regulatory approval in the future.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (“Right to Try Act”), was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new product candidates that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its products available to eligible patients as a result of the Right to Try Act.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

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

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 in other jurisdictions. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Additionally, the collection and use of health data in the European Union is governed by the General Data Protection Regulation (the "GDPR"), which extends the geographical scope of European Union data protection law to non-European Union entities under certain conditions and imposes substantial obligations upon companies and new rights for individuals. Failure to comply with the GDPR and the applicable national data protection laws of the European Union Member States may result in fines up to €20.0 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. The

GDPR may increase our responsibility and liability in relation to personal data that we may process, and we may be required to put in place additional mechanisms in an effort to comply with the GDPR. This may be onerous and if our efforts to comply with GDPR or other applicable European Union laws and regulations are not successful, it could adversely affect our business in the European Union.

Finally, state and foreign laws may apply generally to the privacy and security of information we maintain, and may differ from each other in significant ways, thus complicating compliance efforts. For example, the California Consumer Privacy Act of 2018 (the "CCPA"), which took effect on January 1, 2020, gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. In addition, the CCPA (a) allows enforcement by the California Attorney General, with fines set at $2,500 per violation (i.e., per person) or $7,500 per intentional violation and (b) authorizes private lawsuits to recover statutory damages for certain data breaches. While it exempts some data regulated by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and certain clinical trials data, the CCPA, to the extent applicable to our business and operations, may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. Some observers note that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

Inadequate funding for the FDA, the Securities and Exchange Commission ("SEC") and other government agencies 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 agency have fluctuated in recent years as a result. In addition, government funding of 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, including delays or disruptions due to the COVID-19 pandemic, travel restrictions, and staffing shortages, may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the United States 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 shutdown 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. Separately, in response to the COVID-19 pandemic, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. While the FDA has largely caught up with domestic preapproval inspections, it continues to work through its backlog of foreign inspections. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If we fail to comply with other United States healthcare laws and compliance requirements, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business. Further, our relationships with healthcare professionals, clinical investigators, CROs and third-party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to significant losses, including, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory 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 regulatory approval. Restrictions under applicable federal and state healthcare laws and regulations may include the following:

- the federal Anti-Kickback Statute 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. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties;

- 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. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making, or causing to be made, false statements relating to healthcare matters;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- the FCPA, the U.K. Bribery Act of 2010, and other local anti-corruption laws that apply to our international activities;

- the federal HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”) and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance effort;

- 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 CMS information regarding certain payments and other transfers of value made to covered recipients in the previously year, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; our failure to submit required information timely, accurately, and completely may result in significant civil monetary penalties and may increase our liability under other federal laws or regulations; and

- additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America’s Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union General Data Protection Regulation, which became effective May 2018 also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance effort.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exceptions or safe harbors, it is possible that some of our activities, including those of our contractors or agents who conduct business for or on behalf of us, could be subject to challenge under one or more of such laws. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. We may be subject to private “qui tam” actions brought by individual whistleblowers on behalf of the federal or state governments.

If we were to grow our business and expand our sales organization or rely on distributors outside of the United States, we would be at increased risk of violating these laws or our internal policies and procedures. The risk of us being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and data privacy laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that our business practices 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, 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. Any of the foregoing consequences could seriously harm our business and our financial results. 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.

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 fraud, misconduct or other improper activities. Misconduct by these parties could include intentional, reckless, and negligent conduct that fails to: comply with the regulations of the FDA and other comparable foreign regulatory authorities; provide true, complete and accurate information to the FDA and other comparable foreign regulatory authorities; comply with manufacturing standards we have established; comply with federal and state health care fraud and abuse laws and regulations and similar foreign fraudulent misconduct laws; and accurately report financial information or data or disclose unauthorized activities to us. In particular, research, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, certain customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending our self or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

If we or any contract manufacturers and suppliers we engage fails 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 and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures, the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes, the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. The operations of our contractors may involve the use of hazardous and flammable materials, including chemicals and biological materials, and accordingly may produce hazardous waste products. We 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, including any contamination at our current or past facilities and at third-party facilities, 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 maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, 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.

Our business activities may be subject to the FCPA and similar anti-bribery and anti-corruption laws of other countries. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the UK Bribery Act. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals are owned and operated by the government, and doctors and other hospital employees are employed by the government and would be considered foreign officials under the FCPA, and often the purchasers of pharmaceuticals are government entities; therefore, our dealings with these doctors, hospital employees and purchasers are subject to regulation under the FCPA. Recently, the SEC and DOJ have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, collaborators, or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

Our business activities may be subject to United States and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, United States export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by United States sanctions. For example, the U.S. government and other governments in jurisdictions in which we may operate in the future have imposed severe sanctions and export controls against Russia and Russian interests and threatened additional sanctions and controls in connection with the conflict between Russia and Ukraine. The impact of these measures, as well as potential responses to them by Russia, is currently unknown and they could adversely affect our business, supply chain, business partners or customers.

If we fail to comply with export and import regulations, and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

Further, with rising international trade tensions or sanctions, our business may be adversely affected following new or increased tariffs that result in increased global clinical trial costs as a result of international transportation of clinical drug supplies, as well as the costs of materials and products imported into the United States. Tariffs, trade restrictions or sanctions imposed by the United States or other countries, including as a result geopolitical tension, such as a deterioration in the relationship between the United States and China or escalation in conflict between Russia and Ukraine, including any additional sanctions, export controls or other restrictive actions that may be imposed by the United States and/or other countries against governmental or other entities in Russia, could increase the prices of our and our collaboration partners' drug products, affect our and our collaboration partners' ability to commercialize such drug products, or create adverse tax consequences in the United States or other countries. As a result, changes in international trade policy, changes in trade agreements and the imposition of tariffs or sanctions by the United States or other countries could materially adversely affect our results of operations and financial condition.

Risks Related to Our Reliance on Third Parties

We contract with qualified third parties for the production of FYARRO for commercialization and expect to continue to do so for additional clinical trials. This reliance on third parties, some of which are sole source suppliers, increases the risk that we will not have sufficient quality and quantities of FYARRO to meet demand or otherwise or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have, nor do we plan to acquire, the infrastructure or internal capability to manufacture supplies of FYARRO or any future product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of FYARRO and product candidates for preclinical studies and clinical trials under the guidance of members of our organization. In the case of FYARRO, we rely on a single third-party manufacturer, Fresenius Kabi, LLC ("Fresenius Kabi"), and currently have no alternative manufacturer in place. On January 13, 2022, we entered into a Negotiated Purchase Order Terms and Conditions for Clinical and Commercial

Product, as amended effective as of August 1, 2022 (the “Fresenius Agreement”), with Fresenius Kabi pursuant to which Fresenius Kabi will manufacture FYARRO for intravenous use for us, and we will purchase FYARRO as a finished drug product from Fresenius Kabi, on a purchase-order basis. The Fresenius Agreement, as amended in January 2023, will be effective through March 31, 2024 (or such later date as may be agreed between the parties in writing), and we may purchase FYARRO for either clinical or commercial purposes for use in the United States and Canada. The price of FYARRO will be fixed, subject to the ability of Fresenius Kabi to increase pricing under specified circumstances. We also have an obligation to purchase certain minimum quantities of FYARRO and any failure to purchase those minimum quantities will result in an additional payment from us to Fresenius Kabi. We have other supply agreements in place for key raw materials used in the manufacture of FYARRO such as for the drug substance sirolimus and for human albumin, which are key ingredients in the drug product. If we were to engage another third-party manufacturer, we will be required to verify that the new third-party manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a bridging study, that any new manufacturing process will produce FYARRO or any other product candidate we may develop in the future, if approved, according to the specifications previously submitted to the FDA or another regulatory authority. If we were to experience an unexpected loss of supply of FYARRO or any other product candidate that we may develop in the future for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations in commercializing FYARRO for advanced malignant PEComa, or be required to restart or repeat, any pending or ongoing clinical trials for FYARRO in other indications or for any other product candidates we may develop in the future, in a timely manner or on budget. Moreover, if we are unable to keep up with demand for FYARRO, our revenue could be impaired, market acceptance for FYARRO could be adversely affected.

We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Further, any delay in identifying and qualifying a manufacturer for commercial production could negatively impact the commercialization of FYARRO, and, in the event that we do not have sufficient product to complete our planned clinical trials, it could delay such trials. 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 FYARRO or any of our other product candidates that we may develop in the future according to our schedule and specifications, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements, including manufacturing drug supply pursuant to strictly enforced cGMPs;
- the failure of the third-party contractor to manufacture FYARRO or any of our other product candidates that we may develop in the future according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of our contract manufacturing partners and are dependent on these contract manufacturing partners for compliance with cGMP regulations for manufacturing both active pharmaceutical ingredients (“API”) and finished drug products. To date, we have obtained drug substance and drug product from third-party manufacturers to support preclinical and clinical testing of FYARRO. We are in the process of developing our supply chain for FYARRO, including through the Fresenius Agreement. As we commercialize FYARRO and advance FYARRO for additional indications or any other product candidates we may develop in the future through development, we will consider redundant supply for the API and drug product for FYARRO and each of our product candidates that we may develop in the future to protect against any potential supply disruptions. However, we may be unsuccessful in putting in place such framework agreements or protecting against potential supply disruptions.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or others, they will not be able to pass a pre-approval inspection or secure and/

or maintain regulatory approval for their manufacturing facilities. In addition, we do not have control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, many of our CMOs are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks for the production of such materials and products. As a result, failure to satisfy the regulatory requirements for the production of those materials and products may affect the regulatory clearance of our CMOs facilities generally. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of FYARRO or any of our other product candidates that we may develop in the future or if we withdraw any such approval in the future, we will need to find alternative manufacturing facilities, and those new facilities would need to be inspected and approved by FDA, EMA or comparable regulatory authority prior to commencing manufacturing, which would significantly impact our ability to commercialize FYARRO for advanced malignant PEComa and develop, obtain regulatory approval for or market FYARRO for other indications or any of our other product candidates that we may develop in the future, if approved. Our reliance on CMOs also exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may appropriate our trade secrets or other proprietary information. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on the parties, 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 FYARRO or any of our other product candidates or drugs that we may develop in the future and harm our business and results of operations.

In addition, the manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of FYARRO or in our third-party manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any stability or other issues relating to the manufacture of our product candidates may occur in the future. Further, as product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause FYARRO or any of our other product candidates that we may develop in the future to perform differently and affect commercialization or the results of planned clinical trials or other future clinical trials. In addition, quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at our third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for FYARRO or any of our product candidates that we may develop in the future. Further, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical study costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations, and growth prospects. Our current and anticipated future dependence upon others for the manufacture of FYARRO and any of our other product candidates that we may develop in the future may adversely affect our future profit margins and our ability to commercialize FYARRO or any other product candidates that we may develop in the future that receives regulatory approval on a timely and competitive basis.

We are dependent on a single-source supplier for the drug product FYARRO, and the loss of such supplier could harm our business.

We rely on a single-source supplier, Fresenius Kabi, for our drug product FYARRO. In January 2022, we entered into the Fresenius Agreement, which we amended in January 2023 to, among other things, extend the term of the Fresenius Agreement to March 31, 2024 (or such later date as may be agreed upon between the parties), and amend certain terms related to pricing and the Company's obligation to purchase certain minimum quantities of FYARRO from Fresenius Kabi. We also have supply agreements in place for key raw materials used in the manufacture of FYARRO such as for the drug substance sirolimus and for human albumin, which are key ingredients in the drug product. Our suppliers could discontinue the manufacturing or supply of FYARRO at any time. We do not carry a significant inventory of FYARRO or our key raw materials used in the manufacture of FYARRO. Our suppliers may not be able to meet our demand for their products, either because of acts of nature, the nature of our agreements with those manufacturers or our relative importance to them as a customer, and our manufacturers may decide in the future to discontinue or reduce the level of business they conduct with us either entirely or for a particular territory. The loss of any of the foregoing would require significant time and effort to locate and qualify an alternative source of supply. We currently rely on a single company for such manufacturing for FYARRO. Any contractual disputes between us and such manufacturer, the termination of the Fresenius Agreement or loss of manufacturing ability by such manufacturer could similarly require significant time, effort and expense to locate and qualify an alternative source of manufacturing, which could materially harm our business.

In addition, we might not be able to identify and qualify additional or replacement suppliers for the drug product FYARRO or for the key raw materials used in the manufacture of FYARRO timely or at all or without incurring significant additional costs. We cannot guarantee that we will be able to establish alternative relationships on similar terms, without delay or at all. We may also face regulatory delays or be required to seek additional regulatory clearances or approvals if we experience any delay or deficiency in the quality of products obtained from suppliers or if we have to replace our suppliers. In addition, we do not currently have arrangements in place for redundant supply of the drug product FYARRO or for the key raw materials used in the manufacture of FYARRO.

Establishing additional or replacement suppliers for the drug product FYARRO or for the key raw materials used in the manufacture of FYARRO, if required, or any supply interruption from our suppliers, could limit our ability to manufacture our products, result in production delays and increased costs and adversely affect our ability to deliver products to our customers on a timely basis. Our inability to obtain sufficient quantities of the drug product FYARRO or for the key raw materials used in the manufacture of FYARRO also could adversely affect clinical development of FYARRO in other indications. If we are not able to identify alternate sources of supply for the drug product FYARRO or for the key raw materials used in the manufacture of FYARRO, we will not be able to, or may be delayed in our efforts to, successfully commercialize FYARRO or any other product candidate that we may develop in the future or we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for FYARRO in other indications or for any other product candidates that we may develop in the future.

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 FYARRO for patients or for clinical trials or any other product candidate that we may develop in the future, if approved, could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and highly regulated 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 efficacy. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, as well as sophisticated quality assurance and quality control procedures. Manufacturing drugs is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. 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 efficacy of the products before and after such changes. If microbial, viral or other contaminations or impurities 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 or impurity, which could delay clinical trials and adversely harm our business. If our third-party manufacturers are unable to produce sufficient quantities of consistent quality 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 depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. We entered into a license agreement with Abraxis BioScience, LLC, a wholly owned subsidiary of Celgene Corporation, which is a wholly owned subsidiary of Bristol-Myers Squibb Company (“BMS”) pursuant to which we have licensed exclusive global rights to intellectual property and know-how related to FYARRO (the “BMS License”). We are required to use commercially reasonable efforts or diligent efforts to commercialize products based on the licensed rights and to pay certain royalties based off our net sales, certain sublicense fees and certain other fees. We may not meet these requirements, which could result in a loss or termination of any rights under such agreements. Any termination of these licenses will result in the loss of significant rights and will restrict our ability to commercialize FYARRO.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below under “Risks Related to Our Intellectual Property.” If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

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

We do not have the ability to independently conduct all of our preclinical studies and clinical trials. We currently rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct, supervise and monitor our current or planned preclinical studies and clinical trials of FYARRO for additional indications, and we expect to continue to rely upon third parties to conduct additional preclinical studies and clinical trials of FYARRO for additional indications and other product candidates we may develop in the future. We enter into agreements with third parties that have a significant role in the conduct of our preclinical studies and clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we have limited ability to control the conduct of such third party, the amount or timing of resources that any such third party will devote to our preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. The third parties we rely on for these services may also (i) have staffing difficulties, (ii) fail to comply with contractual obligations, (iii) experience regulatory compliance issues, (iv) undergo changes in priorities or become financially distressed, or (v) have relationships with other entities, some of which may be our competitors, which may draw time and resources from our development programs. The third parties with whom we may contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies and clinical trials being delayed or unsuccessful. Some of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements with a third party, this would delay our drug development activities.

Our reliance on these third parties for such drug development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the general investigational plan and protocols for the trial and legal, regulatory, and scientific requirements and standards. Moreover, the FDA requires us and our third parties to comply with applicable GLP and GCP standards, regulations for conducting, monitoring, recording and reporting the results of preclinical studies and clinical trials to assure that the data and reported results are reliable and accurate and for clinical trials that the rights, integrity and confidentiality of trial participants are protected and that they are adequately informed of the potential risks of participating in clinical trials. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or 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 preclinical studies and clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product candidates produced under current cGMP regulations and will require a large number of test patients. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties. We are also required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not successfully carry out their contractual duties or perform preclinical studies and clinical trials in a satisfactory manner, meet expected deadlines or conduct our preclinical studies and clinical trials in accordance with legal and regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for product candidates that we may develop in the future and will not be able to, or may be delayed in our efforts to, successfully commercialize such product candidates, if approved.

We may form or seek strategic alliances or collaborations in the future. Such alliances and collaborations may inhibit future opportunities, or we may not realize the benefits of such collaborations or alliances.

We may form or seek strategic alliances, joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to FYARRO or any future product candidates that we may develop. We are at risk that any such future collaborations may not be successful.

Factors that may affect the success of our collaborations include the following:

- our collaboration partners may incur financial and cash flow difficulties that force them to limit or reduce their efforts under their collaboration agreement with us;
- our collaboration partners may be pursuing alternative technologies or developing alternative products that are competitive to our technology and products, either on their own or in partnership with others;
- our collaboration partners may terminate their collaboration with us, which could make it difficult for us to attract new partners or adversely affect perception of us in the business and financial communities; and
- our collaboration partners may pursue higher priority programs or change the focus of their development programs, which could affect their commitment to us.

In addition, any future collaboration agreements we may enter into, are generally subject to termination by the counterparty on short notice upon the occurrence of certain circumstances without cause subject to a specified notice period. Accordingly, even if we believe that the development of product candidates is worth pursuing, our partners may choose not to continue with such development. If any of our collaborations are terminated, we may not receive additional milestones or royalties under those collaborations. In addition, we may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner on short notice, and the terms of any additional collaboration or other arrangements that we establish may not be favorable to us. For example, in December 2020, we granted to EOC (as defined herein) exclusive rights to develop and commercialize FYARRO in the EOC Territory (as defined below). Under the EOC License Agreement (as defined herein), we received an upfront payment and were eligible to receive regulatory and sales-based milestone payments upon the occurrence of certain milestone events totaling $257 million, as well as tiered royalties based on annual net sales of FYARRO. In addition, EOC was responsible for development, regulatory submissions, and commercialization in China, Hong Kong, Macau and Taiwan (collectively, the “EOC Territory”). The EOC License Agreement was terminated effective June 27, 2022, and EOC initiated a Request for Arbitration with the International Chamber of Commerce's International Court of Arbitration against us on the same date. Under the EOC License Agreement, we relied on EOC for a substantial portion of the financial resources and for the development, regulatory, and commercialization activities for FYARRO in the EOC Territory. In addition, EOC's termination of the EOC License Agreement prior to completing development or commercialization of the FYARRO under the collaboration adversely impacts the potential approval and our revenue from the licensed product in the EOC Territory and we will not receive future revenues from the collaboration. It may be necessary for us to assume the responsibility at our own expense for the development of FYARRO in the EOC Territory or find another partner for the territory. In that event, we would likely need to seek additional funding and our potential to generate future revenues from FYARRO could be significantly reduced and our business could be materially and adversely harmed. See Notes 9 and 16 to the audited financial statements for more information about the EOC License Agreement, its termination and resulting arbitration.

Future efforts for additional alliances or collaborations may also 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. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Furthermore, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction.

If we cannot maintain successful collaborations, our business, financial condition, and operating results may be adversely affected.

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

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

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

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

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

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

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

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

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

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

If we enter into any collaboration arrangements with any third parties, 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 would pose numerous risks to us, including the following:

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

Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements. For example, on June 27, 2022, EOC elected to terminate the EOC License Agreement, effective immediately, due to alleged material breaches by us. We disagree with, and continue to dispute, EOC's allegations of material breach and do not believe that EOC had a right to terminate the EOC License Agreement for material breach, and accordingly believe that the termination of the EOC License Agreement is a termination for convenience. EOC had the right to terminate the agreement for convenience upon 120 days advance written notice. We waived such notice period in connection with EOC's termination notice and, as a result, the EOC License Agreement was terminated effective June 27, 2022. Under the EOC License Agreement, we relied on EOC for a substantial portion of the financial resources and for the development, regulatory, and commercialization activities for FYARRO in the EOC Territory. In addition, EOC's termination of the EOC License Agreement prior to completing development or commercialization of the FYARRO under the collaboration adversely impacts the potential approval and our revenue from the licensed product in the EOC Territory and we will not receive future revenues from the collaboration. It may be necessary for us to assume the responsibility at our own expense for the development of FYARRO in the EOC Territory or find another partner for the territory. In that event, we would likely need to seek additional funding and our potential to generate future revenues from FYARRO could be significantly reduced and our business could be materially and adversely harmed.

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

Our success is highly dependent on our ability to attract and retain highly skilled executive officers, key scientific personnel 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 operating results. In particular, the loss of one or more of our executive officers or key scientific personnel could be detrimental to us if we cannot recruit suitable replacements in a timely manner. On November 9, 2022, we announced the transition of Neil Desai, our founder, director, President and Chief Executive Officer to Executive Chairman, and the appointment of Brendan Delaney, our Chief Operating Officer, to President and Chief Executive Officer, each effective January 1, 2023. In addition, on March 3, 2023, we announced Mr. Delaney's resignation as President and CEO, effective March 14, 2023, and the appointment of Scott Giacobello, our Chief Financial Officer to Interim CEO and President, effective March 15, 2023, while our Board conducts an executive search for a successor CEO. These leadership transitions, as well as future other senior management changes, could disrupt and have a detrimental effect on our business. We will need to hire additional personnel as we expand our clinical development and commercial activities. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

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

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

If we are unable to successfully establish and maintain sales or marketing capabilities or enter into agreements with third parties to sell or market FYARRO for advanced malignant PEComa or any additional indications that we may seek approval for, or other product candidates, when approved, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

In order to commercialize FYARRO for advanced malignant PEComa or any additional indications that we may seek approval for, or any other product candidate that we may develop in the future, if approved, we must build and maintain 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(s). There are risks involved with establishing and maintaining both our own commercial capabilities and entering into arrangements with third parties to perform these services and we may not be successful in accomplishing these required tasks, which may negatively impact the successful commercialization of our product(s), including FYARRO for advanced malignant PEComa, for example.

Establishing and maintaining an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates that we obtain approval to market 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. If the commercial launch of a product candidate for which we recruit a sales team and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration and such arrangements may prove to be less profitable than commercializing the product on its own. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. 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 sales will suffer, and we may incur significant additional losses.

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 79 full-time employees, including 47 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating as a public company, we expect to need additional managerial, operational, development, 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, EMA and other comparable foreign regulatory agencies’ review process for FYARRO and any other product candidates, 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 commercialize FYARRO and any other product candidates we may develop in the future, if approved, 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 our 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 regulatory approval of FYARRO for additional indications and any other product candidates that we may develop in the future 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

FYARRO and other product candidates that we may develop in the future and, accordingly, may not achieve our research, development and commercialization goals.

Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer security or data privacy 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 in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems, and those of our third-party CROs, other contractors (including sites performing our clinical trials) and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. To the extent that any disruption or security breach were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our product candidates could be delayed. We cannot assure you that our data protection efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties, will prevent significant breakdowns or breaches in systems or other cyber incidents that cause loss, destruction, unavailability, alteration or dissemination of, or damage to, our data that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information or individually identifiable health information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security incident could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed, ongoing 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 expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach. 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 incident were to result in a loss, destruction or alteration of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/ or international 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 of our systems or third-party systems where information important to our business operations or commercial development is stored. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

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

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, such as the COVID-19 pandemic, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party CMOs, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidate or interruption of our business operations. Earthquakes, wildfires or other natural disasters could further disrupt our operations, including at our California headquarters, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party CMOs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

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

Our NOL carryforwards may be unavailable to offset future taxable income because of restrictions under United States tax law. Our NOLs generated in tax years beginning before January 1, 2018 are only permitted to be carried forward for 20 taxable years under applicable United States federal tax law, and therefore could expire unused. Our federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal NOLs in tax years beginning after December 31, 2020 is limited to 80% of our current year taxable income. It is uncertain if and to what extent various states will conform to the Tax Act. As of December 31, 2022, after consideration of the NOLs that have been estimated to expire unused under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), we had federal NOL carryforwards of approximately $167.5 million, $44.1 million of which will begin to expire in 2030, and the remaining $123.4 million do not expire. We also have state NOL carryforwards of approximately $72.0 million available as of December 31, 2022, which begin to expire in 2037.

Under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change" (generally defined as a cumulative change in the corporation's ownership by "5-percent stockholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change taxable income may be limited. Similar rules may apply under state tax laws. We have experienced such ownership changes in the past and we may experience ownership changes in the future as a result of subsequent changes in our stock ownership, some of which are outside our control. To the extent such limitations will cause NOL and research and development credit carryforwards to expire unused, these tax attributes have been removed from our deferred tax asset. Our ability to utilize our NOLs and certain other tax attributes could be limited by an "ownership change" as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations. Limitations may also apply to state NOLs under state law.

United States federal income tax reform could materially adversely affect our financial condition.

Legislation or other changes in United States and international tax laws could increase our tax liability and adversely affect after-tax profitability. For example, the United States recently enacted the Inflation Reduction Act, which implemented a number of changes, including a 1% excise tax on stock buybacks and an alternative minimum tax on adjusted financial statement income. Such enacted and other proposed changes, as well as regulations and legal decisions interpreting and applying these changes, may have significant impacts on our effective tax rate, cash tax expenses and net deferred tax assets in future periods.

A variety of risks associated with marketing FYARRO or any product candidates that we may develop in the future, if approved, internationally could materially adversely affect our business.

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

- differing regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

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

Risks Related to Our Intellectual Property

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

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection in the United States and other countries for our product and product candidates, proprietary technologies and their uses, and know-how related to our business, as well as our ability to operate without infringing upon the valid and enforceable patents and proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product and product candidates, proprietary technologies and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

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

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

Although we own or license twelve (12) issued patents in the United States, we cannot be certain that the claims in our other United States pending patent applications, corresponding international patent applications and patent applications in certain foreign territories, or those of our licensors, will be considered patentable by the United States Patent and

Trademark Office (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 our issued patent will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our current or potential future collaborators will be successful in protecting our product or 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;
- if clinical trials encounter delays, the period of time during which we could market our current or future product candidates under patent protection would be reduced;
- patents may be challenged, invalidated, modified, narrowed, revoked, circumvented, found to be unenforceable, found to be not infringed or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that could limit, interfere with or eliminate our ability to make, use and sell our product or potential product candidates or design around any of our owned, co-owned, or licensed patents;
- since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product; or (ii) invent any of the inventions claimed in our patents or patent applications;
- even when laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us;
- there may be significant pressure on the United States government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop and market competing products or product candidates.

The patent prosecution process is also expensive, complex, and time-consuming, and we and our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we and our licensors will fail to identify patentable aspects of our (or such licensor's) research and development output before it is too late to obtain patent protection. If we are unable to obtain or maintain patent protection with respect to any of our proprietary products and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed.

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

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

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

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. Our pending and future patent applications and those of our licensors may not result in patents being issued that protect our product or product candidates or effectively prevent others from commercializing competitive products or product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and our scope can be reinterpreted after issuance. Even if patent applications we own or in-licenses currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-licenses may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product or product candidates will be protectable or remain protected by valid and enforceable patents.

Our competitors or other third parties may be able to circumvent our patents or the patents of our licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

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

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

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

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

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

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

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

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

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or

- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of the date of this Annual Report, others may hold proprietary rights that could prevent FYARRO or our product candidates from being marketed. For example, various patent offices periodically grant mode of action patents and a third party may have or obtain a patent with claims covering modes of action relevant to our product or product candidates. While these mode of action patents may be difficult to enforce, the third party may assert a claim of patent infringement directed at one of our products or product candidates. Any patent-related legal action or any claim relating to intellectual property infringement that is successfully asserted against us claiming damages and seeking to enjoin commercial activities relating to our products or processes could subject us to significant liability for damages, including treble damages and attorney’s fees if it was determined that we willfully infringed, and require us to obtain a license to manufacture or market our product or product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our current or future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product or 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 or delay us from developing and commercializing our product or product candidates, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of our outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product or product candidates and technology.

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

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

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product or product candidates that we may develop in the future. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements. We may also be unable to license or acquire third-party intellectual property rights on terms that would be favorable to us or allow us to make an appropriate return on our investment or at all. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, PGR, IPR, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents or our licensors' patents in such a way that such patents no longer cover our technology or platform, product or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, product or any product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

The outcome following legal assertions of invalidity and/or unenforceability is unpredictable, and prior art could render our patents or our licensors' patents invalid. There is no assurance that all potentially relevant prior art relating to our patents and patent applications, or the patents and patent applications of our licensors has been found. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or the patents and patent applications of our licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on such product or product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products or product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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

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

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common 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 or developments in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product or product candidates, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

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

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

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

On September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we may not be certain that we or our licensors are the first to either (1) file any patent application related to our product or product candidates or (2) invent any of the inventions claimed in the patents or patent applications.

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

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

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

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

For example, the United States 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 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 United States Congress, the United States federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and the patents we might obtain or license in the future.

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

We may also be subject to claims that our former employees or our licensors or other third parties have an ownership interest in our patents or other intellectual property. Confidentiality and intellectual property assignment agreements may not be honored and may not effectively assign intellectual property rights to us. The assignment of intellectual property rights under these agreements may not be automatic upon the creation of the intellectual property 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 it, to determine the ownership of what we regard as our intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Patent terms may be inadequate to protect our competitive position on our product or product candidates that we may develop in the future 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 United States non-provisional effective filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product or product candidates that we may develop in the future are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to us.

If we do not obtain patent term extension for our product or product candidates that we may develop in the future, our business may be materially harmed.

In January 2022, we filed an application for patent term extension based on the approval of FYARRO. Depending upon the timing, duration and specifics of FDA regulatory approval of our product candidates that we may develop in the future, one or more of our United States patents or those of our licensors may also be eligible for limited patent term restoration under 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 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 or require. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request or require, 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 own, co-own, or have exclusively licensed at least twelve (12) issued patents in the United States and pending patent applications in the United States and other countries, filing, prosecuting and defending patents on our product or product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States, assuming that rights are obtained 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. In addition, the statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications and we may not timely file foreign patent applications.

Further, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, a new unitary patent system will likely be introduced by the end of 2023, which would significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

Competitors may use our technologies in jurisdictions where we do not pursue or have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product or product candidates, and our patents, the patents of our licensors, or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

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

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

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 our owned and in-licensed patents and/or applications will be due to be paid to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications and those of our licensors and any patent rights we may own or license in the future. We have systems in place to remind us to pay these fees, and, in certain instances, we rely on our licensor partners 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 and over the lifetime of our owned patents and applications. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, competitors or other third parties might be able to enter the market earlier than would otherwise have been the case and it could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. However, trade secrets are difficult to protect. For example, we may be required to share our trade secrets with third-party licensees, collaborators, consultants, contractors, or other advisors and we have limited control over the protection of trade secrets used by such third parties. Although we have taken steps to protect our trade secrets and unpatented know-how, including by entering into confidentiality agreements with third parties and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed or that they have been obtained in all circumstances, and it is possible that any of these parties may breach the agreements and may unintentionally or willfully disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. Enforcing a claim that a party illegally obtained, disclosed, used or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. If any of these events occurs or if we otherwise lose protection for our trade secrets or confidential or proprietary information, the value of this information may be greatly reduced, and our competitive position in the marketplace, business, financial condition, results of operations and prospects may be materially adversely affected. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

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

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

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

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

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

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

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

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership 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.

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

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

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by us and our licensors and partners; and
- the priority of invention of patented technology.

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

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

The patent protection and patent prosecution for our product and product candidates that we may develop in the future may be dependent on third parties.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product or product candidates, there may be times when the filing and prosecution activities for patents are controlled by our licensors or collaboration partners, including those licensed to us under our license agreements. If any of our licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product or product candidates that we may develop in the future, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize our product or those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. We collaborate with other companies and institutions with respect to research and development matters. Also, we rely on numerous third parties to provide us with materials that we use to develop our technology. If we cannot successfully negotiate sufficient ownership, licensing, and/or commercial rights to any invention that result from our use of any third-party collaborator’s materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator’s materials, or data developed in a collaborator’s study, our ability to capitalize on the market potential of these inventions or developments may be limited or precluded altogether. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

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

Our licensed patent applications may have been or may be in the future supported through the use of United States government funding awarded by the National Institute of Health or the FDA Office of Orphan Products Development and the Army Medical Research and Development Command. Although we do not currently own issued patents or pending patent applications that have been generated through the use of United States government funding, we have licensed, or may acquire or license in the future, intellectual property rights that have been generated through the use of United States government funding or grant. Pursuant to the Bayh-Dole Act of 1980, the United States government has certain rights in inventions developed with government funding. These United States government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the United States government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (“march-in rights”). The United States government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the United States government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for United States industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for United States industry may limit our ability to contract with non-United States product manufacturers for products covered by such intellectual property.

General Risks

Litigation and legal proceedings, including the EOC dispute, may substantially increase our costs and harm our business.

As described in Note 16 (Commitments and contingencies) to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K, we have been, are, and may in the future become, party to lawsuits and legal proceedings including, without limitation, actions and proceedings in the ordinary course of business relating to our collaboration partners, directors, officers, stockholders, intellectual property rights, employment matters and the safety or efficacy of our products, which will cause us to incur legal fees and other costs related thereto, including potential expenses for the reimbursement of legal fees of officers and directors under indemnification obligations. On June 27, 2022, EOC filed a Request for Arbitration with the International Chamber of Commerce’s International Court of Arbitration against us. In the Request for Arbitration, EOC claims that we breached certain provisions of the EOC License Agreement, including failing to provide certain manufacturing and clinical development information to EOC. As a result, EOC is seeking monetary damages. The arbitration process is ongoing.

The expense of defending against such litigation and legal proceedings may be significant and there can be no assurance that we will be successful in any defense. Further, the amount of time that may be required to resolve such lawsuits or legal proceedings is unpredictable, and these actions may divert management’s attention from the day-to-day operations of our business, which could adversely affect our business, results of operations, and cash flows. Our insurance carriers may deny coverage, may be inadequately capitalized to pay on valid claims, or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our consolidated operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. Litigation and legal proceedings are subject to inherent uncertainties, and an adverse result in such matters that may arise from time to time could have a material adverse effect on our business, results of operations, and financial condition.

Our stock price is volatile.

The market price of our common stock could be subject to significant fluctuations. From the completion of the Merger on August 26, 2021 through December 31, 2022, the market price for our common stock ranged from a low of $11.57 to a high of $33.00. Market prices for securities of early-stage pharmaceutical, biotechnology, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- our ability to obtain regulatory approvals for FYARRO in other indications or for any other product candidates that we may develop in the future, and delays or failures to obtain such approvals;
- the results of current, and any future, nonclinical or clinical trials of FYARRO or any of our product candidates that we may develop in the future;
- the failure of FYARRO or any product candidates that we may develop in the future, if approved for marketing and commercialization, to achieve commercial success;
- any inability to obtain adequate supply of FYARRO or any of our product candidates that we may develop in the future or the inability to do so at acceptable prices;
- the entry into, or termination of, key agreements, including key licensing, supply or collaboration agreements;
- adverse regulatory authority decisions;
- the initiation of material developments in, or conclusion of, disputes or litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others;

- changes in laws or regulations applicable to FYARRO or any of our product candidates that we may develop in the future;
- announcements by commercial partners or competitors of new commercial products, clinical progress (or the lack thereof), significant contracts, commercial relationships, or capital commitments;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors, including deteriorating market conditions due to investor concerns regarding inflation and hostilities between Russia and Ukraine;
- adverse publicity relating to our markets, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies competing with our products and potential products;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- the loss of key employees;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our business and stock;
- changes in the market valuations of similar companies;
- general and industry-specific economic conditions potentially affecting our research and development expenditures;
- sales of our common stock by us or our stockholders in the future, or the anticipation thereof;
- trading volume of our common stock;
- changes in the structure of health care payment systems;
- adverse regulatory decisions;
- trading volume of our common stock; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies or the biotechnology sector. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company’s securities, stockholders have often instituted class action securities litigation against those companies. Regardless of the merits or the ultimate results of such litigation, if instituted, such litigation could result in substantial costs and diversion of management’s attention and resources, which could significantly harm our profitability and reputation.

Additionally, a decrease in our stock price may cause our common stock to no longer satisfy the continued listing standards of Nasdaq. If we are not able to maintain the requirements for listing on Nasdaq, we could be delisted, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock.

We must maintain effective internal control over financial reporting, and if we are unable to do so, the accuracy and timeliness of our financial reporting may be adversely affected, which could have a material adverse effect on our business and stock price.

We must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. In addition, as a public company, the Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our disclosure controls and procedures quarterly and the effectiveness of our internal control over financial reporting at the end of each fiscal year. We rely heavily on direct management oversight of transactions, along with the use of legal and outsourced accounting professionals. As we grow, we plan to hire additional personnel and engage external temporary resources and may implement, document, and modify policies and procedures to maintain effective internal controls. However, we may identify deficiencies and weaknesses or fail to remediate previously identified deficiencies in our internal controls.

The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our audit committee be advised and regularly updated on management's review of internal control over financial reporting. Our management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements that are applicable to us as a public company. If we fail to staff our accounting, finance and information technology functions adequately or maintain internal control over financial reporting adequate to meet the demands that are placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, our business and reputation may be harmed and our stock price may decline. Furthermore, investor perceptions of us may be adversely affected, which could cause a decline in the market price of our common stock.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operation could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and estimates and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, and expenses that are not readily apparent from other sources. For example, in connection with the implementation of the new revenue accounting standard, management makes judgments and assumptions regarding our product sales based on our interpretation of the new standard. The new revenue standard is principle-based, and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice and guidance may evolve as we apply the new standard. If our assumptions underlying our estimates and judgements relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates or judgements, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

We will continue to incur significant increased costs and management resources as a result of operating as a public company.

As a public company, we will continue to incur significant legal, accounting, compliance and other expenses that we did not incur as a private company and these expenses may increase even more since we are no longer an "emerging growth company." Our management and other personnel will need to devote a substantial amount of time and incur significant expense in connection with compliance initiatives. As a public company, we will continue to bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws. In addition, regulations and standards relating to corporate governance and public disclosure, including the SOX, and the related rules and regulations implemented by the SEC and The Nasdaq Stock Market LLC, have increased legal and financial compliance costs and will make some compliance activities more time-consuming. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from our other business 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 practice, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. In the future, it may be more expensive or more difficult for us to obtain director and officer liability insurance, and 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 for our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

If Nasdaq delists our shares of common stock from trading on its exchange for failure to meet Nasdaq's listing standards, we and our stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of new and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

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

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that these sales and others may have on the prevailing market price of our common stock.

On April 15, 2021, we filed a universal shelf registration statement on Form S-3 (the "Shelf Registration Statement") to offer up to $150 million of our securities, which expires on April 15, 2024. We have established, and may in the future establish, "at-the-market" programs pursuant to which we may offer and sell shares of our common stock pursuant to the Shelf Registration Statement. SEC rules provide that companies with a public float of less than $75 million may only sell shares under a Form S-3 shelf registration statement, during any 12-month period, in an amount less than or equal to one-third of the public float. If we do not meet this public float requirement, any offering by us under the Shelf Registration Statement or any future registration statement on Form S-3 that we may file with the SEC will be limited to raising an aggregate of one-third of our public float in any 12-month period.

Our directors and employees may sell our stock through 10b5-1 trading plans or in the market during open windows under our insider trading policy without such plans in place. Sales of our common stock by our officers, directors, holders of 5% or more of our capital stock and their respective affiliates, and employees could be perceived negatively by investors or cause downward pressure on our common stock and cause a reduction in the price of our common stock as a result. We have also registered shares of our common stock that we may issue under our employee equity incentive plans. These shares will be able to be sold freely in the public market upon issuance.

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

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned a significant portion of our outstanding voting stock.

These stockholders, acting together, may be able to impact matters requiring stockholder approval. For example, they may be able to impact the elections of directors, amendments to our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that 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 stockholder and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

Unfavorable market and global economic conditions as a result of multiple global events, including the COVID-19 pandemic, adverse developments affecting the financial services industry, the conflict in Eastern Europe, increasing interest rates and general economic downturns, could adversely affect our business, financial condition or results of operations.

While the potential economic impact brought by multiple adverse global circumstances, such as the COVID-19 pandemic, conflicts in Eastern Europe, potential uncertainty related to Taiwan and its relationship with China, increasing interest rates, adverse developments affecting the financial services industry and general economic downturns are difficult to assess or predict, both as to magnitude and duration, these events have resulted in, and may continue to result in, extreme volatility and disruptions in the capital and credit markets, reducing our ability to raise additional capital through equity, equity-linked or debt financings, which could negatively impact our short-term and long-term liquidity and our ability to operate in accordance with our operating plan, or at all. Additionally, our results of operations could be adversely affected by general conditions in the global economy and financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for FYARRO or our any of our future product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. In the event of prolonged business interruptions due to geopolitical events, we could incur significant losses, require substantial recovery time and experience significant expenditures in order to resume our business or clinical operations. We have no operations in Russia, Belarus or Ukraine, but we do not and cannot know if the current uncertainties in these geopolitical areas, which are unfolding in real-time, may escalate and result in broad economic and security conditions or rationing of medical supplies, which could limit our ability to conduct clinical trials outside the United States or result in material implications for our business. In addition, our insurance policies typically contain a war exclusion of some description and we do not know how our insurers are likely to respond in the event of a loss alleged to have been caused by geopolitical uncertainties. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

In addition, actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (the “FDIC”), as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all.

Our operations and performance may be affected by political or civil unrest or military action, including the current conflict between Russia and Ukraine, terrorist activity, unstable governments and legal systems. As a result of global economic conditions, some third-party payers may delay or be unable to satisfy their reimbursement obligations. Job losses or other economic hardships may also affect patients’ ability to afford healthcare as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare insurance coverage or for other reasons. Our ability to conduct clinical trials in regions experiencing political or civil unrest could negatively affect clinical trial enrollment or the timely completion of a clinical trial. We believe the aforementioned economic conditions could lead to reduced demand for our drug products, which could have a material adverse effect on our revenues, business and results of operations.

Additionally, there is ongoing uncertainty regarding the federal budget and federal spending levels, including the possible impacts of a failure to increase the “debt ceiling.” Any U.S. government default on its debt could have broad macroeconomic effects that could, among other things, disrupt access to capital markets and deepen recessionary conditions. Further, as of December 31, 2022, we had cash, cash equivalents and short-term investments of $172.6 million, consisting of United States Government, commercial paper, corporate debt securities, and agency bonds. Any default by the U.S. government or credit downgrade of the securities we hold could impact the liquidity or valuation of our investments

We are a smaller reporting company. We cannot be certain whether the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors or otherwise limit our ability to raise additional funds.

We are a “smaller reporting company” under applicable securities regulations. A smaller reporting company is a company that, as of the last business day of its most recently completed second fiscal quarter, has (i) an aggregate market value of the company’s voting stock held by non-affiliates, or public float, of less than $250 million or (ii) less than $100 million in revenue and less than $700 million in public float. In addition, a smaller reporting company is able to provide simplified executive compensation disclosures in its filings and has certain other reduced disclosure obligations in our SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. Reduced disclosure in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be stockholders’ sole source of gain, if any, for the foreseeable future.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts our stockholders to replace or remove our management.

Provisions in our amended and restated certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders, and the ability of the board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the “DGCL”), which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us in certain circumstances. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees or our stockholders to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provisions of the DGCL, or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, our amended and restated certificate of incorporation or our bylaws (including the interpretation, validity or enforceability thereof), or (iv) any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. The amended and restated bylaws provide that the federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The 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 our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in the 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. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our bylaws described above.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate headquarters consist of 2,760 square feet of leased office space in Pacific Palisades, California. Our Pacific Palisades lease expires on February 28, 2025. We also lease 10,615 square feet of office space in Morristown, New Jersey. The Morristown lease expires on May 19, 2028.

We believe our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms for our future growth.

Item 3. Legal Proceedings.

For discussion of legal proceedings, see Note 16 (Commitments and contingencies) to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock has traded since the Merger on the Nasdaq Capital Market on August 27, 2021, under the symbol "AADI."

Stockholders

As of March 23, 2023, there were 86 stockholders of record of our common stock.

Dividends

We have never declared nor paid any cash dividends to stockholders. We do not intend to pay cash dividends on our common stock for the foreseeable future, and currently intend to retain any future earnings to fund our operations and the development and growth of our business. The declaration of any future cash dividends, if any, would be at the discretion of our board of directors (subject to limitations imposed under applicable Delaware law) and would depend on our earnings, if any, our capital requirements and financial position, our general economic conditions and other pertinent conditions.

Unregistered Sales of Equity Securities and Use of Proceeds

There have been no unregistered sales of securities other than previously disclosed by us on Form 10-Q or Form 8-K.

Issuer Purchases of Equity Securities

There were no repurchases of shares of common stock made during the year ended December 31, 2022.

Item 6. [Reserved].

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

The following discussion of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and the related notes to those statements thereto appearing elsewhere in this Annual Report on Form 10-K filed with the SEC for the year ending December 31, 2022*. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risk, uncertainties and assumptions. Our actual results could differ materially from those discussed in our forward-looking statements for many reasons, including those risks. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Annual Report. You should read this Annual Report completely, including Part I, Item 1A (Risk Factors) of this Annual Report and the "Cautionary Statement Regarding Forward-Looking Statements" sections of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by our forward-looking statements contained in the following discussion and analysis. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.*

Overview

We are a biopharmaceutical company focused on developing and commercializing precision therapies for genetically defined cancers with alterations in mTOR pathway genes. Our lead drug product, FYARRO®, is a form of sirolimus bound to albumin. Sirolimus is a potent inhibitor of the mTOR biological pathway, the activation of which pathway can promote tumor growth. We believe our approach to utilizing albumin bound sirolimus has the potential to produce transformational therapies to cancer patients with mTOR pathway driver alterations where other mTOR inhibitors have not or cannot be effectively exploited due to problems of pharmacology, effective drug delivery, safety, or effective targeting to the disease site.

In November 2021, the U.S. Food and Drug Administration (the "FDA") approved FYARRO sirolimus protein-bound particles for injectable suspension (albumin-bound) for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor ("PEComa"). On February 22, 2022, we launched FYARRO in the United States for treatment of advanced malignant PEComa. For the fiscal year ended December 31, 2022, we recorded net revenue from product sales of $15.2 million and net loss of $60.5 million. See "Results of Consolidated Operations" for further discussion of our results.

In addition to advanced malignant PEComa, based on exploratory data from our completed Phase 2 registrational study, Advanced Malignant PEComa Trial ("AMPECT"), and our expanded access program for FYARRO, we have initiated a registration-directed tumor-agnostic Phase 2 study ("PRECISION 1") of FYARRO in patients with Tuberous Sclerosis Complex 1 and 2 ("*TSC1* & *TSC2*") alterations. We have completed a Type B meeting with the FDA in which we discussed the trial design and the PRECISION 1 trial was opened for enrollment in the United States during the first quarter of 2022, with dosing of our first patient in March 2022. We anticipate having preliminary data on a meaningful number of patients in the PRECISION 1 trial during the second quarter of 2023.

For more information regarding our business, including FYARRO, AMPECT and the PRECISION 1 trial, see Part I, Item 1 (Business).

Recent Developments

- *Leadership Transition*. Effective January 1, 2023, our board of directors appointed Brendan Delaney, our former Chief Operating Officer, to President and Chief Executive Officer and Neil Desai, our founder, director, and former-President and Chief Executive Officer, to Executive Chairman. Mr. Delaney was also appointed to serve on our board of directors. Effective March 14, 2023, Mr. Delaney resigned from his position as President and Chief Executive Officer and as a member of our board of directors, and, effective March 15, 2023, our board of directors appointed Scott Giacobello, our Chief Financial Officer, as Interim Chief Executive Officer and President. Mr. Giacobello will continue to serve in his role as Chief Financial Officer in addition to his role as Interim Chief Executive Officer and President. In addition, Dr. Desai, the founder of the company and our President and Chief Executive Officer prior to Mr. Delaney, continues to serve as the Executive Chairman and a member of our board of directors and will assist with the leadership transition. The Board has also initiated an executive search for a successor chief executive officer, and, as such, Mr. Giacobello's position of Interim Chief Executive Officer and President will end when a successor is appointed.
- *2022 Private Investment in Public Equity (PIPE) Financing*. On September 22, 2022, we entered into a securities purchase agreement ("Purchase Agreement") for a private placement (the "2022 PIPE Financing") with certain investors ("2022 PIPE Investors"). Upon closing the 2022 PIPE Financing on September 26, 2022, we sold (i) 3,373,526 shares of our common stock, at a purchase price of $12.50 per share, and (ii)

2,426,493 pre-funded warrants (the "Pre-Funded Warrants") to purchase shares of our common stock, at a purchase price of $12.4999 per Pre-Funded Warrant. The Pre-Funded Warrants will have an exercise price of $0.0001 per share of common stock, be immediately exercisable and remain exercisable until exercised in full. In connection with the 2022 PIPE Financing, we entered into a Registration Rights Agreement, dated September 22, 2022 ("2022 PIPE Registration Rights Agreement"), with the 2022 PIPE Investors. Pursuant to the 2022 PIPE Registration Rights Agreement, on October 26, 2022, we filed a registration statement with the Securities and Exchange Commission (the "SEC") for the registration for resale of the securities sold under the Purchase Agreement, including the shares issuable upon the exercise of the Pre-Funded Warrants, which such registration statement was declared effective on November 4, 2022.

At the closing of the 2022 PIPE Financing, the total purchase price paid by the 2022 PIPE Investors was approximately $72.2 million, after deducting $0.3 million of our offering expenses. We intend to use the net proceeds from the 2022 PIPE Financing to fund working capital and other general corporate purposes.

- *Mirati Collaboration*. In October 2022, we entered into a collaboration and supply agreement with Mirati Therapeutics, Inc. ("Mirati") to evaluate the combination of Mirati's adagrasib, a KRAS^{G12C} selective inhibitor, and FYARRO in KRAS ^{G12C} mutant non-small cell lung cancer (NSCLC) and other solid tumors. Under the terms of the agreement, Mirati will be responsible for sponsoring and operating the Phase 1/2 study and we will supply study drug and jointly share the cost of the study.

  The primary objective of this multi-center, single-arm, open-label Phase 1/2 trial is to determine the optimal dose and recommended Phase 2 dose for the combination of adagrasib and FYARRO in patients with KRAS^{G12C-}mutant solid tumors. In addition, the study will investigate the safety, tolerability and efficacy of adagrasib and FYARRO in combination in patients both with and without prior exposure to a KRAS^{G12C} inhibitor. The trial will build on preclinical data showing enhanced anti-tumor efficacy with the combination of adagrasib and FYARRO relative to either agent alone.

BMS License Agreement

We have exclusive rights for certain patents and a non-exclusive license for certain technology and know-how pertaining to ABI-009 (which we refer to as FYARRO) pursuant to an amended and restated license agreement, dated November 15, 2019, as amended August 31, 2021 (the "BMS License Agreement") with Abraxis BioScience, LLC, a wholly owned subsidiary of Celgene Corporation, which is a wholly owned subsidiary of Bristol-Myers Squibb Company ("BMS"). Under the BMS License Agreement, BMS is entitled to receive certain development milestone payments, royalties on net sales from licensed products under the agreement and any sublicense fees. During the year ended December 31, 2022, we recorded royalties of $1.1 million under the terms of this agreement, of which $0.4 million in royalties were accrued as of December 31, 2022. No payments related to milestones under this agreement were paid during the year ended December 31, 2022. See Note 9 to the consolidated financial statements for more information about the BMS License Agreement.

Under the terms of an August 2021 amendment to the license agreement, we paid BMS $5.8 million, representing 50% of the previously outstanding payment obligation under the agreement, following the effective time of the 2021 Private Investment in Public Equity (PIPE) Financing ("2021 PIPE Financing") that occurred in connection with the closing of the reverse acquisition of Aerpio Pharmaceuticals, Inc. Pursuant to the terms of the amendment, the remaining portion of the previously outstanding payment obligation ($5.8 million), which is recorded on our balance sheet as due to licensor, is due on the third anniversary of the effective time of such 2021 PIPE Financing plus any accrued and unpaid interest due thereon.

EOC License Agreement

In December 2020, we entered into the EOC License Agreement with EOC under which we received $14.0 million in January 2021 in non-refundable upfront consideration as partial payment for the rights and licenses granted to EOC by us for the further development and commercialization of FYARRO in the People's Republic of China, Hong Kong Special Administration Region, Macao Special Administrative Region and Taiwan (the "Licensed Territory").

In accordance with the BMS License Agreement, we are required to pay 20% of all sublicense fees to BMS. As such, we recognized $2.8 million of license expense in the fourth quarter of 2020 and had a corresponding $2.8 million sublicense payable to BMS on the balance sheet as of December 31, 2020, which was paid in 2021.

During the fourth quarter of 2021, we recognized license revenue and received $1.0 million from EOC for achieving the FDA approval milestone in November 2021. In accordance with the BMS License Agreement, we recognized $0.2 million of license expense in the fourth quarter of 2021 and had a corresponding $0.2 million sublicense payable to BMS on the balance sheet as of December 31, 2021, which was paid in 2022.

On June 27, 2022, we received written notice from EOC that EOC has elected to terminate the EOC License Agreement, effective immediately. On June 27, 2022, EOC filed a Request for Arbitration with the International Chamber of Commerce's International Court of Arbitration against us. The arbitration process is ongoing. We intend to defend ourselves vigorously in this matter and pursue all relief to which we are entitled. We are unable to estimate the possible loss or range of loss, therefore no amounts have been accrued as of December 31, 2022. See Notes 9 and 16 to the audited financial statements for more information about the EOC License Agreement, its termination and resulting arbitration.

Impact of Negative Global or National Events

Businesses have been and will continue to be impacted by a number of challenging global and national events and circumstances that continue to evolve, including the COVID-19 pandemic, extreme weather conditions, increased economic uncertainty, inflation, rising interest rates, and conflicts in Eastern Europe and in other countries. The extent of the impact of these events and circumstances on our business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and scope of the events and their impact on our development activities, third-party manufacturers, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. We have been and continue to actively monitor the potential impacts that these various events and circumstances may have on our business and we take steps, where warranted, to minimize any potential negative impacts on our business resulting from these events and circumstances. For example, as the COVID-19 pandemic has developed, we have taken numerous steps to help ensure the health and safety of our employees. While we have largely resumed normal operations, any resurgence or worsening of the COVID-19 pandemic may cause us to reinstitute certain measures to protect employee safety, including staggered work hours or reduced in-person staffing, that could result in additional disruption and/or delays in our ability to conduct development activities.

We have been and continue to actively monitor our supply chain in light of these challenging global and national events and circumstances, including our third-party materials suppliers. To date, we have experienced some supply disruptions due to the COVID-19 pandemic, including closures at certain chip manufacturers, which led to extended lead times for FYARRO and diversion of certain lab materials needed to support COVID-19 relief efforts. While certain of these disruptions have been resolved since the start of the COVID-19 pandemic, we are continuing to monitor our supply chain and contingency planning is ongoing with our partners to reduce the possibility of an interruption to our development activities or the availability of necessary materials.

The ultimate impact of these global and national events and circumstances, either individually or in aggregate, is highly uncertain and subject to change. To the extent possible, we are conducting business as usual, with necessary or advisable modifications to mitigate potentially negative impacts to our business. For example, during the COVID-19 pandemic, our clinical trials have been, and may continue to be, affected by the closure of offices, lack of resources or closure of borders, among other measures being put in place around the world and we made certain modifications to employee travel, with masking and vaccination requirements in our offices, and with our employees working remotely fully or intermittently. Any continued inability to travel and conduct face-to-face meetings, as well as constraints surrounding hospital infrastructure and staff, can also make it more difficult to enroll and maintain patients in ongoing or planned clinical trials. We will continue to actively monitor the rapidly evolving situation related to these global and national events, and may take further actions to mitigate potential negative impacts to our business, and that may alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. At this point, the extent to which these global or national events and circumstances may affect our future business, operations and development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain. We will continue to evaluate the impact that these events could have on our operations, financial position, results of operations and cash flows in fiscal year 2023.

August 2021 Reverse Merger

On May 16, 2021, at which time we were operating as "Aerpio Pharmaceuticals, Inc.," we entered into: (i) an Agreement and Plan of Merger ("Merger Agreement") with Aspen Merger Subsidiary, Inc., our wholly-owned subsidiary ("Merger Sub"), and Aadi Subsidiary, Inc. (formerly known as Aadi Bioscience, Inc. ("Private Aadi")); and (ii) a subscription agreement ("Subscription Agreement") with certain investors (the "2021 PIPE Investors"), pursuant to which we agreed to sell shares of our common stock to the 2021 PIPE Investors concurrently with the closing of the Merger (as defined below). See Note 1 to our audited financial statements for more information about the Merger Agreement and the Subscription Agreement.

On August 26, 2021, pursuant to the terms of the Merger Agreement and the Subscription Agreement:

- Merger Sub merged with and into Private Aadi, with Private Aadi surviving as our wholly-owned subsidiary (the "Merger");
- in connection with and immediately prior to the Merger, we effected a reverse stock split of our common stock at a ratio of 15:1 and changed our name from "Aerpio Pharmaceuticals, Inc." to "Aadi Bioscience, Inc";
- at the effective time of the Merger, based on an exchange ratio of 0.3172 (after taking into account the Reverse Stock Split), as calculated under the Merger Agreement (the "Exchange Ratio"), we issued an aggregate of 5,776,660 shares of common stock to the holders of Private Aadi common stock immediately prior to the Merger, including shares of Private Aadi common stock issuable upon the conversion of all shares of preferred stock and convertible promissory notes outstanding immediately prior to the Effective Time;
- at the closing of the Merger, we assumed all of the outstanding and unexercised options to purchase shares of Private Aadi common stock, which options were converted into options to purchase shares of our common stock, as adjusted pursuant to the Merger Agreement based on the Exchange Ratio;
- concurrently with the Closing of the Merger, we issued and sold 11,852,862 shares of common stock to the 2021 PIPE Investors for total gross proceeds of $155 million and, immediately after the closing of the Merger and the 2021 PIPE Financing, the 2021 PIPE Investors and the Private Aadi investors as of immediately prior to the effective time of the Merger owned 55.6% and 29.2%, respectively, of our outstanding common stock on a fully-diluted basis; and
- we entered into a contingent value rights agreement ("CVR Agreement") pursuant to which each of our stockholders as of immediately prior to the effective time of the Merger became entitled to certain contingent value rights entitling them to receive 90% of the net proceeds (calculated as gross consideration minus certain permitted deductions), if any, received by us under the license agreement, dated June 24, 2018, with Gossamer Bio, Inc., as amended (the "Gossamer License Agreement"), and certain other covered agreements, as specified in the CVR Agreement (see Note 1 to our audited financial statements for more information about the CVR Agreement). The CVR Agreement automatically terminated effective July 24, 2022, the date the Gossamer License Agreement terminated.

Key Trends and Factors Affecting Comparability Between Periods

- Commercial sale of FYARRO was launched on February 22, 2022, for the treatment of patients with advanced malignant PEComa. We recorded net product sales of $15.2 million during the year ended December 31, 2022.
- We have built a cross-functional commercial team consisting of marketing, market access and commercial operations and will continue to strategically build our sales and our commercial infrastructure with capabilities designed to scale when necessary to support future commercial launches. Expenses related to our commercial launch including personnel expenses, sales support, and marketing are included in selling, general and administrative expenses for the year ended December 31, 2022. We expect these expenses will continue to increase in 2023, as compared to 2022, with the ongoing commercialization of FYARRO and preparation for potential future launches.
- We continue to build out our research and development team and we expect our research and development costs will increase in 2023, relative to 2022, as a result of significant expenses related to the PRECISION 1 trial which was open to enrollment during the year ended December 31, 2022, with the first patient dosed in March 2022.
- As a public company our expenses have increased from prior year as a privately held company, including (i) costs to comply with the rules and regulations of the SEC and those of the Nasdaq Capital Market ("Nasdaq"), (ii) legal, accounting and other professional services, (iii) insurance, (iv) investor relations activities, and (v) other administrative and professional services.

Liquidity and Capital Resources

As of December 31, 2022, we had $172.6 million of cash, cash equivalents and short-term investments. Based on our current plans, we believe our existing cash, cash equivalents and short-term investments will enable us to conduct our planned operations into 2025. We have incurred net losses in each year since inception and as of December 31, 2022 we had an accumulated deficit of $203.2 million. These losses have resulted principally from costs incurred in connection with research and development activities, selling, general and administrative costs associated with our operations, and costs associated with the Merger. We expect to continue to incur significant expenses and operating losses for the foreseeable future due to the cost of research and development, including conducting preclinical and clinical trials and identifying and designing product candidates, the regulatory approval process for FYARRO outside the United States and in additional indications and any other product candidates we may develop in the future and the commercial launch of FYARRO.

Basis of Presentation

The following discussion highlights our results of operations and the principal factors that have affected our financial condition as well as our liquidity and capital resources for the periods described and provides information that management believes is relevant for an assessment and understanding of the consolidated balance sheets and statements of operations and comprehensive loss presented herein. The following discussion and analysis are based on our consolidated financial statements contained in this Annual Report, which we have prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). You should read the discussion and analysis together with such consolidated financial statements and the related notes thereto.

Components of Statements of Operations and Comprehensive Loss

Revenue

Product Sales, Net

FYARRO was approved by the FDA in November 2021. On February 22, 2022, we launched sales of FYARRO to specialty distributors ("SD"s) and a specialty pharmacy ("SP"). We recognize product sales when the SDs and SP obtain control of the product, which occurs upon delivery. Product sales are recorded at the net sales price, which includes provisions for the following allowances which are reflected either as a reduction to the related account receivable or as an accrued liability, depending on how the allowance is settled:

- *Distribution Fees*: Distribution fees include distribution service fees paid to the SDs and SP based on a contractually fixed percentage of the wholesale acquisition cost ("WAC"). Distribution fees are recorded as an offset to product sales based on contractual terms at the time the sale is recognized.
- *Rebates*: Allowance for rebates include mandated discounts under the Medicaid Drug Rebate Program and TRICARE program. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or statutory requirements. The allowance for rebates is based on contracted or statutory discount rates and expected utilization by benefit plan participants. Our estimates for expected utilization of rebates are based on utilization data received from the SDs and SP since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity. If actual future rebates vary from estimates, we may need to adjust prior period accruals, which would affect product sales in the period of adjustment.
- *Chargebacks*: Chargebacks are discounts and fees that relate to contracts with government and other entities purchasing from the SDs and SP at a discounted price. The SDs and SP charge back to us the difference between the price initially paid by the SDs and SP and the discounted price paid to the SDs and SP by these entities. If actual future chargebacks vary from these estimates, we may need to adjust prior period accruals, which would affect product sales in the period of adjustment.
- *Co-Payment Assistance*: We offer co-payment assistance to commercially insured patients meeting certain eligibility requirement. Co-payment assistance is accrued at the time of product sale to the SDs and SP based on estimated patient participation and average co-pay benefit to be paid per a claim. Our estimated amounts are compared to actual program participation and co-pay amounts paid using data provided by third-party administrators. If actual amounts differ from the original estimates the assumptions being applied are updated and adjustment for prior period accruals will be adjusted in the current period.
- *Product Returns*: Consistent with industry practice, we offer the SDs and SP limited product return rights for damages, shipment errors, and expiring product, provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. We do not allow product returns for product that has been dispensed to a patient. As we receive inventory reports from the SDs and SP and have the ability to control the amount of product that is sold to the SDs and SP, we estimate future potential product returns based on the on-hand channel inventory data and sell-through data obtained from the SDs and SP. In arriving at our estimate, we also consider historical product returns, the underlying product demand, and industry data specific to the specialty pharmaceutical distribution industry.

Grant Revenue

Grant revenue is derived from federal grants, primarily with the FDA. We have determined that the government agencies providing grants to us are not customers. Grant revenue is recognized when there is reasonable assurance of compliance with the conditions of the grant and reasonable assurance that the grant revenue will be received. We recognize grant revenue as reimbursable grant costs are incurred. The costs associated with these reimbursements are reflected as a component of research and development expense in the accompanying statements of operations and comprehensive loss.

With respect to grant revenue derived from reimbursement of direct out-of-pocket expenses for research costs associated with federal contracts, where we act as principal with discretion to choose suppliers, bear credit risk and perform part of the services required in the transaction, we record revenue for the gross amount of the reimbursement. The costs associated with these reimbursements are reflected as a component of research and development expense in the accompanying statements of operations and comprehensive loss.

Operating Expenses

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and related benefits, including share-based compensation, related to our executive, finance, business development, sales and marketing, and other corporate functions. Other general and administrative expenses include professional fees for legal, auditing, tax and business consulting services, insurance costs, intellectual property and patent costs, facility costs and travel costs. We expect that selling, general and administrative expenses will increase in the future as we expand our operating activities. Additionally, we have incurred, and expect to continue to incur, significant additional expenses associated with being a public company that we did not incur as a privately-held company, including (i) costs to comply with the rules and regulations of the SEC and those of Nasdaq, (ii) legal, accounting and other professional services, (iii) insurance, (iv) investor relations activities, and (v) other administrative and professional services.

Research and Development Expenses

Research and development expenses, which consist primarily of costs associated with our product research and development efforts, are expensed as incurred. Research and development expenses consist primarily of: (i) employee related costs, including salaries, benefits and share-based compensation expense for employees engaged in scientific research and development functions; (ii) third-party contract costs relating to research, formulation, manufacturing, nonclinical studies and clinical trial activities; (iii) external costs of outside consultants who assist with technology development, regulatory affairs, clinical development and quality assurance; (iv) payments made under our third-party licensing agreements; and (v) allocated facility-related costs.

Costs for certain activities, such as manufacturing, nonclinical studies and clinical trials are generally recognized based on the evaluation of the progress of completion of specific tasks using information and data provided by our vendors and collaborators. Research and development activities are central to our business. We expect to increase our investment in research and development in order to advance FYARRO in additional indications through clinical trials. As a result, we expect that our research and development expenses will increase substantially in the foreseeable future as we continue to invest in research and development activities, pursue clinical development of FYARRO in additional indications and any other product candidates we may develop in the future and expand our product candidate pipeline.

The process of commercialization and conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Accordingly, to the extent that our product candidates continue to advance into clinical trials, including larger and later-stage clinical trials, our expenses will increase substantially and may become more variable.

Impairment of Acquired Contract Intangible Asset

Impairment of acquired contract intangible asset relates to a write down of the acquired contract intangible asset to fair value. During the year ended December 31, 2021, we recognized an impairment of $74.2 million to bring the carrying amount of the contract intangible asset down to its estimated fair value of $3.9 million at August 26, 2021. During the year ended December 31, 2022, we recognized an impairment charge of $3.7 million to fully impair the contract intangible asset based on Gossamer's termination of the Gossamer License Agreement as a result of Gossamer not meeting its primary or secondary endpoint in the UC-SHIFT clinical trial.

Cost of Goods Sold

Cost of goods sold consist primarily of royalties paid to BMS, costs incurred on sales of FYARRO and costs to manufacture and prepare the product for sales subsequent to the FDA approval in November 2021. Costs incurred prior to the FDA approval were expensed when incurred.

Other Income, Net

Other income, net consists of the change in fair value of convertible promissory notes and interest expense related to such notes. These expenses are partially offset by interest income earned on cash, cash equivalents and short-term investments, and gain on extinguishment of debt.

Income Tax Expense

During the years ending December 31, 2022 and 2021, we recognized zero and $2,000 of income tax expense on the statement of operations and comprehensive loss, respectively. Since our formation in 2011, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned tax credits, due to our uncertainty of realizing a benefit from those items.

Results of Consolidated Operations:

The following table presents the results of operations for the periods indicated (amounts in thousands):

	Year Ended December 31, 2022	Year Ended December 31, 2021
Revenue		
Product sales, net	$ 15,216	$ —
License revenue	—	1,000
Grant revenue	—	120
Total revenue	15,216	1,120
Operating expenses		
Selling, general and administrative	40,176	18,511
Research and development	32,662	19,670
Cost of goods sold	1,335	—
Impairment of acquired contract intangible asset	3,724	74,156
Total operating expenses	77,897	112,337
Loss from operations	(62,681)	(111,217)
Other income, net	2,168	1,129
Loss before income tax expense	(60,513)	(110,088)
Income tax expense	—	(2)
Net loss	$ (60,513)	$ (110,090)

Comparison of Years Ended December 31, 2022 and 2021

Product Sales, Net

Our product sales, net consist of sales of FYARRO since its launch in the United States on February 22, 2022. Product sales, net for the year ended December 31, 2022 were $15.2 million. There were no product sales for the year ended December 31, 2021.

License Revenue

During the year ended December 31, 2021, we recognized $1.0 million of revenue upon achieving the FDA approval milestone from EOC Pharma as consideration pursuant to the EOC License Agreement. This revenue was recognized when earned. No license revenue was recognized during the year ended December 31, 2022.

Grant Revenue

Grant revenue amounts can vary from period to period depending on the funding and work performed. Grant revenue decreased by $0.1 million for the year ended December 31, 2022, compared to the same period in 2021, primarily due to a decrease in the eligible expenses for grant reimbursement incurred during 2022 compared to 2021. The period for eligible grant reimbursement with the FDA ended during the year ended December 31, 2021. There were no new grants during the year ended December 31, 2022.

Operating Expenses

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the year ended December 31, 2022, were $40.2 million, an increase of $21.7 million, compared to $18.5 million for the year ended December 31, 2021.

The increase was driven by the following in support of our increased headcount, commercial and marketing expenses, and expenses related to being a public company. We expect these expenses to continue to increase to support future launches:

- $13.4 million in personnel related expenses due to increased headcount, incentive bonuses and share-based compensation. Sales and administrative headcount increased to 32 employees at December 31, 2022 from 17 employees at December 31, 2021;
- $4.0 million of legal, insurance and other related expenses;
- $2.9 million of commercial and marketing expenses; and
- $1.4 million of consulting expenses.

Research and Development Expenses

The following table presents our research and development expenses for the periods indicated (amounts in thousands):

	Year Ended December 31,	
	2022	2021
Personnel expense	$ 18,526	$ 4,359
Consultants	4,543	2,458
External clinical development	8,347	5,838
Clinical drug product manufacturing	818	6,646
Other expense	428	369
Total research and development expense	$ 32,662	$ 19,670

Research and development expenses for the year ended December 31, 2022, were $32.7 million, an increase of $13.0 million, compared to $19.7 million for the year ended December 31, 2021. The increase was primarily driven by a $16.3 million increase in expenses related to headcount, consultants, and other expenses, a $2.5 million increase in clinical development expenses related to the PRECISION 1 trial, offset by a $5.8 million decrease related to clinical drug product manufacturing.

Cost of Goods Sold

Cost of goods sold was $1.3 million reflecting primarily royalties incurred on product sold during the year ended December 31, 2022. There were no cost of goods sold during the year ended December 31, 2021.

Impairment of Acquired Contract Intangible Asset

During the year ended December 31, 2022, we recorded a $3.7 million impairment charge to reduce the carrying value of the intangible asset to its fair value of zero, based on a formal notice of termination we received on April 25, 2022 from Gossamer for the Gossamer License Agreement. The Gossamer License Agreement terminated effective July 24, 2022.

During the year ended December 31, 2021, we recorded a $74.2 million impairment charge to reduce the carrying value of the intangible asset to its fair value to $3.9 million at the Effective Times, as a result of the excess fair value ascribed to the acquired contract intangible asset related to the Merger.

Other Income, Net

The following table sets forth our other income, net:

	Year Ended December 31,	
	2022	2021
Change in fair value of convertible promissory notes	$ —	$ 1,585
Gain upon extinguishment of debt	—	196
Interest income	2,398	13
Interest expense	(230)	(665)
Total other income	$ 2,168	$ 1,129

Other income, net for the year ended December 31, 2022, was $2.2 million of income, compared to $1.1 million of income for the year ended December 31, 2021. The change was primarily driven by interest income of $2.4 million from investment holdings in the year ended December 31, 2022 compared to $1.6 million of non-cash income related to the change in fair value of the convertible promissory notes and a $0.2 million gain recognized on the extinguishment of the Paycheck Protection Program loan forgiven by the Small Business Administration in the year ended December 31, 2021.

Liquidity and Capital Resources

Overview

As of December 31, 2022, we had $172.6 million of cash, cash equivalents and short-term investments. Prior to and as of the date of filing this Annual Report on Form 10-K, we had and continue to have access to and control over all our cash, cash equivalents and short-term investments, notwithstanding the closure of Silicon Valley Bank (as discussed below and elsewhere in this Annual Report on Form 10-K). Based on our current plans, we believe our existing cash, cash equivalents and short-term investments will enable us to conduct our planned operations into 2025.

We have incurred net losses in each year since inception and as of December 31, 2022, we had an accumulated deficit of $203.2 million. Our net losses were $60.5 million and $110.1 million for the years ended December 31, 2022 and 2021, respectively. These losses have resulted principally from costs incurred in connection with research and development activities, selling, general and administrative costs associated with our operations, and costs associated with the Merger. We expect to continue to incur significant expenses and operating losses for the foreseeable future due to the cost of research and development, including conducting preclinical studies and clinical trials, identifying and designing product candidates, the regulatory approval process for FYARRO in additional indications, outside the United States and any other product candidates we may develop in the future, and the commercial launch of FYARRO. We expect our expenses, and the potential for losses, to increase substantially as we conduct clinical trials of FYARRO, in additional indications and seek to expand our pipeline.

From inception through December 31, 2022, we received funding of $25.4 million from our initial seed financing and the sale of Series A convertible preferred stock, $9.1 million from the issuance of convertible promissory notes, $145.4 million, net from the 2022 PIPE Financing in connection with the Merger, $29.7 million of cash assumed in the Merger, and $72.2 million, net cash proceeds from the 2022 PIPE Financing.

Shelf Registration Statement; $75M At the Market Offering

On March 17, 2022, we entered into a Sales Agreement (the “Sales Agreement”) with Cowen and Company, LLC (“Cowen”), with respect to an “at the market offering” pursuant to which we may offer and sell, from time to time at our sole discretion, shares of our common stock having aggregate gross proceeds of up to $75.0 million through Cowen as our sales agent. Under the Sales Agreement, we will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limitations on the number or dollar value of shares that may be sold in any one trading day and any minimum price below which sales may not be made. We will pay Cowen 3.0% of the aggregate gross proceeds from each sale of shares of common stock under the Sales Agreement. As of December 31, 2022, no shares of common stock had been sold under the Sales Agreement.

The shares of our common stock to be offered and sold under the Sales Agreement will be issued and sold pursuant to our shelf registration statement on the Form S-3 (File No. 333-255129), which was filed with the SEC on April 8, 2021, and which became effective on April 15, 2021. We filed a prospectus supplement with the SEC on March 21, 2022 in connection with the offer and sale of the shares pursuant to the Sales Agreement.

The shelf registration statement allows us to sell from time to time up to $150.0 million of common stock, preferred stock, debt securities, warrants, or units comprised of any combination of these securities, for our own account in one or more offerings. The shelf registration statement is intended to provide us flexibility to conduct registered sales of our securities, subject to market conditions and our future capital needs. The terms of any offering under the shelf registration statement will be established at the time of such offering and will be described in a prospectus supplement filed with the SEC prior to the completion of any such offering.

On September 22, 2022, the Company entered into the Purchase Agreement for the 2022 PIPE Financing with the 2022 PIPE Investors for the sale by the Company of 3,373,526 shares of the Company’s common stock for a price of $12.50 per share and Pre-Funded Warrants to purchase an aggregate of 2,426,493 shares of the Company's common stock, at a purchase price of $12.4999 per Pre-Funded Warrant. The Pre-Funded Warrants are exercisable at an exercise price of $0.0001 and will be exercisable until exercised in full. The 2022 PIPE Financing closed on September 26, 2022. Aggregated net proceeds, after deducting certain expenses incurred of $0.3 million related to the issuance of the shares were $72.2 million.

The following table summarizes our cash flows for the years presented (amounts in thousands):

	Year Ended December 31,	
	2022	2021
Net cash used in operating activities	$ (49,640)	$ (22,423)
Net cash (used in) provided by investing activities	(132,886)	25,153
Net cash provided by financing activities	72,620	141,804
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (109,906)	$ 144,534

Operating Activities

Our cash used in operating activities primarily results from our net loss adjusted for non-cash expenses, changes in working capital components, amounts due to contract research organizations to conduct our clinical programs and employee-related expenditures for research and development and selling, general and administrative activities. Our cash flows from operating activities will continue to be affected by spending to commercialize FYARRO in advanced malignant PEComa, advance and support FYARRO in additional indications in the clinic, develop new product candidates, and other operating and general administrative activities, including operating as a public company.

For the year ended December 31, 2022, cash used in operating activities was $49.6 million and resulted from (i) our net loss of $60.5 million, and (ii) a $1.8 million net decrease in our working capital accounts, primarily driven by an increase in accounts receivable and inventory related to the commercial launch of FYARRO in February 2022; offset by (i) a decrease in accounts payable and accrued expenses, and $12.7 million in non-cash adjustments, which was primarily related to share-based compensation expense, the impairment of the contract intangible asset, and depreciation and amortization expense.

For the year ended December 31, 2021, cash used in operating activities was $22.4 million and resulted from (i) our net loss of $110.1 million offset by non-cash adjustments totaling $75.4 million, which was primarily related to impairment of the acquired contract intangible asset of $74.2 million, and (ii) a $12.3 million net increase in our working capital accounts, primarily driven by the receipt of the $14.0 million upfront payment on accounts receivable pursuant to the EOC License Agreement.

Investing Activities

Cash used in investing activities for the year ended December 31, 2022 related to purchases of short-term investments $145.2 million, offset by maturities of $12.8 million.

Cash provided by investing activities for the year ended December 31, 2021 related to cash acquired in connection with the Merger of $29.7 million offset by $4.5 million of transaction related expenses.

Financing Activities

Cash provided by financing activities for the year ended December 31, 2022 related to $72.5 million gross cash proceeds from our 2022 PIPE Financing, $0.4 million from exercise of stock options and $0.3 million in proceeds from the issuances of stock under the ESPP, offset by $0.7 million of financing costs related to the 2021 PIPE Financing and the 2022 PIPE Financing.

Cash provided by financing activities for the year ended December 31, 2021 includes $155.0 million gross cash proceeds from our 2021 PIPE Financing and $0.8 million from exercise of stock options, partially offset by $9.6 million of issuance costs related to the 2021 PIPE Financing, and $4.4 million of dividends paid to preferred stockholders.

Contractual Obligations and Commitments

In April 2022, we entered into a lease for 10,615 square feet of office space in Morristown, New Jersey. The term of the lease is seventy-three months unless terminated sooner.

Rent expense is being recorded on a straight-line basis. Rent expense related to the Pacific Palisades and Morristown leases was $0.4 million and $0.2 million for the years ended December 31, 2022 and 2021, respectively. See Note 8 to the consolidated financial statements for details related to future lease payments.

In January 2022, we entered into a Negotiated Purchase Order Terms and Conditions for Clinical and Commercial Product, as amended effective as of August 1, 2022 (the "Fresenius Agreement"), with Fresenius Kabi, LLC ("Fresenius Kabi"), pursuant to which Fresenius Kabi will manufacture FYARRO for us and we will purchase FYARRO as a finished drug product from Fresenius Kabi, on a purchase-order basis. The Fresenius Agreement contains specific activities such as non-cancellable commitments, minimum purchase commitments, and binding annual forecasts. Under the Fresenius Agreement, which is effective through March 31, 2024 (or such later date as may be agreed between the parties in writing), we may purchase FYARRO for either clinical or commercial purposes for use in the United States and Canada.

In August 2021, we entered into an amendment to extend the lease of our 2,760 square feet of office space in Pacific Palisades, California. We exercised an option, under our prior lease agreement, to extend the term of the lease for an additional three-year period. Included in the renewal were nine months of rent abatement and a rent escalation clause.

We also have contracts with various organizations to conduct research and development activities, including clinical trial organizations to manage clinical trial activities and manufacturing companies to manufacture the drug product used in the clinical trials. The scope of the services under these research and development contracts can be modified and the contracts cancelled by us upon written notice. In the event of a cancellation, we would be liable for the cost and expenses incurred to date as well as any close out costs of the service arrangement.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). These accounting principles require us to make certain estimates, judgements and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements, as well as the reported amounts of revenues and expenses during the periods presented. We believe that the estimates, judgments and assumptions are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. To the extent there are material differences between these estimates, judgments or assumptions and actual results, our financial statements will be affected. Historically, revisions to our estimates have not resulted in a material change to our financial statements.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

We recognize revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC Topic 606, Revenue from Contracts with Customer ("Topic 606"), the following five steps are performed: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation.

Net Product Sales

We sell our product primarily through a limited number of specialty distributors (SDs) and specialty pharmacy (SP) customers. The delivery of our product represents a single performance obligation for these transactions, and we record net product sales when control is transferred to the customer, which occurs upon receipt by the customer. The transaction price for net product sales represents the amount we expect to receive, which is net of estimated distribution fees, government-mandated rebates, chargebacks, co-payment assistance, and estimated product returns. Accruals are established for these deductions, and actual amounts incurred are offset against applicable accruals. We reflect these accruals as either a reduction in the related account receivable from the distributor or as an accrued liability, depending on the nature of the sales deduction. Sales deductions are based on management's estimates that consider channel mix and experience to date.

Estimates are assessed periodically and updated to reflect current information. These estimates involve a substantial degree of judgment, in particular, for government-mandated rebates and chargebacks, such as for the Medicaid and 340B programs.

Research and Development Costs

We incur substantial expenses associated with clinical trials. Accounting for clinical trials relating to activities performed by CROs and other external vendors requires us 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 preclinical studies, contract manufacturing activities and clinical activities. The diverse nature of services being provided under CRO and other vendor arrangements, the different terms and milestone 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. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in the accrued and other current liabilities or prepaid expenses, as applicable, on the balance sheets and within research and development expense on the consolidated statements of operations and comprehensive loss. In estimating the duration of a clinical study, we evaluate the start-up, treatment and wrap-up periods, payment 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 estimates and related accounts on the balance sheet. 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 may be used to conduct and manage clinical trials on our behalf. We generally 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.

Share-Based Compensation

We recognize all share-based payments to employees, including grants of employee stock options in the consolidated statements of operations and comprehensive loss based on their fair values. All of our share-based awards, to employees, non-employees, officers, and directors, are subject only to service-based vesting conditions. We estimate the fair value of our share-based awards using the Black-Scholes option pricing model, which requires the input of assumptions, including (i) the expected stock price volatility, (ii) the calculation of expected term of the award, (iii) the risk-free interest rate based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. treasury notes with maturities approximately equal to the expected term of the stock options and (iv) expected dividends. Options granted during the year have a maximum contractual term of ten years. Forfeitures are recognized and accounted for as they occur.

Due to the historical lack of a public market for the trading of our common stock following the Merger and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to ours, including stage of product development and life science industry focus. We believe the group selected has sufficient similar economic and industry characteristics and includes companies that are most representative of us.

We have limited historical stock option activity and therefore estimate the expected term of stock options granted to employees, officers, and directors using the simplified method, which represent the average of the contractual term of the stock option and its weighted-average vesting period, to calculate the expected term, as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term for options granted to employees, and utilize the contractual term for options granted to non-employees. The expected term is applied to the stock option grant group as a whole, as we do not expect substantially different exercise or post-vesting termination behavior among our employee population.

Compensation expense related to awards to employees is calculated on a straight-line basis by recognizing the grant date fair value over the associated service period of the award, which is generally the vesting term. For the years ended

December 31, 2022 and 2021, we recognized share-based compensation expense, net of estimated forfeitures, in the statements of operations and comprehensive loss as follows (amounts in thousands):

	Year Ended December 31,	
	2022	2021
Selling, general and administrative	$ 6,333	$ 1,449
Research and development	3,310	657
Total	$ 9,643	$ 2,106

As of December 31, 2022, total unamortized share-based compensation was $28.8 million which we expect to recognize over a weighted average period of 2.7 years. The intrinsic value of all outstanding stock options as of December 31, 2022 was $2.8 million.

Merger and Acquired Contractual Intangible Asset

Aerpio issued common stock in the Merger based on the terms of the Merger Agreement. For accounting purposes, however, we concluded under GAAP that Private Aadi has acquired Aerpio. We based this conclusion having evaluated the terms of the Merger Agreement and other factors including: (i) the stockholders of Private Aadi owned approximately 66.8% of the voting rights of the Company as of immediately following the Merger (but prior to the 2021 PIPE Financing); (ii) three (3) of seven (7) members of the board of directors of the Company post-Merger were composed of directors designated by Private Aadi under the terms of the Merger Agreement, and one (1) member of the board of directors of the Company post-Merger was a director mutually designated by Private Aadi and Aerpio; (iii) existing members of Private Aadi's management became the management of the Company post-Merger; (iv) the 2021 PIPE Investors consist of individuals and funds, and for purpose of this analysis, while they owned approximately 55.6% on a fully-diluted basis, as of immediately following the Merger (and after giving effect to the 2021 PIPE Financing), no one individual or fund held more shares than the holders of Private Aadi collectively owned immediately following the Merger and they are not considered to be a single voting group; and (v) following the Merger, the Company is headquartered in Pacific Palisades, California, and all ongoing operations of the combined company are those of Private Aadi.

Further, under GAAP we have accounted for the Merger as a reverse asset acquisition rather than a business combination. Accounting as an asset acquisition is significantly different than the accounting for a merger transaction as a business combination. Among other things, we have not recognized any goodwill on our consolidated balance sheet as there may have been had the Merger been accounted for as a business combination. A central element to the accounting model conclusion is the determination of whether a business or an asset or a group of assets is acquired. A business is defined in ASC 805, Business Combinations, as an integrated set of inputs and processes that are capable of generating outputs that have the ability to provide a return to its investors or owners. Typical inputs include long-lived assets (including intangible assets or rights to use long-lived assets), intellectual property and the ability to obtain access to required resources. Typical processes include strategic, operational and resource management processes that are typically documented or evident through an organized workforce. We considered all of the above factors when determining whether a business was acquired in the Merger and concluded that Aerpio did not meet the definition of a business.

Upon closing of the Merger, substantially all of the fair value is concentrated in cash, working capital and a long-lived contract intangible asset related to Aerpio's license agreement with Gossamer Bio. Inc., under which 90% of any future net cash proceeds will be remitted to CVR Holders and paid through the CVRs. In accordance with GAAP for asset acquisitions, the excess purchase price over the fair value of the acquired assets and liabilities ($78.1 million) was ascribed to the acquired contract intangible asset. However, due to the significant excess purchase price being allocated over the fair value of the acquired contractual intangible asset, we determined that an indicator of impairment was present, and we assessed the contract intangible asset as compared to expectations of contingent future cash flows. We concluded that our estimate of gross cash flows potentially accruing to us under the license agreement is likely to be less than the excess purchase price of the fair value of the acquired assets and liabilities ascribed to the acquired contract intangible asset. As a result, we performed a valuation of the acquired contract intangible asset and recognized an impairment of $74.2 million to adjust the carrying amount of the contractual intangible asset to its estimated fair value of $3.9 million. During the year ended December 31, 2022, upon receipt of the Notice of Termination, we impaired the contract intangible asset by $3.7 million to its estimated fair value of zero based on receipt of the formal notice of termination from Gossamer for the Gossamer License Agreement.

The license agreement with Gossamer Bio. Inc. includes potential payments to us in the event of certain development and commercialization milestones and sales-based royalties. Our fair value determination of the intangible asset utilized a scenario-based, risk-adjusted, discounted cash flow model with respect to the potential development milestone payments and a Monte Carlo option-pricing model with respect to the sales-based milestone and royalty payments:

- We determined fair value of the potential development milestone payments under the license agreement with inputs based on certain subjective assumptions, including (a) the probability of clinical success determined with reference to various academic studies reporting probabilities of approval for clinical trials; (b) an estimate of the time to achievement of the clinical milestones; and (c) a counterparty credit risk premium determined with reference to the borrowing costs of a benchmark group of comparable market participants.
- Application of the Monte Carlo simulation model in valuing the potential sales-based milestone and royalties involves making assumptions for (a) the probability of clinical success determined with reference to various academic studies reporting probabilities of approval for clinical trials; (b) our forecast of potential revenues, revenue uptake rate and the period of time from a prospective commercial launch to peak sales, and an estimate of peak sales for each successfully commercialized product covered under the license agreement; (c) drift equal to the risk free rate on revenues following a multivariate Geometric Brownian Motion; (d) a counterparty credit risk premium determined with reference to the borrowing costs of a benchmark group of comparable market participants; and (e) a revenue metric risk premium determined with reference to a long-term risk-free rate, a weighted-average cost of capital, revenue volatility and asset volatility.

Recent Accounting Pronouncements

See Note 2 to the consolidated financial statements for a discussion of recent accounting pronouncements.

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

We are a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required by this Item.

Item 8. Consolidated Financial Statements and Supplementary Data.

Beginning on the following page are the consolidated financial statements with applicable notes and the related Report of Independent Registered Public Accounting Firm.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors
Aadi Bioscience, Inc.
Pacific Palisades, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Aadi Bioscience, Inc. (the “Company”) as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, stockholders’ equity (deficit), and cash flows for the years then ended and the related notes (collectively, referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at 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 consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

Critical Audit Matter

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

Product Revenue Allowances for Chargebacks and Government Rebates

As described in Note 2 to the consolidated financial statements, revenue from product sales is recognized net of estimates for variable consideration consisting of chargebacks, government rebates, distribution fees, co-payment assistance, and product returns. This variable consideration is recorded in the same period that the related revenue is recognized and creates variability for the consideration that the Company expects to receive. Liabilities related to government rebates and chargebacks involve the use of assumptions and judgments that include consideration of historical claims experience, channel mix, unbilled claims, claims submission time lags, and inventory levels in the distribution channel.

We identified management's estimated allowance for government rebates and chargebacks as a critical audit matter. The principal consideration that led to our determination is the judgement required to evaluate the estimated government rebates and chargebacks that will be processed based upon the limited period of time for which the company has been processing rebates and chargebacks. Auditing these elements involved subjective auditor judgement due to the nature and extent of audit effort to address these matters.

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

- Evaluating the significant accounting policies relating to government rebates and chargebacks as well as the Company's application of the policies, for appropriateness and reasonableness.
- Evaluating historical sales subsequent to product launch eligible for government rebates and chargebacks to assess the reasonableness of the estimate for government rebates and chargebacks unprocessed as of year-end.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2017

San Diego, California

March 28, 2023

AADI BIOSCIENCE, INC.

Consolidated Balance Sheets
(Amounts in thousands, except share data and par value)

	Year Ended December 31, 2022	2021
Current assets:		
Cash and cash equivalents	$ 39,019	$ 148,989
Short-term investments	133,541	—
Accounts receivable, net	1,862	—
Inventory	1,861	—
Prepaid expenses and other current assets	3,746	2,283
Total current assets	180,029	151,272
Property and equipment, net	508	57
Operating lease right-of-use assets	1,522	557
Intangible asset, net	—	3,811
Other assets	2,178	2,213
Total assets	$ 184,237	$ 157,910
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,519	$ 6,439
Accrued liabilities	14,922	8,703
Operating lease liabilities, current portion	394	131
Total current liabilities	18,835	15,273
Operating lease liabilities, net of current portion	1,267	474
Due to licensor (Note 9)	5,757	5,757
Total liabilities	25,859	21,504
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized; no shares issued and outstanding as of December 31, 2022 and 2021	—	—
Common stock, $0.0001 par value, 300,000,000 shares authorized; 24,435,007 and 20,894,695 shares issued and outstanding as of December 31, 2022 and 2021, respectively	2	2
Additional paid-in capital	361,689	279,089
Accumulated other comprehensive loss	(115)	—
Accumulated deficit	(203,198)	(142,685)
Total stockholders' equity	158,378	136,406
Total liabilities and stockholders' equity	$ 184,237	$ 157,910

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

AADI BIOSCIENCE, INC.

Consolidated Statements of Operations

(Amounts in thousands, except share data and earnings per share amounts)

	Year Ended December 31,	
	2022	**2021**
Revenue		
Product sales, net	$ 15,216	$ —
License revenue	—	1,000
Grant revenue	—	120
Total revenue	15,216	1,120
Operating expenses		
Selling, general and administrative	40,176	18,511
Research and development	32,662	19,670
Cost of goods sold	1,335	—
Impairment of acquired contract intangible asset	3,724	74,156
Total operating expenses	77,897	112,337
Loss from operations	(62,681)	(111,217)
Other income (expense)		
Change in fair value of convertible promissory notes	—	1,585
Gain upon extinguishment of debt	—	196
Interest income	2,398	13
Interest expense	(230)	(665)
Total other income, net	2,168	1,129
Loss before income tax expense	(60,513)	(110,088)
Income tax expense	—	(2)
Net loss	(60,513)	(110,090)
Cumulative dividends on convertible preferred stock	—	(647)
Net loss attributable to common stockholders	$ (60,513)	$ (110,737)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.69)	$ (12.41)
Weighted average number of common shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	22,511,237	8,923,369

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

AADI BIOSCIENCE, INC.

Consolidated Statements of Comprehensive Loss
(Amounts in thousands)

	Year Ended December 31,	
	2022	**2021**
Net loss	$ (60,513)	$ (110,090)
Change in unrealized loss on short-term investments	(115)	—
Comprehensive loss	$ (60,628)	$ (110,090)

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

Table of Contents

AADI BIOSCIENCE, INC.

Consolidated Statements of Stockholders' Equity (Deficit)

(Amounts in thousands, including share amounts)

	Stockholders' Equity									
	Series Seed Preferred Stock		Series A Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Par Value	Shares	Par Value	Shares	Par Value				
Balance at December 31, 2020	734	$ —	7,212	$ 1	2,542	$ 1	$ 20,161	$ —	$ (32,595)	$ (12,432)
Issuance of common stock upon exercise of stock options	—	—	—	—	73	—	833	—	—	833
Issuance of common stock to PIPE Investors, net of issuance costs	—	—	—	—	11,853	1	145,383	—	—	145,384
Issuance of common stock to former stockholders of Aerpio upon Merger	—	—	—	—	3,209	—	105,888	—	—	105,888
Conversion of convertible promissory note into common stock upon Merger	—	—	—	—	698	—	9,130	—	—	9,130
Conversion of convertible preferred stock into common stock upon Merger	(734)	—	(7,212)	(1)	2,520	—	—	—	—	(1)
Share-based compensation expense	—	—	—	—	—	—	2,106	—	—	2,106
Cumulative dividends paid on Series A preferred stock	—	—	—	—	—	—	(4,412)	—	—	(4,412)
Net loss	—	—	—	—	—	—	—	—	(110,090)	(110,090)
Balance at December 31, 2021	—	$ —	—	$ —	20,895	$ 2	$ 279,089	$ —	$ (142,685)	$ 136,406
Issuance of common stock upon exercise of stock options	—	—	—	—	132	—	401	—	—	401
Issuance of common stock upon exercise of warrants	—	—	—	—	7	—	55	—	—	55
Share-based compensation expense	—	—	—	—	—	—	9,643	—	—	9,643
Issuance of shares under the employee stock purchase plan	—	—	—	—	27	—	323	—	—	323
Issuance of common stock to PIPE Investors, net of issuance costs	—	—	—	—	3,374	—	72,178	—	—	72,178
Other comprehensive loss	—	—	—	—	—	—	—	(115)	—	(115)
Net loss	—	—	—	—	—	—	—	—	(60,513)	(60,513)
Balance at December 31, 2022	—	$ —	—	$ —	24,435	$ 2	$ 361,689	$ (115)	$ (203,198)	$ 158,378

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

AADI BIOSCIENCE, INC.

Consolidated Statements of Cash Flows
(Amounts in thousands)

	Year Ended December 31, 2022	2021
Cash flows from operating activities:		
Net loss	$ (60,513)	$ (110,090)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment of acquired contract intangible asset	3,724	74,156
Share-based compensation expense	9,643	2,106
Amortization of premiums and discounts on short-term investments, net	(1,215)	—
Change in fair value of convertible promissory notes	—	(1,585)
Non-cash interest expense	—	665
Gain upon extinguishment of debt	—	(196)
Non-cash lease expense	382	171
Depreciation and amortization expense	159	105
Changes in operating assets and liabilities:		
Accounts receivable	(1,862)	14,149
Inventory	(1,861)	—
Prepaid expenses and other current assets	(1,463)	(2,166)
Other non-current assets	437	481
Operating lease liabilities, net	(291)	(129)
Accounts payable and accrued liabilities	3,220	8,290
Other liabilities	—	(8,380)
Net cash used in operating activities	(49,640)	(22,423)
Investing activities:		
Purchases of property and equipment	(444)	(46)
Purchases of short-term investments	(145,192)	—
Maturities of short-term investments	12,750	—
Cash acquired in connection with the Merger	—	29,700
Transaction expenses related to the Merger	—	(4,501)
Net cash (used in) provided by investing activities	(132,886)	25,153
Financing activities:		
Proceeds from issuance of common stock and prefunded warrants to PIPE Investors	72,500	—
Issuance of common stock upon exercise of stock options	401	833
Proceeds from issuance under employee stock purchase plan	323	—
Issuance of common stock upon exercise of warrants	55	—
Deferred offering costs paid for financing	(337)	—
Costs incurred in connection with issuance of common stock	(322)	(9,617)
Proceeds from the issuance of common stock to PIPE Investors	—	155,000
Dividends paid	—	(4,412)
Net cash provided by financing activities	72,620	141,804
Net (decrease) increase in cash, cash equivalents and restricted cash	(109,906)	144,534
Cash, cash equivalents and restricted cash at beginning of year	148,989	4,455
Cash, cash equivalents and restricted cash at end of year	$ 39,083	$ 148,989

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

AADI BIOSCIENCE, INC.

Consolidated Statements of Cash Flows (continued)
(Amounts in thousands)

	Year Ended December 31, 2022	2021
Supplemental disclosure of cash flow information:		
Interest paid during the period	$ 230	$ 22
Costs incurred in connection with issuance of common stock paid during the period	$ 322	$ —
Supplemental disclosure of non-cash activities:		
Issuance of common stock upon Merger	$ —	$ 105,888
Conversion of convertible promissory note into common stock upon Merger	$ —	$ 9,130
Amounts accrued for purchases of property and equipment	$ 80	$ —
Right-of-use assets obtained in exchange for operating lease liabilities	$ 1,241	$ 610

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Organization and Operations

Aadi Bioscience, Inc. (together with its subsidiaries, the "Company" or "Aadi") is a biopharmaceutical company focused on developing and commercializing precision therapies for genetically defined cancers with alterations in mTOR pathway genes. Aadi's lead drug product, FYARRO®, is a form of sirolimus bound to albumin. Sirolimus is a potent inhibitor of the mTOR biological pathway, the activation of which pathway can promote tumor growth, and inhibits downstream signaling from mTOR. In November 2021, the U.S. Food and Drug Administration (the "FDA") approved FYARRO sirolimus protein-bound particles for injectable suspension (albumin-bound) for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor ("PEComa"). On February 22, 2022, Aadi launched FYARRO in the United States for treatment of advanced malignant PEComa. FYARRO is licensed to Aadi by Abraxis BioScience, LLC, a wholly owned subsidiary of Celgene Corporation.

The Company's historical operations have consisted principally of performing research and development activities and raising capital. The Company's activities are subject to significant risks and uncertainties, including failing to secure additional funding before sustainable revenues and profit from operations are achieved.

Merger with Aerpio Pharmaceuticals, Inc. and Name Change

On May 16, 2021, the Company, then operating as Aerpio Pharmaceuticals, Inc. ("Aerpio"), entered into the Agreement and Plan of Merger ("Merger Agreement") with Aspen Merger Subsidiary, Inc., a Delaware corporation and a direct, wholly owned subsidiary of Aerpio ("Merger Sub") and Aadi Subsidiary, Inc. (formerly known as Aadi Bioscience, Inc. ("Private Aadi")).

Pursuant to the terms set forth in the Merger Agreement and effective August 26, 2021 (the "Effective Time"): (i) Merger Sub merged with and into Private Aadi, with Private Aadi surviving as a wholly owned subsidiary of Aerpio (the "Merger"), (ii) Aerpio changed its name to Aadi Bioscience, Inc. in connection with and immediately prior to the Effective Time, and (iii) Aerpio effected a 15:1 reverse stock split of the Aerpio common stock ("Reverse Stock Split") immediately prior to the Effective Time. At the Effective Time, each share of Private Aadi common stock outstanding immediately prior to the Effective Time, including the shares of Private Aadi common stock issuable upon the conversion of all shares of preferred stock and convertible promissory notes immediately prior to the closing of the Merger, were converted into the right to receive shares of the Company's common stock based on an exchange ratio of 0.3172 (the "Exchange Ratio"), after taking into account the Reverse Stock Split.

Pursuant to the Merger Agreement, Aerpio assumed all of the outstanding and unexercised options to purchase shares of Private Aadi capital stock under the Private Aadi Amended and Restated 2014 Equity Incentive Plan (the "Private Aadi Plan"), and, in connection with the Merger, such options were converted into options to purchase shares of the Company's common stock based on the Exchange Ratio. At the closing of the Merger at the Effective Time, the Company issued an aggregate of 5,776,660 shares of common stock to holders of Private Aadi common stock, including in respect of shares of Private Aadi common stock issued upon the conversion of all shares of preferred stock and convertible promissory notes outstanding immediately prior to the Effective Time.

The Merger has been accounted for using the reverse asset acquisition method under U.S. generally accepted accounting principles ("GAAP"). For accounting purposes, Private Aadi is considered to have acquired the Company and the Merger has been accounted for as a reverse asset acquisition. The estimated fair value of total consideration given was $110.4 million based on 3,208,718 shares of common stock at $33.00 per share, after taking into account the Reverse Stock Split, outstanding immediately prior to the Effective Time, plus Private Aadi's transaction costs. Private Aadi is considered the accounting acquirer even though the Company issued the common stock in the Merger based on the terms of the Merger Agreement and other factors including: (i) following the Merger, the stockholders of Private Aadi collectively owned a substantial portion of the voting rights of the Company; (ii) three (3) of seven (7) members of the board of directors of the Company post-Merger were composed of directors designated by Private Aadi under the terms of the Merger Agreement, and one (1) member of the board of directors of the Company post-Merger was a director mutually designated by Private Aadi and Aerpio; (iii) existing members of Private Aadi's management became the management of the Company post-Merger; (iv) the 2021 Private Investment in Public Equity (PIPE) Investors (as defined below) consist of individuals and funds, and for purpose of this analysis, as of immediately following the Merger (and after giving effect to the 2021 PIPE Financing), no one individual or fund held more shares than the holders of Private Aadi collectively owned immediately following the Merger and they are not considered to be a single voting group; and (v) following the Merger, the Company is named "Aadi Bioscience, Inc." and headquartered in Pacific Palisades, California, and all ongoing operations of the Company are those of Private Aadi. To determine the accounting for this transaction under GAAP, a company must assess whether an integrated set of assets and activities should be accounted for as an acquisition of a business or an asset acquisition. Upon closing of the Merger, substantially all of the fair value is concentrated in cash, working capital and a long-lived contract intangible asset. As such, the acquisition was treated as an asset acquisition. The net assets of Aerpio have been recorded at their relative fair value in the consolidated financial statements of the Company and the reported operating results prior to the Merger will be those of Private Aadi.

In connection with the closing of the Merger, Private Aadi's board of directors declared a 4% cumulative dividend on its preferred stock of $4.4 million which was paid at the Effective Time.

Contingent Value Rights and Contingent Value Rights Agreement

In connection with the Merger, the Company entered into a Contingent Value Rights Agreement, dated as of August 26, 2021 (the "CVR Agreement"), with a legacy director of the Company, as Holder Representative (as defined in the CVR Agreement), and American Stock Transfer & Trust Company, LLC, as Rights Agent (as defined in the CVR Agreement), in accordance with the terms of the Merger Agreement. The CVR Agreement entitled each holder of Aerpio common stock as of immediately prior to the closing of the Merger (each, a "CVR Holder") to receive one contingent value right ("CVR") for each outstanding share of the Company common stock held by such CVR Holder as of immediately prior to the closing of the Merger, each representing the right to receive certain net proceeds, if any, derived from the CVR completed during a CVR Payment Period, which means successive six-month periods, prior to the expiration of the CVR Term (as defined in the CVR Agreement), with any potential payment obligations continuing until the earlier of (a) the 20-year anniversary of the Effective Time and (b) the time at which the license agreement dated June 24, 2018, as amended (the "Gossamer License Agreement") with Gossamer Bio, Inc. ("Gossamer"), the underlying basis for the CVR, has expired or been terminated.

On April 25, 2022, the Company received a formal notice of termination from Gossamer for the Gossamer License Agreement (the "Notice of Termination"), that related to Gossamer's GB004 product candidate, a legacy product candidate of the Company's predecessor, Aerpio, after Gossamer announced that its Phase 2 SHIFT-UC clinical trial studying GB004 in patients with mild-to-moderate active ulcerative colitis did not meet the primary or secondary endpoints at week 12 and the study was being terminated for lack of treatment benefit. The Gossamer License Agreement terminated effective July 24, 2022.

Based on the Notice of Termination, the Company fully impaired the Gossamer License Agreement intangible asset during the year ended December 31, 2022. In connection with the termination of the Gossamer License Agreement, the CVR Agreement automatically terminated in accordance with its terms and the CVRs were automatically cancelled and forfeited without any consideration or payment, in each case effective July 24, 2022.

2021 Private Investment in Public Equity (PIPE) Financing and Subscription Agreement

On May 16, 2021, the Company entered into a subscription agreement ("Subscription Agreement") with certain investors (the "2021 PIPE Investors"), pursuant to which it would sell shares of its Common Stock concurrently with the closing of the Merger (the "2021 PIPE Financing"). The 2021 PIPE Investors purchased an aggregate of 11,852,862 shares of common stock of the Company (the "2021 PIPE Shares") for an aggregate purchase price of $155.0 million pursuant to the Subscription Agreement. The aggregate net proceeds for the issuance and sale of the 2021 PIPE Shares were $145.4 million, after deducting certain expenses incurred that were direct and incremental to the issuance of the 2021 PIPE Shares. At the closing of the 2021 PIPE Financing, the Company entered into a Registration Rights Agreement, dated August 26, 2021 ("Registration Rights Agreement"), with the 2021 PIPE Investors.

Immediately following the Effective Time, and after giving effect to the Reverse Stock Split and the 2021 PIPE Financing, there were approximately 20.8 million shares of common stock of the Company outstanding. Immediately following the Effective Time and after giving effect to the Reverse Stock Split and the 2021 PIPE Financing: (i) the Private Aadi stockholders owned approximately 29.2% of the outstanding shares of common stock; (ii) Aerpio's stockholders immediately prior to the Merger, whose shares of common stock, as adjusted for the Reverse Stock Split, remain outstanding after the Merger, owned approximately 15.2% of the outstanding shares of common stock; and (iii) the 2021 PIPE Investors owned approximately 55.6% of the outstanding shares of common stock, in each case as calculated on a fully-diluted basis.

2022 Private Investment in Public Equity (PIPE) Financing

On September 22, 2022, the Company entered into a securities purchase agreement ("Purchase Agreement") with certain investors ("2022 PIPE Investors") for a private placement of shares of common stock and pre-funded warrants to purchase shares of common stock (the "2022 PIPE Financing"). Upon the closing of the 2022 PIPE Financing on September 26, 2022, the Company sold (i) 3,373,526 shares of its common stock at a purchase price of $12.50 per share, and (ii) 2,426,493 pre-funded warrants (the "Pre-Funded Warrants") to purchase shares of common stock at a purchase price of $12.4999 per pre-funded warrant. The Pre-Funded Warrants have an exercise price of $0.0001 per share of common stock, are immediately exercisable and remain exercisable until exercised in full. The holders of Pre-Funded Warrants may not exercise a Pre-Funded Warrant if the holder, together with its affiliates, would beneficially own more than 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise; provided, that the holders of Pre-Funded Warrants may increase or decrease such percentages not in excess of 19.99% by providing at least 61 days' prior notice to the Company. The aggregate net proceeds for the 2022 PIPE Financing were $72.2 million after deducting certain expenses incurred that were direct and incremental to the issuance of the shares of $0.3 million.

On September 26, 2022, the Company and the 2022 PIPE Investors entered into a Registration Rights Agreement, (the "2022 PIPE Registration Rights Agreement"), providing for the registration for resale of the securities sold under the Purchase Agreement, including the shares issuable upon the exercise of the Pre-Funded Warrants, that are not then registered on an effective registration statement, pursuant to a registration statement filed with the Securities and Exchange Commission (the "SEC").

The Company has granted the 2022 PIPE Investors customary indemnification rights in connection with the 2022 PIPE Registration Rights Agreement. The Purchasers have also granted the Company customary indemnification rights in connection with the 2022 PIPE Registration Rights Agreement.

Liquidity

Since inception, the Company has devoted substantially all of its resources to research and development activities, business planning, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these operations and has only recently begun to realize revenues from its planned principal operations commencing with the commercial sale of FYARRO.

The Company has experienced net losses since its inception and expects to continue to incur net losses into the foreseeable future. The Company had an accumulated deficit of $203.2 million as of December 31, 2022 and a net loss of $60.5 million and $110.1 million for the years ended December 31, 2022 and 2021, respectively. To date, these operating losses have been funded primarily from outside sources of invested capital through the issuance of convertible promissory notes, grant funding, the sale of securities, and proceeds from license agreements.

The Company had cash, cash equivalents and short term investments of $172.6 million at December 31, 2022. Management believes the Company's current cash, cash equivalents and short-term investments will provide sufficient funds to enable the Company to meet its obligations for at least twelve months from the filing date of this report. If the Company is unable to achieve and maintain profitability, it will need additional financing to support its continuing operations and pursue its strategic objectives. Additional financing may be achieved through a combination of equity offerings, and debt financings. The Company may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all.

On March 17, 2022, the Company entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen"), pursuant to which the Company may offer and sell, from time to time at the Company's sole discretion, shares of its common stock having an aggregate offering price of up to $75.0 million through Cowen as its sales agent for an at-the-marketing-offering. As of December 31, 2022, no shares of common stock had been sold under the Sales Agreement.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements, and the related disclosures, have been prepared in accordance with GAAP and SEC regulations and, in the opinion of management include all adjustments necessary for a fair presentation of the results of operations, financial position, changes in stockholders' equity and cash flows for each period presented. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). All adjustments are of a normal recurring nature. The Company's consolidated financial statements are stated in U.S. dollars. Certain prior year amounts have been reclassified to conform to the current year presentation.

On August 26, 2021, when the Company closed the Merger, all outstanding shares of common stock along with preferred stock of Private Aadi were exchanged for new shares of common stock of the Company and the approximately 8.1 million shares of Private Aadi capital stock held by stockholders of Private Aadi immediately prior to the Merger were exchanged for approximately 2.5 million shares of common stock of the Company based on the Exchange Ratio. The authorized number of shares of common stock was not reduced and remains at 300.0 million. The par value of the Company's common stock remains unchanged at $0.0001 per share.

Also on August 26, 2021, and immediately prior to the closing of the Merger, the Company effected the Reverse Stock Split. Accordingly, all share and per share amounts for the period presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the Reverse Stock Split. No fractional shares were issued in connection with the Reverse Stock Split. Unless otherwise noted, all references to shares of the Company's common stock and per share amounts have also been adjusted to reflect the Exchange Ratio.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on short-term investments. Comprehensive loss has been reflected in the statements of operations and comprehensive loss for all periods presented.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company has identified its Chief Executive Officer as the chief operating decision maker and the Company views its operations and manages its business in one operating segment, which is the business of developing and commercializing proprietary therapeutics. All the assets and operations of the Company's sole operating and reportable segment are located in the United States.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. In the opinion of management, all adjustments that are considered necessary for fair presentation have been included. The most significant estimates in the Company's consolidated financial statements relate to fair value of the intangible asset, fair value of the convertible promissory notes, gross-to-net accruals, share-based compensation expense and accrued research and development costs. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash and cash equivalents, and investments in money market funds, United States government treasury bills, commercial paper, corporate bonds, and government agency debt securities. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. While the Company has not experienced any losses in such deposits, the recent failure of Silicon Valley Bank, at which the Company holds cash and cash equivalents in multiple accounts, exposed the Company to credit risk prior to the resolution by the Federal Deposit Insurance Corporation in a manner that fully protected all depositors. The Company has not experienced any losses on deposits since inception.

The Company's accounts receivable is derived from customers located principally in the United States. The Company performs ongoing credit evaluations of its customers and maintains allowances for potential credit losses on customers' accounts when deemed necessary. The Company does not typically require collateral from its customers. Credit losses historically have not been material. The Company continuously monitors customer payments and maintains an allowance for doubtful accounts based on its assessment of various factors including historical experience, age of the receivable balances, and other current economic conditions or other factors that may affect customers' ability to pay.

Customer Concentration

The majority of the Company's revenue for the year ended December 31, 2022 was from two companies at 58% and 41% of the Company's revenue, respectively.

Additionally, one customer accounted for 100% of the net accounts receivable as of December 31, 2022.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid marketable securities purchased with original maturities of three months or less at the time of purchase date to be cash equivalents. As of December 31, 2022 and 2021, cash and cash equivalents included money market investments totaling $32.0 million and $140.0 million, respectively. Restricted cash consists of a letter of credit secured by restricted cash in connection with one of the Company's office leases described in Note 8, and is included in other assets on the consolidated balance sheet. The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated statements of cash flows (amounts in thousands):

	As of December 31,	
	2022	2021
Cash and cash equivalents	$ 39,019	$ 148,989
Restricted cash, non-current	64	—
Total cash, cash equivalents and restricted cash	$ 39,083	$ 148,989

Fair Value Option

The Company elected the fair value option to account for its convertible promissory notes which were issued in 2019 and 2020. The Company recorded the convertible promissory notes at fair value with changes in fair value recorded in the statements of operations. As of December 31, 2022 and 2021, there were no convertible notes outstanding as they were converted to shares of Private Aadi common stock immediately prior to the closing of the Merger.

Fair Value of Financial Instruments

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

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

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

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions which reflect those that a market participant would use

Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of fair value assets and liabilities and their placement within the fair value hierarchy levels.

In determining the fair value of its financial instruments, the Company considers the source of observable market data inputs, liquidity of the instrument, the credit risk of the counterparty to the contract, and its risk of nonperformance. In the case fair value is not observable, for the items subject to fair value measurements, the Company applies valuation techniques deemed the most appropriate under the GAAP guidance based on the nature of the assets and liabilities being measured.

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

Short-term investments

The Company invests in various types of securities, including United States government and commercial paper and corporate debt securities. The Company classifies its investments as available-for-sale and records them at fair value based upon market prices at period end. Unrealized gains and losses that are deemed temporary in nature are recorded in accumulated other comprehensive loss as a separate component of stockholders' equity. Dividend and interest income are recognized when earned. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of investments sold. The Company classifies short-term investments with remaining maturities greater than one year as current assets because such short-term investments are available to fund the Company's current operations.

At each balance sheet date, the Company assesses available-for-sale securities in an unrealized loss position to determine whether the unrealized loss is other-than-temporary. When the Company determines that a decline in the fair value below its cost basis is other-than-temporary, the Company recognizes an impairment loss in the period in which the other-than-temporary decline occurred. There have been no other-than-temporary impairments recognized during any of the periods presented. See Note 4 for further information.

Accounts Receivable, Net

Accounts receivable are recorded net of customer allowances for chargebacks and allowance for doubtful accounts. Allowance for chargebacks is based on contractual terms. The Company estimates the allowance for doubtful accounts based on existing contractual payment terms, actual payment patterns of its customers and individual customer circumstances. As of December 31, 2022, $0.1 million of customer allowances for chargebacks was recorded. No allowances were recorded as of December 31, 2021. No receivables were written off for the years ended December 31, 2022 and 2021.

Inventory

Inventory is stated at the lower of cost or estimated net realizable value. The Company uses actual costing methodology determined on a first-in, first-out method. The Company capitalizes inventory costs associated with its products based upon regulatory approval when, based on management’s judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed. Prior to FDA approval of FYARRO, all costs related to the manufacturing of FYARRO were charged to research and development expense in the period incurred, therefore the inventory balance was zero at December 31, 2021.

Details of inventory are presented as follows (amounts in thousands).

	As of December 31, 2022
Raw materials	$ 944
Work in process	—
Finished goods	917
Total	$ 1,861

Property and Equipment, Net

Property and equipment, consisting of computers, furniture and fixtures, office equipment, construction in process and leasehold improvements are stated at cost, less accumulated depreciation. Property and equipment is depreciated using the straight-line method over the estimated useful lives of the assets, generally three to five years. Such costs are periodically reviewed for recoverability when impairment indicators are present.

Details of property and equipment are presented as follows (amounts in thousands).

	As of December 31,	
	2022	2021
Computers and software	$ 338	$ 51
Construction in process	77	—
Furniture and fixtures	65	36
Leasehold improvements	129	—
Total	$ 609	$ 87
Accumulated depreciation	(101)	(30)
Property and equipment, net	$ 508	$ 57

Intangible Asset, Net

The Company’s intangible asset consisted of a single asset, the Gossamer License Agreement, assumed in the Merger. The intangible asset was stated at fair value and amortized using the straight-line method over its estimated useful life of 14.3 years. During the year ended December 31, 2021, the acquired intangible asset was reduced to its estimated fair value of $3.9 million at the Effective Time. During the year ended December 31, 2022, the intangible asset's fair value was reduced to zero based on the termination of the Gossamer License Agreement effective July 24, 2022 (see Note 6).

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property, equipment, and the intangible asset for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. An impairment was recorded for the long-lived intangible asset during the year ended December 31, 2022 based on the termination of the Gossamer License Agreement effective July 24, 2022 (see Note 6).

Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. If both criteria are met, the Company records the associated lease liability and corresponding right-of-use asset upon commencement of the lease using the implicit rate or a discount rate based on a credit-adjusted secured borrowing rate commensurate with the term of the lease. The Company does not recognize assets or liabilities for leases with lease terms of less than 12 months.

The Company additionally evaluates leases at their inception to determine if they are to be accounted for as an operating lease or a finance lease. A lease is accounted for as a finance lease if it meets one of the following five criteria: (i) the lease has a purchase option that is reasonably certain of being exercised, (ii) the present value of the future cash flows is substantially all of the fair market value of the underlying asset, (iii) the lease term is for a significant portion of the remaining economic life of the underlying asset, (iv) the title to the underlying asset transfers at the end of the lease term, or (v) if the underlying asset is of such a specialized nature that it is expected to have no alternative uses to the lessor at the end of the term. Leases that do not meet the finance lease criteria are accounted for as an operating lease. Operating lease assets represent a right to use an underlying asset for the lease term and operating lease liabilities represent an obligation to make lease payments arising from the lease. Operating lease liabilities with a term greater than one year and their corresponding right-of-use assets are recognized on the balance sheet at the commencement date of the lease based on the present value of lease payments over the expected lease term.

Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. As the Company’s leases do not typically provide an implicit rate, the Company utilizes the appropriate incremental borrowing rate, determined as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and in a similar economic environment. For finance leases, depreciation expense is recognized for the leased asset acquired and interest expense is recognized related to the portion of the financing in the statements of operations and comprehensive loss. For operating leases, lease cost is recognized on a straight-line basis over the lease term and variable lease payments are recognized as operating expense in the period in which the obligation for those payments is incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes, insurance, and other operating costs that are passed on from the lessor in proportion to the space leased by the Company. The Company has elected the practical expedient to not separate between lease and non-lease components.

Commitments and Contingencies

The Company recognizes a liability with regard to loss contingencies when it believes it is probable a liability has been incurred, and the amount can be reasonably estimated. If some amount within a range of loss appears at the time to be a better estimate than any other amount within the range, the Company accrues that amount. When no amount within the range is a better estimate than any other amount the Company accrues the minimum amount in the range. The Company has not recorded any such liabilities as of December 31, 2022 and 2021.

Revenue Recognition and Related Allowances

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC Topic 606, Revenue from Contracts with Customers (“Topic 606”), the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Net Sales

FYARRO was approved by the FDA in November 2021. On February 22, 2022, the Company launched sales of FYARRO to specialty distributors (“SDs”) and a specialty pharmacy (“SP”). The Company recognizes product sales when the SDs and SP obtain control of the product. Product sales are recorded at the net sales price, which includes provisions for the following allowances which are reflected either as a reduction to the related account receivable or as an accrued liability, depending on how the allowance is settled:

Distribution Fees: Distribution fees include distribution service fees paid to the SDs and SP based on a contractually fixed percentage of the wholesale acquisition cost (“WAC”). Distribution fees are recorded as an offset to product sales based on contractual terms at the time revenue from the sale is recognized.

Rebates: Allowance for rebates includes mandated discounts under the Medicaid Drug Rebate Program and TRICARE program. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or statutory requirements. The allowance for rebates is based on contracted or statutory discount rates and expected utilization by benefit plan participants. The Company’s estimates for expected utilization of rebates are based on utilization data received from the SDs and SP since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter’s activity. If actual future rebates vary from estimates, the Company may need to adjust prior period accruals, which would affect product sales in the period of adjustment.

Chargebacks: Chargebacks are discounts and fees that relate to contracts with government and other entities purchasing from the SDs and SP at a discounted price. The SDs and SP charge back to the Company the difference between the price initially paid by the SDs and SP and the discounted price paid to the SDs and SP by these entities. If actual future chargebacks vary from these estimates, the Company may need to adjust prior period accruals, which would affect product sales in the period of adjustment.

Co-Payment Assistance: The Company offers co-payment assistance to commercially insured patients meeting certain eligibility requirement. Co-payment assistance is accrued at the time of product sale to SDs and SP based on estimated patient participation and average co-pay benefit to be paid per a claim. The Company estimated amounts are compared to actual program participation and co-pay amounts paid using data provided by third-party administrators. If actual amounts differ from the original estimates the assumptions being applied are updated and adjustment for prior period accruals will be adjusted in the current period.

Product Returns: Consistent with industry practice, the Company offers the SDs and SP limited product return rights for damages, shipment errors, and expiring product, provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. The Company does not allow product returns for product that has been dispensed to a patient. As the Company receives inventory reports from the SDs and SP and has the ability to control the amount of product that is sold to the SDs and SP the Company’s estimate of future potential product returns is based on the on-hand channel inventory data and sell-through data obtained from the SDs and SP. In arriving at its estimate, the Company also considers historical product returns, the underlying product demand, and industry data specific to the specialty pharmaceutical distribution industry.

The total amount deducted from gross product sales for the allowances described above for the year ended December 31, 2022 was $2.4 million. The following table summarizes the consolidated activities and ending balance of all of the Company's gross-to-net sales adjustments (amounts in thousands):

	Balance at Beginning of Year	Provision for Current Period Sales	Payments	Balance at End of Year
Year ended December 31, 2022	$ —	$ 2,438	$ (1,004)	$ 1,434

Grant Revenue

The Company’s grant revenues are derived from federal grants with the FDA. The Company has determined that the government agencies providing grants to the Company are not customers. Grant revenue is recognized when there is reasonable assurance of compliance with the conditions of the grant and reasonable assurance that the grant revenue will be received. The Company recognizes grant revenues as reimbursable grant costs are incurred. The costs associated with these reimbursements are reflected as a component of research and development expense in the accompanying statements of operations and comprehensive loss.

With respect to grant revenue derived from reimbursement of direct out-of-pocket expenses for research costs associated with federal contracts, where the Company acts as principal with discretion to choose suppliers, bears credit risk, and performs part of the services required in the transaction, the Company records revenue for the gross amount of the reimbursement. The costs associated with these reimbursements are reflected as a component of research and development expense in the accompanying statements of operations and comprehensive loss.

Revenue Under License Agreement

The Company generates revenues from payments received under a license agreement. Under such license agreement, the Company recognizes revenue when it transfers promised goods or services to partners in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with partners, the Company performs the following five steps: (i) identifies the promised goods or services in the contract; (ii) identifies the performance obligations in the contract, including whether they are distinct in the context of the contract; (iii) determines the transaction price, including the constraint on variable consideration; (iv) allocates the transaction price to the performance obligations in the contract; and (v) recognizes revenue when (or as) the Company satisfies the performance obligations.

For revenue from such license agreement, the Company generally collects an upfront license payment from the license partner and is also entitled to receive event-based payments subject to the license partner's achievement of specified development, regulatory and sales-based milestones. In addition, the Company is generally entitled to royalties if products under the license agreement are commercialized.

Transaction price for a contract represents the amount to which the Company is entitled in exchange for providing goods and services to the partner. Transaction price does not include amounts subject to uncertainties unless it is probable that there will be no significant reversal of revenue when the uncertainty is resolved. Apart from the upfront license payment, all other fees the Company may earn under such license agreements are subject to significant uncertainties of product development. Achievement of many of the event-based development and regulatory milestones may not be probable until such milestones are actually achieved. This generally relates to milestones such as obtaining regulatory approvals and successful completion of clinical trials. With respect to other development milestones, e.g., dosing of a first patient in a clinical trial, achievement could be considered probable prior to its actual occurrence, based on the progress towards commencement of the trial. The Company does not include any amounts subject to uncertainties in the transaction price until it is probable that the amount will not result in a significant reversal of revenue in the future. At the end of each reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the estimate of the overall transaction price.

Because such agreements generally only have one type of performance obligation, a license, which is generally all transferred at the same time as agreement inception, allocation of the transaction price among multiple performance obligations is not required. Upfront amounts allocated to licenses are recognized as revenue when the licenses are transferred to the partners. Development milestones and other fees are recognized in revenue when their occurrence becomes probable.

Research and Development

Research and development expenses consist of costs incurred in performing research and development activities, including salaries and benefits, materials and supplies, preclinical expenses, share-based compensation expense, contract services, and other external development expenses. The Company records research and development activities conducted by third-party service providers, which include work related to preclinical studies, clinical trials, and contract manufacturing activities, to research and development expense as incurred. The Company is required to estimate the amount of services provided but not yet invoiced and include these expenses in accrued expenses on the balance sheet and within research and development expenses in the statements of operations and comprehensive loss. These expenses are a significant component of the Company's research and development expenses and require significant estimates and judgments. The Company accrues for these expenses based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers. As actual expenses become known, the Company adjusts its accrued expenses.

Share-Based Compensation

The Company recognizes all share-based payments to employees, including grants of employee stock options in the consolidated statements of operations and comprehensive loss based on their fair values. All of the Company's share-based awards, to employees, non-employees, officers, and directors, are subject only to service-based vesting conditions. The Company estimates the fair value of its share-based awards using the Black-Scholes option pricing model, which requires the input of assumptions, including (i) the expected stock price volatility, (ii) the calculation of expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Options granted during the year have a maximum contractual term of ten years. Forfeitures are recognized and accounted for as they occur.

Due to the historical lack of a public market for the trading of the Company's securities and a lack of company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to the Company, including stage of product development and life science industry focus. The Company believes the group selected has sufficient similar economic and industry characteristics and includes companies that are most representative of the Company.

The Company has limited historical stock option activity and therefore estimates the expected term of stock options granted to employees, officers, and directors using the simplified method, which represents the average of the contractual term of the stock option and its weighted-average vesting period, to calculate the expected term, as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term for options granted to employees, and utilizes the contractual term for options granted to non-employees. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the stock options. Compensation expense related to awards to employees is calculated on a straight-line basis by recognizing the grant date fair value over the associated service period of the award, which is generally the vesting term.

Employee Stock Purchase Plan

Stock-based compensation expense for employee stock purchases under the Company's 2021 Employee Stock Purchase Plan (the "2021 ESPP") is recorded at the estimated fair value of the purchase as of the plan enrollment date and is recognized as expense on a straight-line basis over the applicable six-month ESPP offering period.

Income Taxes

Income taxes have been accounted for using the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates applicable to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance against deferred tax assets is recorded if, based upon the weight of all available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. The Company recognizes interest and penalties related to uncertain tax positions, if any exist, in income tax expense.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Basic and diluted weighted average shares of common stock outstanding for the year ended December 31, 2022, includes the weighted average effect of 2,426,493 Pre-Funded Warrants, which were issued in September 2022, for the purchase of shares of common stock, for which the remaining unfunded exercise price is $0.0001 per share.

Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company's potentially dilutive securities, which include convertible promissory notes, convertible preferred stock, outstanding stock options and warrants have been excluded from the computation of diluted net loss per share as they would be anti-dilutive.

Net loss per share is presented as the more dilutive of the treasury stock and as-converted method or the two-class method required for participating securities. The Series A convertible preferred stock is considered a participating security and does not have a contractual obligation to share in Private Aadi's losses. As such, the two-class method was not required.

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because their inclusion would be anti-dilutive:

	Year Ended December 31,	
	2022	2021
Options to purchase common stock	2,990,423	1,749,876
Warrants to purchase common stock	29,167	36,667

The table above excludes the conversion of the principal balance and accrued interest on the convertible promissory notes which converted into 698,018 shares of common stock in conjunction with the closing of the Merger.

Accounting Pronouncements Not Yet Adopted

In August 2020, the FASB issued ASU 2020-06, "*Debt – Debt with Conversion and Other Options*" (Subtopic 470-20) and "Derivatives and Hedging – Contracts in Entity's Own Equity" (Subtopic 815-40). This new guidance is intended to reduce the complexity of accounting for convertible instruments. The guidance also addresses how convertible instruments are accounted for in the diluted earnings per share calculation and requires enhanced disclosures about the terms of convertible instruments. Entities may adopt ASU 2020-06 using either a partial retrospective or fully retrospective method of transition. This ASU is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years for smaller reporting companies. The Company is currently evaluating the impact the adoption of ASU 2020-06 will have on the Company's consolidated financial statements.

In 2016, the FASB issued ASU 2016-13 "*Financial Instruments - Credit Losses*" which (i) significantly changes the impairment model for most financial assets that are measured at amortized cost and certain other instruments from an incurred loss model to an expected loss model which will be based on an estimate of current expected credit loss; and (ii) provides for recording credit losses on available-for-sale debt securities through an allowance account. The standard also requires certain incremental disclosures. Subsequently, the FASB issued several ASUs to clarify, improve, or defer the adoption of ASU 2016-13. This ASU is effective for fiscal years beginning January 2023. The Company is currently evaluating the impact the adoption of ASU 2016-13 will have on the Company's financial statements.

3. Fair Value Measurement

The following table sets forth the recurring fair value of the Company's financial assets and liabilities, allocated into the Level 1, Level 2 and Level 3 hierarchy that were measured at fair value on a recurring basis (amounts in thousands):

	Fair Value Measurements as of December 31, 2022			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Money market funds (1)	$ 32,035	$ —	$ —	$ 32,035
U.S. government treasury bills	70,708	—	—	70,708
Commercial paper	—	53,296	—	53,296
Corporate bonds	—	4,250	—	4,250
Government agency	—	5,287	—	5,287
Total financial assets	$ 102,743	$ 62,833	$ —	$ 165,576

	Fair Value Measurements as of December 31, 2021			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Money market funds (1)	$ 140,032	$ —	$ —	$ 140,032

(1) Included in cash and cash equivalents in the accompanying balance sheets.

As of December 31, 2022 gross unrealized losses for cash equivalents and investments was $0.1 million. As of December 31, 2022, all marketable securities had a contractual maturity of less than one year.

Intangible Asset Impairment

During the year ended December 31, 2021, the Company recognized an impairment of $74.2 million of the contract intangible asset acquired in connection with the Merger and reduced the contract intangible asset to its estimated fair value of $3.9 million at the Effective Time. This represented a Level 3 fair value measurement as factors used to develop the estimated fair value are unobservable inputs that are not supported by market activity.

During the year ended December 31, 2022, upon receipt of the Notice of Termination, the Company impaired the contract intangible asset by $3.7 million to its estimated fair value of zero (which represented a Level 3 fair value measurement) based on receipt of the formal notice of termination from Gossamer for the Gossamer License Agreement.

4. Short-Term Investments and Cash and Cash Equivalents

The Company's short-term investments, which consist of highly liquid securities, are classified as available-for-sale and are stated at fair value. The following table summarizes the Company's short-term investments (in thousands):

	Maturity (In Years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds		$ 32,035	$ —	$ —	$ 32,035
U.S. government treasury bills	Less than 1	70,812	4	(108)	70,708
Commercial paper	Less than 1	53,296	—	—	53,296
Corporate bonds	Less than 1	4,276	—	(26)	4,250
Government agency	Less than 1	5,272	15	—	5,287
Total		$ 165,691	$ 19	$ (134)	$ 165,576

5. Merger

The Merger was accounted for as a reverse asset acquisition because substantially all of the fair value was concentrated in cash, working capital, and a long-lived contract intangible asset (See Note 1).

The estimated fair value of total consideration given was $110.4 million as detailed below and is based on 3,208,718 shares of common stock, after taking into account the Reverse Stock Split, outstanding immediately prior to the Effective Time.

Number of common shares of the combined company to be owned by Aerpio shareholders	3,208,718
Multiplied by the fair value per share of Aerpio common stock on August 26, 2021	$ 33.00
Fair value of Aerpio common stock	105,887,694
Aadi transaction costs	4,500,864
Purchase price	$ 110,388,558

The allocation of the purchase price is as follows (amounts in thousands):

	August 26, 2021
Cash and cash equivalents	$ 29,700
Other current assets	2,709
Intangible asset (1)	78,062
Deposits	20
Accounts payable and accrued liabilities	(103)
Purchase price	$ 110,388

(1) The long-lived intangible asset represented Aerpio’s out-licensing agreement with Gossamer Bio., Inc. In accordance with GAAP for asset acquisitions, the excess purchase price over the fair value of the acquired assets and liabilities was ascribed to the acquired contract intangible asset. Subsequently, the Company recorded an impairment and the licensing agreement was terminated. See Note 6 for additional information.

6. Intangible Asset

The Company recorded a long-lived contract intangible asset as a result of the Merger, related to the Gossamer License Agreement, which was assumed in the Merger. In accordance with GAAP, for asset acquisitions, the excess purchase price over the fair value of the acquired assets and liabilities was ascribed to the acquired contract intangible asset. Due to the significant excess purchase price being allocated over the fair value of the acquired contract intangible asset, the Company determined that an indicator of impairment was present. The contract intangible asset was assessed for recoverability using an undiscounted cash flow model, which resulted in undiscounted cash flows below the carrying amount. At the Effective Time, the Company recognized an impairment of $74.2 million to bring the carrying amount of the contract intangible asset down to its estimated fair value of $3.9 million. The fair value estimate of the intangible asset relates to contingent cash flows expected from the out-licensing arrangement, of which 90% of any future net cash proceeds will be remitted to CVR Holders and paid through the CVRs. The useful life of the intangible asset was estimated to be approximately 14.3 years.

On April 25, 2022, the Company received a formal notice of termination from Gossamer for the Gossamer License Agreement, relating to Gossamer’s GB004 product candidate, a legacy product candidate of the Company's predecessor, Aerpio, after Gossamer announced that its Phase 2 SHIFT-UC clinical trial studying GB004 in patients with mild-to-moderate active ulcerative colitis did not meet the primary or secondary endpoints at week 12 and the study was being terminated for lack of treatment benefit. The Gossamer License Agreement terminated effective July 24, 2022. Based on the termination of the Gossamer License Agreement, the Company fully impaired the intangible asset, $3.7 million, of which the Gossamer License Agreement is the underlying asset, during the year ended December 31, 2022.

Amortization expense was $87,000 and $95,000 for the years ended December 31, 2022 and 2021, respectively.

The following table presents a roll forward of the finite-lived intangible asset for the years ended December 31, (amounts in thousands):

	Year Ended December 31,	
	2022	2021
Intangible asset, net, beginning of year	$ 3,811	$ —
Additions	—	78,062
Amortization	(87)	(95)
Impairment of contract intangible	(3,724)	(74,156)
Intangible asset, net, end of year	$ —	$ 3,811

7. Accrued Liabilities

Details of accrued liabilities are presented as follows (amounts in thousands):

	As of December 31,	
	2022	2021
Accrued bonus	$ 5,463	$ 1,465
Accrued clinical	2,399	2,507
Accrued professional fees	1,814	1,948
Advanced customer payments	1,571	—
Accrued salaries and payroll	1,299	152
Accrued contract manufacturing	405	2,287
Accrued other - sales related	1,435	—
Accrued other	536	344
Total accrued liabilities	$ 14,922	$ 8,703

8. Operating Lease

In April 2019, the Company entered into a twenty-eight month facility lease agreement for office space in Pacific Palisades, California (the “Pacific Palisades Lease”). The Pacific Palisades Lease commenced on May 1, 2019, included four months of rent abatement and a rent escalation clause and was set to expire on August 31, 2021. In August 2021, the Company exercised its option to extend the term of the Pacific Palisades Lease for an additional three-year period and entered into an amendment to the lease agreement (the “Pacific Palisades Lease Amendment”). Pursuant to the Pacific Palisades Lease Amendment, the Company and the landlord agreed to extend the term for an additional period of three (3) years and six (6) months, until February 28, 2025, with an option to renew for an additional three (3) years in accordance with the terms of the Pacific Palisades Lease. Included in the Pacific Palisades Lease Amendment were nine months of rent abatement and a rent escalation clause.

In April 2022, the Company entered into a lease agreement for office space in Morristown, New Jersey (the “Morristown Lease”). The Morristown Lease has a term of seventy-three months, unless terminated sooner, and includes rent abatement for the first three months and the forty-seventh and forty-eighth calendar months after lease commencement. Included in the Morristown Lease are fixed rent escalations of approximately 2% on each anniversary year of the lease term.

The following table summarizes information related to the Company's lease (amounts in thousands):

	As of December 31, 2022	As of December 31, 2021
Assets:		
Operating lease right-of-use assets	$ 1,522	$ 557
Liabilities:		
Operating lease liabilities, current	$ 394	$ 131
Operating lease liabilities, non-current	1,267	474
Total operating lease liabilities	$ 1,661	$ 605

Rent expense for the years ended December 31, is presented on the following table (amounts in thousands):

	Year Ended December 31, 2022	Year Ended December 31, 2021
Operating lease rent expense	$ 382	$ 188

Cash paid for leases and included in operating cash flows for the years ended December 31, is presented on the following table (amounts in thousands):

	Year Ended December 31, 2022	Year Ended December 31, 2021
Cash paid included in operating cash flows	$ 291	$ 129

The future minimum lease payments required under the operating lease as of December 31, 2022, are summarized below (amounts in thousands):

Future Minimum Lease Payments:	
2023	$ 500
2024	512
2025	320
2026	231
2027	280
Thereafter	110
Total minimum lease payments	$ 1,953
Less: amount representing interest	(292)
Present value of operating lease liabilities	$ 1,661
Less: operating lease liabilities, current	(394)
Operating lease liabilities, non-current	$ 1,267
Weighted average remaining lease term (in years)	4.53
Weighted average incremental borrowing rate	7.5 %

9. License Agreements

Bristol-Meyers Squibb Company License Agreement

On April 9, 2014, the Company entered into a license agreement (as amended the "BMS License Agreement") with Bristol-Myers Squibb Company ("BMS") for exclusive rights for certain patents and a non-exclusive license for certain technology and know-how pertaining to FYARRO.

The BMS License Agreement will remain in effect from the effective date of April 9, 2014 until expiration of all milestone and royalty payment obligations under the agreement, unless terminated by either of the parties upon giving an advance notice as specified in the BMS License Agreement. Under the terms of the BMS License Agreement, BMS agreed to supply the Company with licensed products of FYARRO necessary for clinical or non-clinical development.

Under the terms of the BMS License Agreement, BMS is entitled to receive certain development milestone payments, royalties on net sales from licensed products under the agreement and any sublicense fees. During the year ended December 31, 2022, royalties on net product sales were $1.1 million, of which $0.4 million in royalties were accrued as of December 31, 2022. No payments related to milestones were paid during the years ended December 31, 2022 and 2021.

On August 30, 2021, the Company and BMS entered into Amendment No. 1 (the "Amendment") to the BMS License Agreement related to certain intellectual property rights of BMS pertaining to the compound known as FYARRO. Under the terms of the Amendment, the Company paid BMS $5.8 million representing 50% of the previously outstanding payment obligation under the terms of the BMS License Agreement, following the Effective Time of the 2021 PIPE Financing. Pursuant to the terms of the Amendment, the remaining previously outstanding payment obligation of $5.8 million, is due on the third anniversary of the Effective Time, or August 26, 2024 plus any accrued and unpaid interest due thereon ("Balloon Payment"). The Balloon Payment shall accrue interest, beginning August 26, 2021 until paid in full, at a rate equal to 4.00% per annum based on the weighted average amount outstanding during the applicable calendar quarter, and interest is payable quarterly in arrears. In addition, the parties agreed to amend the royalty rates payable to BMS based on net sales of products subject to the BMS License Agreement.

On December 8, 2020, the Company entered into a license agreement ("EOC License Agreement") with EOC Pharma (Hong Kong) Limited ("EOC") under which the Company received $14.0 million in January 2021 in non-refundable upfront consideration as partial payment for the rights and licenses granted to EOC by the Company for the further development and commercialization of FYARRO in the People's Republic of China, Hong Kong Special Administration Region, Macao Special Administrative Region and Taiwan (the "Licensed Territory"). In accordance with the BMS License Agreement, the Company is required to pay 20% of all sublicense fees to BMS. As such, the Company recognized $2.8 million of license expense in the year ended December 31, 2021 and had a corresponding $2.8 million sublicense payable to BMS on the balance sheet as of December 31, 2021, which was paid in 2022.

During the year ended December 31, 2021, the Company recognized license revenue and received $1.0 million from EOC for achieving the FDA approval milestone on November 22, 2021. In accordance with the BMS License Agreement, the Company recognized $0.2 million of license expense in the year ended December 31, 2021 and had a corresponding $0.2 million sublicense payable to BMS on the balance sheet as of December 31, 2021, which was paid in 2022.

EOC License Agreement

In December 2021, the Company entered into the EOC License Agreement with EOC for the further development of ABI-009, now called FYARRO, and commercialization of FYARRO in the Licensed Territory. Under the terms of the agreement, the Company granted to EOC an exclusive, royalty-bearing license to develop and commercialize the product in the Licensed Territory. The term of the EOC License Agreement was set to continue until the expiration of the royalty obligations under the agreement.

On June 27, 2022, the Company received written notice from EOC that EOC elected to terminate the EOC License Agreement, effective immediately, due to alleged material breaches by the Company under such agreement. The Company disagrees with EOC's allegations of material breach and does not believe that EOC had a right to terminate the EOC License Agreement for material breach, and accordingly believes that the termination of the EOC License Agreement is a termination for convenience. EOC had the right to terminate the agreement for convenience upon 120 days advance written notice. The Company waived such notice period in connection with EOC's termination notice and, as a result, the EOC License Agreement was terminated effective June 27, 2022. Either party had the right to terminate the EOC License Agreement in the event that the other party breaches the agreement and fails to cure the breach, becomes insolvent or challenges certain of the intellectual property rights licensed under the agreement. On June 27, 2022, EOC filed a Request for Arbitration with the International Chamber of Commerce's International Court of Arbitration against the Company. The arbitration process is ongoing.

The Company assessed the EOC License Agreement and concluded that EOC is a customer and identified the license of ABI-009 provided to EOC as the sole performance obligation. The $14.0 million upfront payment received from EOC is non-refundable and non-creditable and is considered fixed consideration. The Company recognized revenue of $14.0 million in the year ended December 31, 2020 when the EOC License Agreement was signed, and the $14.0 million upfront payment was received in January 2021.

The potential milestone payments and royalty payments under the EOC License Agreement were considered variable consideration and were constrained with respect to revenue recognition notification from EOC that the milestone and royalty payments had been achieved.

The Company was eligible to receive an additional $257.0 million in the aggregate upon achievement of certain development, regulatory, and sales milestones, as well as tiered royalties on net sales in the Licensed Territory. Under the terms of the EOC License Agreement, EOC was obligated to fund all research, development, regulatory, marketing and commercialization activities in the defined Licensed Territory. See Note 16 to these audited financial statements for more information about the arbitration process regarding the EOC License Agreement.

10. Convertible Notes

Private Aadi received $8.1 million in October 2019 ("October 2019 Convertible Notes") and $1.0 million in January 2020 for the proceeds in connection with the issuance of convertible promissory notes ("January 2020 Convertible Notes," and together with October 2019 Convertible Notes "Convertible Notes"). The October 2019 Convertible Notes were issued to existing equity holders of Private Aadi. The Convertible Notes originally had a maturity date of one year from the date of issuance and an escalating interest rate of 6% per annum for the first four months following the effective date of the loan agreement, 8% per annum for the fifth and sixth months, and 10% per annum for the remaining six months of the note term until maturity at twelve months.

In November 2020, Private Aadi entered into an amendment to the Convertible Notes, whereby the term was extended from one year to two years. The amendment was accounted for as a debt modification.

In May 2021, Private Aadi entered into an amendment to the Convertible Notes, whereby upon the closing of the Merger (see Note 1), the outstanding principal amount of the Convertible Notes and all accrued and unpaid interest as of immediately prior to the closing of the Merger would automatically convert into fully paid and nonassessable shares of Private Aadi common stock at a price per share equal to $4.80 and would be concurrently exchanged for shares of the Company's common stock based on the Exchange Ratio. In conjunction with the closing of the Merger on August 26, 2021, the outstanding Convertible Notes were converted into shares of Private Aadi common stock which were concurrently exchanged for 698,018 shares of the Company's common stock based on the Exchange Ratio. At the date of conversion, the Convertible Notes were marked to market and valued at $9.5 million, resulting in a gain on conversion of $0.4 million in the year ended December 31, 2021.

11. Payroll Protection Program Loan

In May 2020, Private Aadi was approved for a $0.2 million Small Business Administration Paycheck Protection Program loan, as provided for in the Coronavirus Aid, Relief and Economic Security Act ("PPP Loan"). Under certain conditions, the PPP Loan and accrued interest were forgivable after a twenty-four-week covered period as long as the loan proceeds were used for eligible expenses, including payroll, benefits, rent and utilities, and the company maintains certain payroll levels. The amount of loan forgiveness was subject to reduction if the Company terminates employees or reduces salaries during the twenty-four-week covered period. The unforgiven portion of the loan was payable over two years at an interest rate of 1%, with a deferral of payments for the ten months following the end of the twenty-four-week covered period. On April 29, 2021, the Company received notification from the SBA that the Company's Forgiveness Application of the PPP Loan and accrued interest was approved in full, and the Company had no further obligations related to the PPP Loan. Accordingly, the Company recorded a gain on the forgiveness of the PPP Loan totaling $0.2 million.

12. Stockholders' Equity (Deficit)

Preferred Stock

As of December 31, 2022 and 2021, under the Company's certificate of incorporation, as amended and restated, the Company has 10,000,000 shares of preferred stock, par value $0.0001 per share, in authorized capital with no shares outstanding.

Series Seed Preferred Stock

On February 23, 2017, Private Aadi converted from a limited liability company to a corporation and at that time converted 734,218 membership units into shares of Series Seed Preferred Stock. All outstanding shares of Series Seed Preferred Stock were converted into Private Aadi's common stock and concurrently exchanged for the Company's common stock based on the Exchange Ratio in connection with the closing of the Merger.

Series A Preferred Stock

In February and March 2017, Private Aadi sold and issued in a private placement 5,847,940 shares of Series A Preferred Stock at $3.42 per share (the "Series A Financing"). Upon the closing of the Series A Financing, convertible notes issued in 2015 converted into 482,426 shares of Series A Preferred Stock at 85% of the $3.42 price per share (the "Series A Original Issue Price") paid by the Series A Financing investors. Convertible notes issued in 2017 converted into 881,286 shares of Series A Preferred Stock at the Series A Original Issue Price. All outstanding shares of Series A Preferred Stock were converted into shares of Private Aadi common stock and concurrently exchanged for the Company's common stock based on the Exchange Ratio in connection with the closing of the Merger.

Common Stock and Pre-Funded Warrants

As of December 31, 2022 and 2021, the Company had 300,000,000 shares of authorized common stock with par value of $0.0001 per share under the Company's certificate of incorporation, as amended and restated. As of December 31, 2022 and 2021, the shares of common stock outstanding were 24,435,007 and 20,894,695, respectively.

In conjunction with the closing of the Merger, the Company issued an aggregate of 2,558,218 shares of common stock to holders of Private Aadi common stock in exchange for all of the Private Aadi capital stock outstanding immediately prior to the closing of the Merger. Concurrently with the closing of the Merger, the 2021 PIPE Investors purchased an aggregate of 11,852,862 shares of the Company's common stock for an aggregate purchase price of $155.0 million pursuant to the Subscription Agreement entered into with the Company on May 16, 2021. The aggregate net proceeds, after deducting certain expenses incurred that were direct and incremental to the issuance of the 2021 PIPE shares, was $145.4 million.

In March 2022, the Company entered into the Sales Agreement with Cowen, with respect to an "at the market offering" program pursuant to which the Company may offer and sell, from time to time at its sole discretion, shares of common stock having aggregate gross proceeds of up to $75.0 million through Cowen as its sales agent. As of December 31, 2022, no shares of common stock had been sold pursuant to the Sales Agreement.

On September 22, 2022, the Company entered into the Purchase Agreement for the 2022 PIPE Financing with the 2022 PIPE Investors for the sale by the Company of 3,373,526 shares of the Company's common stock for a price of $12.50 per share and Pre-Funded Warrants to purchase an aggregate of 2,426,493 shares of the Company's common stock at a purchase price of $12.4999 per Pre-Funded Warrant. The Pre-Funded Warrants are exercisable at an exercise price of $0.0001 and will be exercisable until exercised in full. The 2022 PIPE Financing closed on September 26, 2022. Aggregated net proceeds, after deducting certain expenses incurred of $0.3 million related to the issuance of the shares were $72.2 million.

On September 22, 2022, the Company and the Purchasers entered into the 2022 PIPE Registration Rights Agreement providing for the registration for resale of the securities sold under the Purchase Agreement, including the shares issuable upon the exercise of the Pre-Funded Warrants, that are not then registered on an effective registration statement, pursuant to a registration statement filed with the SEC. The Pre-Funded Warrants meet the criteria to be classified within stockholders' equity. As of December 31, 2022, all Pre-Funded Warrants are still outstanding.

Dividends

The holders of common stock are entitled to receive cash dividends, if and when declared by the board of directors of the Company (the "board of directors"). Since the Company's inception, no cash dividends have been declared or paid to the holders of common stock.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution, or winding-up of the Company, the holders of common stock are entitled to share ratably in the Company's assets.

Voting

The holders of common stock are entitled to one vote for each share of common stock held at all meetings of stockholders and written actions in lieu of meetings.

13. Share-Based Compensation

2014 Plan (as amended and restated in February 2017, the "Private Aadi Plan")

In connection with the Merger, the Company assumed the Private Aadi Plan, which was amended and restated in February 2017, and the issued and outstanding stock options under the Private Aadi Plan (the Private Aadi common stock underlying the awards was adjusted for shares of the Company's common stock pursuant to the Merger Agreement). The Private Aadi Plan allowed for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock unit awards and other stock awards. In connection with the closing of the Merger and the adoption of the 2021 Plan (as defined below), no further awards will be issued under the Private Aadi Plan.

The options that are granted from the Private Aadi Plan are exercisable at various dates as determined upon grant and will expire no more than ten years from their date of grant. The Private Aadi Plan stock options generally vest over a four-year term.

2011 Plan and 2017 Plan

In connection with the closing of the Merger, the Company assumed the Aerpio 2011 Equity Incentive Plan (the "2011 Plan") and the Aerpio 2017 Stock Option and Incentive Plan (the "2017 Plan," and together with the 2011 Plan, the "Prior

Plans”). No new awards will be granted under the Prior Plans effective as of the closing of the Merger and adoption of the 2021 Plan (as defined below).

2021 Plan

At the closing of the Merger, the Company adopted the Aadi Bioscience, Inc. 2021 Equity Incentive Plan (the “2021 Plan”), which permits the award of stock options stock appreciation rights, restricted stock, restricted stock units, performance units and performance grants to employees, members of the board of directors, and outside consultants.

Subject to the adjustment provisions contained in the 2021 Plan and the evergreen provision described below, a total of 2,070,784 shares of common stock were initially reserved for issuance pursuant to the 2021 Plan. In addition, the shares reserved for issuance under the 2021 Plan include any shares of common stock (i) subject to awards of stock options or other awards granted under the Prior Plans that expire or otherwise terminate without having been exercised in full and shares of common stock granted under the Prior Plans that are forfeited or repurchased by the Company, and (ii) any shares of common stock subject to stock options or similar awards granted under the Private Aadi Plan that were assumed in the Merger (provided that the maximum number of shares that may be added to the 2021 Plan pursuant to this sentence is 764,154 shares).

The number of shares available for issuance under the 2021 Plan also will include an annual increase, or the evergreen feature, on the first day of each of the Company’s fiscal years, beginning with the Company’s fiscal year 2022, equal to the least of:

- 2,070,784 shares of common stock;
- a number of shares equal to 4% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year; or
- such number of shares as the board of directors or its designated committee may determine.

As a result of the evergreen increase, a total of 977,400 shares were added to the 2021 Plan on January 1, 2023.

Shares issuable under the 2021 Plan are authorized, but unissued, or reacquired shares of common stock. If an award expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an exchange program, or, with respect to restricted stock, restricted stock units, performance units or performance shares, is forfeited to or repurchased by the combined company due to failure to vest, the unpurchased shares (or for awards other than stock options or stock appreciation rights, the forfeited or repurchased shares) will become available for future grant or sale under the 2021 Plan (unless the 2021 Plan has terminated).

As of December 31, 2022, zero, 299,039, 101,024 and 2,590,360 shares were outstanding under the 2011 Plan, Private Aadi Plan, 2017 Plan and 2021 Plan, respectively.

The following table summarizes the stock option activity during the year ended December 31, 2022:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, January 1, 2022	1,749,876	$ 20.71	8.48	$ 10,007
Granted	1,583,038	15.28		
Exercised	(132,084)	3.04		
Expired/cancelled	(210,407)	20.61		
Outstanding as of December 31, 2022	2,990,423	$ 19.28	8.59	$ 2,849
Options exercisable as of December 31, 2022	722,198	$ 18.53	6.84	$ 2,251
Vested and expected to vest as of December 31, 2022	2,990,423	$ 19.28	8.59	$ 2,849

As of December 31, 2022, the aggregate intrinsic value of options outstanding was $2.8 million. For the years ended December 31, 2022 and 2021, the weighted-average grant-date fair value of options granted was $12.20 and $18.88 per share, respectively.

As of December 31, 2022, there was $28.8 million of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted average period of 2.7 years.

The total intrinsic value of the options exercised during the years ended December 31, 2022 and 2021 was $1.3 million and $1.0 million, respectively.

As of December 31, 2022, and 2021, 853,760 and 1,390,606 shares were reserved for issuance under the 2021 Plan, respectively.

Compensation Expense Summary

The Company recognized the following compensation cost related to employee and non-employee share-based compensation activity for the periods presented (amounts in thousands):

	Year Ended December 31,	
	2022	2021
Selling, general and administrative	$ 6,333	$ 1,449
Research and development	3,310	657
Total	$ 9,643	$ 2,106

Included in the year ended December 31, 2021 is $0.3 million of expense related to the acceleration of vesting associated with individual awards assumed in the Merger.

In connection with the retirement of an employee, the Company has modified its previously granted equity awards to continue vesting 64,436 shares, which would have otherwise been forfeited in May 2022 as a result of such retirement and extended the exercise ability of the former employee's vested and outstanding options. The incremental share-based compensation expense as a result of the modification was $0.3 million for the year ended December 31, 2022.

The Company uses the Black-Scholes option pricing model to determine the estimated fair value for share-based awards. Option pricing and models require the input of various assumptions, including the option's expected life, expected dividend yield, price volatility and risk-free interest rate of the underlying stock.

The calculation was based on the following assumptions:

	Year Ended December 31,	
	2022	2021
Weighted average grant date fair value (per share)	$12.20	$18.88
Risk-free interest rate	1.46% - 4.23%	0.84% - 1.38%
Expected volatility	85.91% - 89.35%	85.21% - 87.88%
Expected term (in years)	5.5 - 6.1	5.1 - 6.3
Expected dividend yield	—	—

The Company determines the assumptions used in the option pricing model in the following manner:

Risk-Free Interest Rate – For the determination of the risk-free interest rates, the Company utilizes the U.S. Treasury yield curve for instruments in effect at the time of measurement with a term commensurate with the expected term assumption.

Expected Volatility – Due to the Company's limited historical stock price volatility data, the Company based its estimate of expected volatility on the estimated and expected volatilities of a guideline group of publicly traded companies. For these analyses, the Company selected companies with comparable characteristics including enterprise value, risk profiles, and with historical share price information sufficient to meet the expected life of the share-based awards. The Company computes the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of its share-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Expected Dividend – The expected dividend yield is assumed to be zero since the Company has never paid dividends and does not have current plans to pay any dividends on its common stock.

Expected Term – The Company estimates the expected term of its stock options granted to employees and non-employee directors using the simplified method, whereby, the expected term equals the average of the vesting term and the original contractual term of the option. The Company utilizes this method since it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term.

Prior to the Company's Merger, given the absence of a public trading market for the Company's common stock, its board of directors exercised their judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of the Company's common stock underlying the stock options, such as: contemporaneous valuations performed by independent third-party specialists, its stage of development, including the status of its research and development efforts of its therapeutic candidates and the material risks related to its business and industry, its results of operations and financial condition, including its levels of capital resources, the prices at which its sold shares of its convertible preferred stock, the rights, preferences and privileges of its convertible preferred stock relative to those of its common stock, the conditions in the biotechnology industry and the economy in general, the stock price performance and volatility of comparable life sciences public companies, as well as recently completed mergers and acquisitions of peer companies, the likelihood of achieving a liquidity event for the holders of its common stock or convertible preferred stock, such as an IPO or a sale of the Company given prevailing market conditions, trends and developments in its industry, external market conditions affecting the life sciences and biotechnology sectors, and the lack of liquidity of its common stock, among other factors.

Subsequent to the Company’s Merger, the fair value of the Company’s common stock is determined based on its closing market price on the date of the grant. The Company’s board of directors intended all options granted to be exercisable at a price per share not less than the per share fair value of its common stock underlying those options on the grant date.

Warrants to Purchase Common Stock

The Company had warrants outstanding for the purchase of 29,167 and 36,666 shares of the Company’s common stock at December 31, 2022 and 2021, respectively. These warrants were assumed in the Merger and were issued by Aerpio in October 2019, for the purchase of 40,000 shares (after taking into account the Reverse Stock Split) of the Company’s common stock at an exercise price of $7.29 per share (after taking into account the Reverse Stock Split). These warrants were fully vested as of the date of the Merger and expire on October 24, 2024. During the year ended December 31, 2022, 7,500 warrants were exercised. At the grant date, the fair value of these awards was determined using a Black-Scholes option pricing model.

The number of shares and the exercise price shall be adjusted for standard anti-dilution events such as stock splits, combinations, reorganizations, or issue shares as part of a stock dividend. The warrants meet the criteria to be classified within stockholders’ equity.

14. Employee Stock Purchase Plan

On August 17, 2021, a special meeting of the Company’s stockholders was held to approve the Merger and related matters, at which the Company's stockholders considered and approved the Company’s 2021 ESPP which permits participants to contribute up to 15% of their eligible compensation during defined rolling six-month offering periods to purchase the Company’s common stock. The purchase price of the shares will be 85% of the lower of the fair market value of the Company’s common stock on the first day of trading of the offering period or on the applicable purchase date. Upon approval of the 2021 ESPP by the stockholders, Aerpio’s Amended and Restated 2017 Employee Stock Purchase Plan terminated. An aggregate of 519,563 shares of common stock have been reserved for issuance under the 2021 ESPP. The number of shares of common stock available for issuance under the 2021 ESPP will be increased on the first day of each fiscal year beginning with the 2022 fiscal year in an amount equal to the least of (i) 310,617 shares of common stock, (ii) one percent (1%) of the outstanding shares of all classes of common stock on the last day of the immediately preceding fiscal year, or (iii) an amount to be determined by the board of directors or its designated committee no later than the last day of the immediately preceding fiscal year. On January 1, 2023, 244,350 shares of common stock were added to the 2021 ESPP. Shares of common stock issuable under the 2021 ESPP will be authorized, but unissued, or reacquired shares of common stock. If the Company’s capital structure changes because of a stock dividend, stock split or similar event, the number of shares that can be issued under the 2021 ESPP will be appropriately adjusted. The Company opened enrollment into the ESPP in May 2022.

The Company uses the Black-Scholes model to determine the estimated fair value for purchases under the 2021 ESPP. Black-Scholes models require the input of various assumptions, including the expected life, expected dividend yield, price volatility and risk-free interest rate of the underlying stock.

The calculation was based on the following assumptions:

	Year Ended December 31, 2022
Strike price (per share)	$11.40 - $11.66
Risk-free interest rate	1.54% - 4.40%
Expected volatility	92.59% - 105.68%
Expected term (in years)	0.5
Expected dividend yield	—

As of December 31, 2022 and 2021, 492,361 and 310,617 shares of common stock were available for issuance under the 2021 ESPP, respectively. The Company had an outstanding liability of $76,000 at December 31, 2022, which will be recognized over six months. No liability was outstanding as of December 31, 2021. During the years ended December 31, 2022 and 2021, 27,202 and zero shares were issued under the 2021 ESPP, respectively.

15. Income Taxes

The Company recorded income tax expense of zero and $2,000 for the years ended December 31, 2022 and 2021, respectively. The Company continues to maintain a full valuation allowance.

A reconciliation of the statutory federal income tax with the provision for income taxes are as follows:

	Year Ended December 31,	
	2022	2021
Federal tax at statutory rate	21.0 %	21.0 %
State income tax, net of federal benefit	1.8	0.5
Nondeductible interest	—	(0.1)
Other permanent items	(0.1)	0.4
Officers Compensation	(1.7)	—
Nondeductible impairment	—	(13.8)
Research credit	2.4	0.9
Change in valuation allowance	(23.4)	(8.9)
Effective tax rate	— %	— %

Significant components of the Company's deferred tax assets and liabilities are as follows (amounts in thousands):

	As of December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 38,548	$ 34,228
Research and development tax credits	5,168	3,732
Section 174 capitalized research expense	5,417	—
Other	4,219	1,214
Total deferred tax assets	53,352	39,174
Valuation allowance	(52,766)	(38,410)
Total gross deferred tax assets, net of valuation allowance	586	764
Deferred tax liabilities:		
Other	(586)	(764)
Total gross deferred tax liabilities	(586)	(764)
Net deferred tax assets / (liabilities)	$ —	$ —

Deferred income tax assets and liabilities are recorded for differences between the financial statement and tax basis of the assets and liabilities that will result in taxable or deductible amounts in the future based on enacted laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized in future periods.

The Company has evaluated the available evidence supporting the realization of its gross deferred tax assets, including the amount and timing of future taxable income and has determined it is more likely than not that the assets will not be realized. As a result, the Company has concluded that a full valuation allowance against its deferred tax asset is necessary at this time.

As of December 31, 2022, the Company has federal and state net operating loss ("NOL") carryforwards of $167.5 million and $72.0 million, respectively. Of the amount of federal and state NOL carryforwards, $123.4 million and $16.5 million, respectively, can be carried forward indefinitely. The remaining federal and state NOL carryforwards begin to expire in 2030 and 2037, unless previously utilized. The Company also has federal and state research credit carryforwards of approximately $5.0 million and $2.3 million, respectively, unless previously utilized. The federal and New Jersey research credit carryforwards will begin to expire in 2037 and 2027, respectively, unless previously utilized. The California research and development (“R&D”) credit will carry forward indefinitely. The increase in the valuation allowance is $14.4 million and $28.2 million for the years ended December 31, 2022 and 2021, respectively.

Pursuant to Section 382 and 383 of the Internal Revenue Code (“IRC”), utilization of the Company’s NOL carryforwards and R&D credits may be subject to annual limitations in the event of any significant future changes in its ownership structure. These annual limitations may result in the expiration of NOL carryforwards and R&D credits prior to utilization. As of December 31, 2022, the Company has completed an IRC Section 382 analysis through the date of the Merger. Ownership changes were identified that will result in annual limitations on future utilization of NOL and R&D credit carryforwards. To the extent such limitations will cause NOL and R&D credit carryforwards to expire unused, these tax attributes have been removed from deferred tax asset table above.

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

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination by tax authorities.

The following table summarizes the changes to the Company’s gross unrecognized tax benefits for the years ended December 31, 2022 and 2021 (amounts in thousands):

	As of December 31,	
	2022	2021
Balance at the beginning of year	$ 2,674	$ 2,404
Decrease related to prior year positions	2	(24)
Increase related to current year positions	704	294
Balance at the end of year	$ 3,380	$ 2,674

Due to the existence of the valuation allowance, future recognition of previously unrecognized tax benefits will not impact the Company’s effective tax rate. The Company’s practice is to recognize interest and penalties related to income tax matters in income tax expense. The Company is subject to taxation in the United States federal and certain state jurisdictions. The Company’s tax years from inception are subject to examination by the United States federal and state authorities due to the carryforward of unutilized NOLs and R&D credits. The Company does not anticipate the unrecognized tax benefits to change materially within the next twelve months.

The Company had no accrued interest and no penalties related to income tax matters in the Company’s balance sheet as of December 31, 2022 and has not recognized interest or penalties in the Company’s statement of operations and loss for the year ended December 31, 2022. Further, the Company is not currently under examination by any federal, state or local tax authority.

The CARES Act provides sweeping tax changes in response to the COVID-19 pandemic. Some of the more significant provisions are removal of certain limitations on utilization of NOL’s, increasing the loss carryback period for certain losses to five years, and increasing the ability to deduct interest expense, as well as amending certain provisions of the previously enacted Tax Cuts and Jobs Act. As of December 31, 2022, the Company has not recorded any material adjustments to its income tax provision related to the provisions with the CARES Act. The Company will continue to analyze the impact that the CARES Act will have, if any, on its financial positions, results of operations or cash flows.

16. Commitments and Contingencies

Litigation

From time to time, the Company could be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. Regardless of the outcome, legal proceedings can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources and other factors.

On June 27, 2022, EOC filed a Request for Arbitration with the International Chamber of Commerce’s International Court of Arbitration against the Company. In the Request for Arbitration, EOC claims that the Company breached certain provisions of the EOC License Agreement, including failing to provide certain manufacturing and clinical development information to EOC. As a result, EOC is seeking monetary damages. The arbitration process is ongoing. The Company intends to defend itself vigorously in this matter and pursue all relief to which the Company is entitled. The Company is unable to estimate the possible loss or range of loss, therefore no amounts have been accrued as of December 31, 2022. See Note 9 to these audited financial statements for more information about the EOC License Agreement and its termination.

Purchase Commitments

The Company has ongoing contracts with vendors for clinical trials and contract manufacturing. These contracts are generally cancellable, with notice, at the Company's option. The Company recorded accrued expenses of $2.8 million and $4.8 million in its consolidated balance sheet for expenditures incurred by clinical and contract manufacturing vendors as of December 31, 2022 and 2021, respectively.

At December 31, 2022 the Company had one significant contract with Fresenius Kabi that contains specific activities including non-cancellable commitments, minimum purchase commitments, and binding annual forecasts. As of December 31, 2022, there were non-cancellable purchase commitments related to the purchase of inventory for $1.9 million to be paid in 2023.

Mirati Collaboration.

In October 2022, the Company entered into a collaboration and supply agreement with Mirati Therapeutics, Inc. ("Mirati") to evaluate the combination of Mirati's adagrasib, a KRASG12C selective inhibitor, and FYARRO in KRAS G12C mutant non-small cell lung cancer (NSCLC) and other solid tumors. Under the terms of the agreement, Mirati will be responsible for sponsoring and operating the Phase 1/2 study and the Company will supply study drug and jointly share the cost of the study.

The primary objective of this multi-center, single-arm, open-label Phase 1/2 trial is to determine the optimal dose and recommended Phase 2 dose for the combination of adagrasib and FYARRO in patients with KRASG12C-mutant solid tumors. In addition, the study will investigate the safety, tolerability and efficacy of adagrasib and FYARRO in combination in patients both with and without prior exposure to a KRASG12C inhibitor. The trial will build on preclinical data showing enhanced anti-tumor efficacy with the combination of adagrasib and FYARRO relative to either agent alone.

For the year ended December 31, 2022 the Company incurred no expenses related to the Mirati collaboration.

17. Employee Retirement Plan

The Company maintains a 401(k) plan (the "401k Plan") created in 2015 for the benefit of its employees. All employees who have attained the age of 21 are eligible to participate in the 401k Plan as of the first entry date, as defined by the 401k Plan document, following the employment date. Each employee can contribute a percentage of compensation up to a maximum of the statutory limits per year. Company contributions are discretionary. Contributions of $0.5 million and zero were made during the years ended December 31, 2022 and 2021.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our Company's reports under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Interim Chief Executive Officer and President, and Chief Financial Officer, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

In connection with the preparation of this Annual Report for the year ended December 31, 2022, an evaluation was performed under the supervision and with the participation of our management, including our Interim Chief Executive Officer and President, and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of December 31, 2022. Based on that evaluation, our Interim Chief Executive Officer and President, and Chief Financial Officer has concluded based upon the evaluation described above that, as of December 31, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for us. Internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) is a process to provide reasonable assurance regarding the reliability of our financial reporting for external purposes in accordance with U.S. generally accepted accounting principles. Internal control over financial reporting includes maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for preparation of our consolidated financial statements; providing reasonable assurance that receipts and expenditures of company assets are made in accordance with management authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of company assets that could have a material effect on our consolidated financial statements would be prevented or detected on a timely basis. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our consolidated financial statements would be prevented or detected.

Under the supervision of and with the participation of our principal executive and financial officer, our management conducted an evaluation of the effectiveness, as of December 31, 2022, of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2022.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act during the fourth quarter ended December 31, 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 other information required by this item is omitted from this Annual Report on Form 10-K and is incorporated herein by reference from our definitive proxy statement relating to our 2023 Annual Meeting of Stockholders (the "Definitive Proxy Statement").

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Our code of business conduct and ethics is available on our website, which is located at www.aadibio.com. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website, or in a current report on Form 8-K as may be required by law.

Amended and Restated Bylaws

As disclosed under Item 5.03 of our Current Report on Form 8-K filed with the SEC on December 7, 2022, on December 6, 2022, our Board of Directors, upon recommendation of the Nominating and Corporate Governance Committee of the Board, amended and restated our amended and restated bylaws, effective immediately. The bylaws were amended and restated, among other things, to:

- revise the procedures and requirements for the nomination of directors and the submission of proposals for consideration at meetings of stockholders, including by adding a requirement that a stockholder seeking to nominate director(s) at a meeting of stockholders deliver to the Company reasonable evidence that it has complied with the requirements of Rule 14a-19 of the Exchange Act no later than five business days before the meeting;
- revise certain additional procedures related to stockholder meetings to conform to the provisions of the Delaware General Corporation Law, as recently amended (the "DGCL");
- update various provisions regarding directors, Board committees and officers; and
- make various updates throughout to conform to current Delaware law (including the recent amendments to the DGCL) and to make ministerial changes, clarifications, and other conforming revisions.

The foregoing description is qualified in its entirety by reference to the Amended and Restated Bylaws, a copy of which was filed as Exhibit 3.1 to our Form 8-K filed on December 7, 2022 and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item 11 will be contained in the Definitive Proxy Statement and is incorporated herein by reference.

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

The information required by this Item 12 will be contained in the Definitive Proxy Statement 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 contained in the Definitive Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 will be contained in the Definitive Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statements.

(a)(1) Financial Statements.

The consolidated financial statements required by this item are submitted in a separate section beginning on page 117 of this Annual Report.

(a)(2).Financial Statement Schedules.

All schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

(a)(3) Exhibits.

The exhibits filed as part of this Annual Report are set forth on the Exhibit Index immediately preceding the signature page of this Annual Report. The Exhibit Index is incorporated herein by reference.

Exhibit Index

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated May 16, 2021, by and among the registrant, Aadi Bioscience, Inc. and Aspen Merger Subsidiary, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on May 17, 2021).
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on December 7, 2022).
4.1*	Description of Registrant's Capital Stock.
4.2	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on September 22, 2022).
10.1	Form of Securities Purchase Agreement, dated September 22, 2022, by and among the Company and the Purchasers (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on September 22, 2022).
10.2	Form of Registration Rights Agreement, dated September 22, 2022, by and among the Company and the Purchasers (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on September 22, 2022).
10.3	Registration Rights Agreement dated August 26, 2021, by and between Aadi Bioscience, Inc. (formerly known as Aerpio Pharmaceuticals, Inc.) and certain purchasers listed therein (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).
10.4*#	Amended and Restated Employment Agreement, dated November 8, 2022, by and between Aadi Bioscience, Inc. and Neil Desai, Ph.D.
10.5#	Executive Employment Agreement, dated October 28, 2021, by and between Aadi Bioscience, Inc. and Scott Giacobello.
10.6#	Aadi Bioscience, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).
10.7#	Form of Stock Option Agreement under the Aadi Bioscience, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).
10.8#	2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).

10.9#	Aadi Bioscience, Inc. Amended and Restated 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.9 to the Registrant’s Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).
10.10#	Form of Stock Option Agreement under the Aadi Bioscience, Inc. Amended and Restated 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to the Registrant’s Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).
10.11#	Form of Indemnification Agreement between Aadi Bioscience, Inc. and each of its directors and executive officers (incorporated by reference to Exhibit 10.11 to the Registrant’s Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).
10.13+	Amended and Restated License Agreement by and between Abraxis BioScience, LLC and Aadi Bioscience, Inc. dated November 15, 2019 (incorporated by reference to Exhibit 10.13 to the Registrant’s Quarterly Report on Form 10-Q (File No. 001-38560) filed with the SEC on November 10, 2021).
10.14+	Amendment No. 1 to the Amended and Restated License Agreement between Abraxis BioScience, LLC and Aadi Bioscience, Inc. dated August 30, 2021 (incorporated by reference to Exhibit 10.14 to the Registrant’s Quarterly Report on Form 10-Q (File No. 001-38560) filed with the SEC on November 10, 2021).
10.15*	Office Lease dated April 19, 2019 by and between BRE Sunset Coast, LLC and Aadi Bioscience, Inc.
10.16	First Amendment to Office Lease dated August 30, 2021 by and between BRE Sunset Coast, LLC and Aadi Bioscience, Inc. (incorporated by reference to Exhibit 10.15 to the Registrant’s Quarterly Report on Form 10-Q (File No. 001-38560) filed with the SEC on November 10, 2021).
10.17*#	Amended and Restated Employment Agreement dated November 8, 2022, by and between Brendan Delaney and Aadi Bioscience, Inc.
10.18#	Employment Agreement dated October 19, 2021, by and between Loretta Itri and Aadi Bioscience, Inc. (incorporated by reference to Exhibit 10.17 to the Registrant’s Quarterly Report on Form 10-Q (File No. 001-38560) filed with the SEC on November 10, 2021).
10.19#	Senior Cash Incentive Bonus Plan. (incorporated by reference to Exhibit 10.15 in the Registrant’s Annual Report on Form 10-K (File No. 000-53057) filed with the SEC on March 15, 2017).
10.20+	Negotiated Purchase Order Terms and Conditions for Clinical and Commercial Product, dated as of January 13, 2022, by and between Aadi Bioscience, Inc. and Fresenius Kabi, LLC (incorporated by reference to Exhibit 10.1 to the Registrant’s Current Report on Form 8-K (File No. 001-38560) filed with the SEC on September 20, 2021).
10.21*+	Amendment No.1 to the Negotiated Purchase Order Terms and Conditions for Clinical and Commercial Product, dated as of January 16, 2023, by and between Aadi Bioscience, Inc. and Fresenius Kabi, LLC.
10.22	Sales Agreement, dated as of March 17, 2022, by and between Aadi Bioscience, Inc. and Cowen and Company, LLC (incorporated by reference to Exhibit 1.1 to the Registrant’s Current Report on Form 8-K (File No. 001-38560) filed with the SEC on March 17, 2022).
21.1*	List of Subsidiaries of the Company
23.1*	Consent of BDO USA LLP
31*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	IXBRL Inline Instance Document
101.SCH	IXBRL Inline Taxonomy Extension Schema Document
101.CAL	IXBRL Inline Taxonomy Extension Calculation Linkbase Document
101.DEF	IXBRL Inline Taxonomy Extension Definition Linkbase Document

101.LAB	IXBRL Inline Taxonomy Extension Label Linkbase Document
101.PRE	IXBRL Inline Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

* Filed herewith.
** Indicates the exhibit is being furnished, not filed, with this report
\# Indicates a management contract or any compensatory plan, contract or arrangement.
\+ Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K

Item 16. Form of 10-K Summary

We may voluntarily include a summary of information required by Form 10-K under this Item 16. We have elected not to include such summary information.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

AADI BIOSCIENCE, INC.

Date: March 28, 2023

By: */s/ Scott Giacobello*
Scott Giacobello
Interim Chief Executive Officer and President, and Chief Financial Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Scott Giacobello and Stephen Rodin, and each of them, as his or her true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for him or her in any and all capacities, to sign 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 attorney-in-fact, proxy and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact, proxy and agent, or his or her substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Scott Giacobello **Scott Giacobello**	Interim Chief Executive Officer and President, and Chief Financial Officer (Principal Executive, Financial and Accounting Officer)	March 28, 2023
/s/ Caley Castelein **Caley Castelein, M.D.**	Chairman	March 28, 2023
/s/ Behzad Aghazadeh **Behzad Aghazadeh, Ph.D.**	Director	March 28, 2023
/s/ Anupam Dalal **Anupam Dalal, M.D.**	Director	March 28, 2023
/s/ Neil Desai **Neil Desai, Ph.D.**	Director, Executive Chairman	March 28, 2023
/s/ Karin Hehenberger **Karin Hehenberger, M.D., Ph.D.**	Director	March 28, 2023
/s/ Richard Maroun **Richard Maroun, J.D.**	Director	March 28, 2023
/s/ Emma Reeve **Emma Reeve**	Director	March 28, 2023

Exhibit 4.1

**DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED**

The common stock, par value $0.0001 per share ("Common Stock"), of Aadi Bioscience, Inc., a Delaware corporation (the "Company," "us," "we," or "our"), is registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The following description sets forth certain general terms and provisions of our Common Stock. These descriptions are in all respects subject to and qualified in their entirety by, and should be read in conjunction with, the applicable provisions of, our Amended and Restated Certificate of Incorporation, (the "Charter") and our Amended and Restated By-laws (the "Bylaws") (each of which is incorporated herein by reference and copies of which are incorporated by reference as exhibits to our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission) and the applicable provisions of the Delaware General Corporation Law ("DGCL").

Authorized Capital Stock

Our authorized capital stock consists of 300,000,000 shares of Common Stock and 10,000,000 shares of undesignated preferred stock, par value $0.0001 per share ("Preferred Stock").

Common Stock

Dividends

The holders of outstanding shares of Common Stock are entitled to receive dividends out of assets or funds legally available for the payment of dividends of such times and in such amounts as the Company's board of directors (the "Board") from time to time may determine.

Voting

Holders of Common Stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. There is no cumulative voting of the election of directors then standing for election.

Distributions on Liquidation

Upon liquidation, dissolution or winding up of the Company, the assets legally available for distribution to stockholders are distributable ratably among the holders of our Common Stock after payment of liquidation preferences, if any, on any outstanding payment of other claims of creditors. Each outstanding share of Common Stock is duly and validly issued, fully paid and non-assessable.

Other Rights

Our Common Stock is not entitled to pre-emptive rights and is not subject to conversion or redemption.

Relationship to Preferred Stock

Shares of Preferred Stock may be issued from time to time in one or more series, each of which will have such distinctive designation or title as shall be determined by our board of directors prior to the issuance of any shares thereof. Preferred Stock will have such voting powers, full or limited, or no voting powers, and such preferences and relative, participating, optional or other special rights and such qualifications, limitations or restrictions thereof, as shall be stated in such resolution or resolutions providing for the issue of such class or series of Preferred Stock as may be adopted from time to time by the board of directors prior to the issuance of any shares thereof. Subject to the terms of any Preferred Stock designation that we may adopt from time to time, the Board is further authorized to increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares of any such series then outstanding) the number of shares of any series, subject to the powers, preferences and rights, and the qualifications, limitations and restrictions thereof stated in the Charter or the resolution of the Board originally fixing the number of shares of such series. Except as may be otherwise specified by the terms of any series of Preferred Stock, if the number of shares of any series of Preferred Stock is so decreased, then the Company shall take all such steps as are necessary to cause the shares constituting such decrease to resume the status which they had prior to the adoption of the resolution originally fixing the number of shares of such series.

While we do not currently have any plans for the issuance of Preferred Stock, the issuance of such Preferred Stock could adversely affect the rights of the holders of common stock and, therefore, reduce the value of the common stock. It is not possible to state the actual effect of the issuance of any shares of Preferred Stock on the rights of holders of the common stock until the Board determines the specific rights of the holders of the Preferred Stock; however, these effects may include:

- Restricting dividends on the common stock;
- Diluting the voting power of the common stock;
- Impairing the liquidation rights of the common stock; or
- Delaying or preventing a change in control of our company without further action by the stockholders.

Other than in connection with shares of Preferred Stock (as explained above), which Preferred Stock is not currently designated nor contemplated by the Company, the Company does not believe that any provision of its Charter or Bylaws would delay, defer or prevent a change in control.

No shares of Preferred Stock are issued and outstanding as of the date of our Annual Report on Form 10-K with which this Exhibit 4.1 is filed as an exhibit or incorporated by reference.

Pre-Funded Warrants

As of March 27, 2023, the Company had [2,426,493] pre-funded warrants to purchase up to [2,426,493] shares of its Common Stock.

Exercisability

The pre-funded warrants are exercisable at any time after their original issuance. The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part by delivering to the Company a duly executed exercise notice and by payment in full in immediately available funds for the number of shares of Common Stock purchased upon such exercise. As an alternative to payment in immediately available funds, the holder may, in its sole discretion, elect to exercise the warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of Common Stock determined according to the formula set forth in the pre-funded warrant. No fractional Common Stock will be issued in connection with the exercise of a pre-funded warrant. In lieu of fractional shares, the Company will pay the holder an amount in cash equal to the fractional amount multiplied by the fair market value of any fractional shares.

Exercise Limitations

Under the terms of the pre-funded warrants, the Company may not effect the exercise of any pre-funded warrant, and a holder will not be entitled to exercise any portion of any pre-funded warrant, which, upon giving effect to such exercise, would cause the aggregate number of shares of Common Stock beneficially owned by the holder (together with its affiliates) to exceed 4.99% of the number of shares of Common Stock outstanding immediately after giving effect to the exercise. However, any holder may increase or decrease such percentage to any other percentage not in excess of 19.99% upon at least 61 days' prior notice from the holder to the Company.

Exercise Price

The exercise price per whole Common Stock purchasable upon the exercise of the pre-funded warrants is $0.0001 per warrant share. The exercise price of the pre-funded warrants is subject to appropriate adjustment in the event of certain share dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the Company's Common Stock.

Anti-Takeover Effects of our Charter and Bylaws and Delaware Law

Certain provisions of Delaware law and our Charter and Bylaws may have an anti-takeover effect, for example, by permitting issuances that would dilute the stock ownership of a person seeking to effect a change in the composition of the Board or contemplating a tender offer or other transaction for the combination of the Company with another company. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the price of our Common Stock.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our Board. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the DGCL, which prohibits a person deemed an “interested stockholder” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date such person becomes an interested stockholder unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the Board, such as discouraging takeover attempts that might result in a premium over the price of our Common Stock.

Undesignated Preferred Stock

The ability to authorize undesignated Preferred Stock makes it possible for our board of directors to issue Preferred Stock with voting or other rights or preferences that could impede the success of any attempt to change control of our company. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

Special Stockholder Meetings

Our Charter provides that a special meeting of stockholders may be called only the chairperson of the Board, the chief executive officer of the Company, the president of the Company or the Board acting pursuant to a resolution adopted by a majority of the total number of authorized directorships, whether or not there exist any vacancies or other unfilled seats in previously authorized directorships.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our Bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the Board or a committee of the Board.

Elimination of Stockholder Action by Written Consent

Our Charter eliminates the right of stockholders to act by written consent without a meeting.

Classified Board; Election and Removal of Directors

Our Board is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of our Common Stock outstanding will be able to elect all of our directors. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Choice of Forum

Our Bylaws provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, then the United States District Court for the District of Delaware) will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL or our Charter or Bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine (the "Delaware Forum Provision"). In addition, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act against any person in connection with any offering of our securities, including, without limitation and for the avoidance of doubt, any auditor, underwriter, expert, control person or other defendant.

The provisions of the DGCL, our Charter and our Bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the price of our Common Stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, NY 11219, and its telephone number is (718) 921-8260.

Stock Exchange Listing

Our Common Stock is listed on the Nasdaq Capital Market under the symbol "AADI."

AADI BIOSCIENCE, INC.

AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT

This Amended and Restated Executive Employment Agreement (the "**Agreement**") is entered into as of November 8, 2022 by and between Aadi Bioscience, Inc. ("**Aadi**"), and Neil Desai, Ph.D. ("**Executive**"). This Agreement will be effective as of January 1, 2023 (the "**Effective Date**") except as otherwise expressly provided herein and amends and restates the Employment Agreement by and between the Executive and the Company, dated August 23, 2021 (the "**Prior Agreement**"). Aadi, together with any other subsidiaries and their respective successors, including the entity employing you, shall be referred to in this letter as the "**Company.**"

1. Prior to Effective Date. Prior to the Effective Date, the terms and conditions of the Prior Agreement will continue to apply to Executive's employment with the Company, except for Sections 7 and 12 below (and those provisions necessary to construe or give effect to such Sections, including Sections 4(c) and 8(c)), which shall be effective as of the date hereof.

2. Duties and Scope of Employment.

(a) Positions and Duties. Effective as of the Effective Date, Executive will serve as the Company's Executive Chairman, reporting solely to the Chairman of the Board of Directors of Aadi (the "**Board**"). Executive will render such business and professional services in the performance of Executive's duties, consistent with Executive's position within the Company, as will reasonably be assigned to Executive by the Chairman of the Board. The period of Executive's employment under this Agreement is referred to herein as the "**Employment Term**." On termination of the Employment Term, regardless of the reason for such termination, Executive shall immediately (and with contemporaneous effect) resign any directorships, offices or other positions that he may hold in the Company or any affiliate of the Company, unless otherwise agreed in writing by Executive and the Company.

(b) Board Membership. During the Employment Term, Executive will continue to serve on the Board, subject to any required Board and stockholder approval. In addition, Executive will serve as the Chairman of a Research & Development Committee upon creation by the Board.

(c) Obligations. During the Employment Term, Executive will perform Executive's duties faithfully and to the best of Executive's ability and will devote Executive's reasonable business efforts and time to the Company, subject to the terms hereof.

(d) Principal Location of Services. Executive shall perform his duties during the Employment Term out of offices located in Los Angeles Metropolitan area. Executive shall be permitted to work remotely but shall undertake such travel within or outside of the United States and shall be present in the Company's offices located in the Los Angeles Metropolitan area, as is necessary or otherwise reasonably determined by the Company for the efficient operations of the Company.

3. At-Will Employment. The parties agree that Executive's employment with the Company will be "at-will" employment and may be terminated at any time with or without Cause or notice. Executive understands and agrees that neither Executive's job performance nor promotions, commendations, bonuses or the like from the Company give rise to or in any way serve as the basis for modification, amendment, or extension, by implication or otherwise, of Executive's employment with the Company. However, as described in this Agreement, Executive may be entitled to severance benefits depending on the circumstances of Executive's termination of employment with the Company.

4. Compensation.

(a) Base Salary. Effective as of the Effective Date, the Company will pay Executive an annual salary of $624,000 as compensation for Executive's employment services to the Company (the "**Base Salary**"). The Base Salary will be paid periodically in accordance with the Company's normal payroll practices and be subject to the usual, required withholdings. Executive's salary will be subject to review and adjustments will be made based upon the Company's normal performance review practices.

(b) Target Bonus. Effective as of the Effective Date, Executive will be eligible to receive an annual bonus of with a target amount equal to 60% of Executive's Base Salary upon achievement of performance objectives to be determined by the Board or its authorized committee (the "**Committee**") in its sole discretion (the "**Target Bonus**"). Executive's actual bonus for the Company's fiscal year 2022 will be determined without regard to the execution of this Agreement by the parties and will be determined consistent with other senior executives of the Company. The achieved portion of Executive's Target Bonus, if any, will be paid, less applicable withholdings, as soon as practicable after the Committee determines that the Target Bonus has been earned, but in no event shall the Target Bonus be paid after the later of (i) the fifteenth (15^{th}) day of the third (3^{rd}) month following the close of the Company's fiscal year in which the Target Bonus is earned or (ii) March 15 following the calendar year in which the Target Bonus is earned.

(c) Stock Option. Effective on the first trading day following the Effective Date, Executive will be granted a nonstatutory stock option to purchase 150,000 shares of the Company's common stock at an exercise price per share equal to the fair market value of the Company's common stock on the date of grant, which will be the closing price of the Company's common stock as reported by the Nasdaq Stock Market on the first trading day following the Effective Date (the "**Option**"). Subject to the accelerated vesting provisions set forth herein, the Option will vest as to twenty-five percent (25%) of the shares subject to the Option one (1) year after the Effective Date, and as to $1/48^{th}$ of the shares subject to the Option monthly thereafter on the same day of the month as the Effective Date (and if there is no corresponding day, the last day of the month), so that the Option will be fully vested and exercisable four (4) years from the Effective Date, subject to Executive continuing to provide services to the Company through the relevant vesting dates. Except as provided herein, the Option will be subject to the terms and conditions of an equity incentive plan and related stock option agreement (in the Company's then-standard form for executive officers) approved by the Board or Committee (collectively, the "**Equity Documents**").

(d) Equity. During the Employment Term, Executive will be eligible to receive equity awards pursuant to any plans or arrangements Aadi may have in effect from time to time. The Committee will determine in its discretion whether Executive will be granted any equity awards and the terms of any equity award in accordance with the terms of any applicable plan or arrangement that may be in effect from time to time.

5. Employee Benefits. During the Employment Term, Executive will be entitled to participate in the employee benefit plans currently and hereafter maintained by the Company of general applicability to other senior executives of the Company. The Company reserves the right to cancel or change the benefit plans and programs it offers to its employees at any time. Executive shall also be entitled to five weeks of vacation, accruing annually, and participation in any 401(k) or employee benefit plan established by the Company, each as subject to the terms and conditions of such plans or programs adopted by the Company.

6. Expenses. The Company will reimburse Executive for reasonable travel, entertainment or other expenses incurred by Executive in the furtherance of or in connection with the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy as in effect from time to time.

7. Severance. Upon termination of Executive's employment for any reason, the Company will pay Executive (or provide Executive with, as applicable) (i) his Base Salary accrued through the date of termination, (ii) earned but unused vacation and paid time off as of the date of termination, (iii) reimbursement of expenses properly incurred prior to termination and properly documented in accordance with the Company's policy and (iv) all benefits, including continuation and conversion rights, provided upon termination of employment under the Company's employee benefit plans and policies in accordance with the terms of such plans and policies (the "**Accrued Obligations**") within the time period required by applicable law, but in any event within thirty (30) days following his termination date.

(a) Termination for other than Cause, Death or Disability Apart from a Change of Control. If, outside of the Change of Control Period, (i) the Company (or any parent or subsidiary or successor of the Company) terminates Executive's employment with the Company other than for Cause, death or Disability (except as otherwise provided below), or (ii) Executive resigns from such employment for Good Reason, then, subject to Section 7, Executive will be entitled to receive:

(i) continuing payments of severance pay from the Company for a period of eighteen (18) months equal to an amount each month equal to the sum of (A)(x) one hundred and fifty percent (150%) of Executive's Base Salary rate, as then in effect, *plus* (y) one hundred and fifty percent (150%) of the sum of all performance bonuses paid to Executive for the Company's fiscal year immediately preceding the fiscal year in which Executive's termination of employment occurs *divided by* (B) 18. The severance will be paid, less applicable withholdings, in installments over the severance period described herein with the first payment to commence on the sixty-first (61st) day following Executive's termination of employment (and include any severance payments that otherwise would have been paid to Executive within the sixty (60) days following Executive's termination date), with any remaining payments paid in accordance with the Company's normal payroll practices for the remainder of the severance period following Executive's termination of employment (subject to any delay as may be required by Section 7(c)).

(ii) if Executive elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("**COBRA**") within the time period prescribed pursuant to COBRA for Executive and Executive's eligible dependents, then the Company will reimburse Executive for the COBRA premiums for such coverage (at the coverage levels in effect immediately prior to Executive's termination) until the earlier of (A) a period of eighteen (18) months from the date of termination or (B) the date upon which Executive and/or Executive's eligible dependents are no longer eligible for COBRA continuation coverage. The reimbursements will be made by the Company to Executive consistent with the Company's normal expense reimbursement policy. Notwithstanding the first sentence of this Section 6(a)(ii), if the Company determines in its sole discretion that it cannot provide the foregoing benefit without potentially violating, or being subject to an excise tax under, applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company will in lieu thereof provide to Executive a taxable monthly payment, payable on the last day of a given month (except as provided by the following sentence), in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue the group health coverage for Executive and/or Executive's eligible dependents in effect on the termination of employment date (which amount will be based on the premium for the first month of COBRA coverage), which payments will be made regardless of whether Executive and/or Executive's eligible dependents elect COBRA continuation coverage and will commence on the month following Executive's termination of employment and will end on the earlier of (x) the date upon which Executive obtains other employment or (y) the date the Company has paid an amount equal to eighteen (18) payments. Any such taxable monthly payments that otherwise would have been paid to Executive within the sixty (60) days following Executive's termination date instead will be paid on the sixty-first (61st) day following Executive's termination of employment, with any remaining payments paid as provided in the prior sentence (subject to any delay as may be required by Section 7(c)). For the avoidance of doubt, the taxable payments in lieu of COBRA reimbursements may be used for any purpose, including, but not limited to continuation coverage under COBRA, and will be subject to all applicable tax withholdings.

(iii) Executive's outstanding and unvested equity awards subject solely to service-based vesting (i.e., not to include awards subject to performance vesting) will accelerate vesting as to the number of shares of Company common stock subject to such awards that would have otherwise vested had Executive continued to be employed by the Company for an additional eighteen (18) months following termination of Executive's employment.

(iv) Executive's outstanding stock option awards will remain exercisable until the earlier of (a) twelve (12) months following the date of Executive's termination of employment, or (b) the expiration of the term of such Company stock option award set forth in the applicable Company stock option agreement.

(v) If such termination occurs before the Option has been granted to Executive, effective immediately prior to such termination, the Company will grant to Executive the Option and clauses (iii) and (iv) shall be given effect with respect to the Option.

(vi) The Company will pay Executive (x) a pro rata annual bonus for the year in which such termination occurs based on actual performance (but treating all individual performance goals, if any, as achieved at target levels) (the "**Pro Rata Bonus**"), and (y) any earned but unpaid annual bonus for a performance year that ended prior to the date of termination (the "**Prior Year Bonus**"), which Pro Rata Bonus and Prior Year Bonus, as applicable, shall be paid at the time set forth in Section 4(b) above.

(b) Termination for other than Cause, Death or Disability or Resignation by Executive for Good Reason Related to a Change of Control. If, within the Change of Control Period (i) the Company (or any parent or subsidiary or successor of the Company) terminates Executive's employment with the Company other than for Cause, death or Disability (except as otherwise provided below), or (ii) Executive resigns from such employment for Good Reason, then, subject to Section 8, Executive will be entitled to receive:

(i) a lump sum payment from the Company equal to one hundred and fifty percent (150%) of the sum of: (A) Executive's Base Salary, as then in effect, or if greater, at the level in effect immediately prior to the Change of Control, *plus* (B) Executive's Target Bonus in effect for the fiscal year in which Executive's termination of employment occurs. The severance will be paid, less applicable withholdings, on the sixty-first (61st) day following Executive's termination of employment in accordance with the Company's normal payroll practices (subject to any delay as may be required by Section 7(c)). For the avoidance of doubt, if (x) Executive incurred a termination of employment prior to a Change of Control that qualifies Executive for severance payments under Section 6(a)(i); and (y) a Change of Control occurs within the three (3)-month period following Executive's termination of employment that qualifies Executive for the superior benefits under this Section 6(b)(i), then Executive shall be entitled to a lump-sum payment of the amount calculated under this Section 6(b)(i), less amounts already paid under Section 6(a)(i).

(ii) if Executive elects continuation coverage pursuant to COBRA within the time period prescribed pursuant to COBRA for Executive and Executive's eligible dependents, then the Company will reimburse Executive for the COBRA premiums for such coverage (at the coverage levels in effect immediately prior to Executive's termination) until the earlier of (A) a period of eighteen (18) months from the date of termination or (B) the date upon which Executive and/or Executive's eligible dependents are no longer eligible for COBRA continuation coverage. The reimbursements will be subject to the same conditions, limitations, and restrictions as the COBRA benefits described in

Section 6(a)(ii); provided, however, that if the Company provides Executive a taxable monthly payment in lieu of COBRA reimbursement, such payment will be subject to the same conditions, limitations, and restrictions as COBRA benefits described in Section 6(a)(ii). For the avoidance of doubt, if (x) Executive incurred a termination of employment prior to a Change of Control that qualifies Executive for COBRA benefits under Section 6(a)(ii); and (y) a Change of Control occurs within the three (3)-month period following Executive's termination of employment that qualifies Executive for the benefits under this Section 6(b)(ii), then Executive's benefits under this Section 6(b)(ii) shall be offset by the benefits already provided to Executive under Section 6(b)(i).

(iii) accelerated vesting as to one hundred percent (100%) of all of Executive's then-outstanding and unvested equity awards to acquire the Company's common stock (as well as, if applicable, all property, rights and awards issued in substitution for Company equity awards, whether such substitute awards are payable in equity, cash or any other medium).

(iv) Executive's outstanding stock option awards will remain exercisable until the earlier of (a) twelve (12) months following the date of Executive's termination of employment, or (b) the expiration of the term of such Company stock option award as set forth in the applicable Company stock option agreement.

(v) If such termination occurs before the Option has been granted to Executive, effective immediately prior to such termination, the Company will grant to Executive the Option and clauses (iii) and (iv) shall be given effect with respect to the Option.

(vi) The Company will pay Executive (x) the Pro Rata Bonus and (y) any applicable Prior Year Bonus, which Pro Rata Bonus and Prior Year Bonus, as applicable, shall be paid at the time set forth in Section 4(b) above.

(c) Termination for Cause, Death or Disability; Resignation without Good Reason. If Executive's employment with the Company (or any parent or subsidiary or successor of the Company) terminates voluntarily by Executive (except upon resignation for Good Reason), for Cause by the Company or due to Executive's death or Disability, then (i) all vesting will terminate immediately with respect to Executive's outstanding equity awards, (ii) all payments of compensation by the Company to Executive hereunder will terminate immediately (except that the Company will pay Executive (or provide Executive with, as applicable) (or, if applicable, his estate) the Accrued Obligations within thirty (30) days following his termination date), except that Executive shall be entitled to the Prior Year Bonus and (unless Executive's employment is terminated for Cause) the Pro Rata Bonus, in each case, which shall be paid at the time set forth in Section 4(b) above, and (iii) Executive will otherwise only be eligible for severance benefits in accordance with the Company's established policies, if any, as then in effect. Notwithstanding the foregoing, if Executive's employment with the Company terminates due to his death or Disability within eighteen (18) months following the date hereof, for purposes of applying Section 7(a) or Section 7(b) (as otherwise applicable), Executive will be deemed to have been terminated without Cause on the date Executive's employment terminates due to death or Disability and Executive will be entitled to the payments and benefits provided under Section 7(a) or Section 7(b) (as otherwise applicable) following the date of such termination.

(d) Exclusive Remedy. In the event of a termination of Executive's employment with the Company (or any parent or subsidiary or successor of the Company), the provisions of this Section 7 are intended to be and are exclusive and in lieu of any other rights or remedies to which Executive or the Company may otherwise be entitled, whether at law, tort or contract, in equity, or under this Agreement, including any prior employment agreements entered into between the Company and Executive. Executive will be entitled to no severance or other benefits upon termination of employment with respect to acceleration of award vesting or severance pay other than those benefits expressly set forth in this Section 7.

8. Conditions to Receipt of Severance; No Duty to Mitigate.

(a) Separation Agreement and Release of Claims. The receipt of any severance pursuant to Section 7(a) or 7(b) will be subject to Executive signing and not revoking a separation agreement and release of claims in a form reasonably satisfactory to the Company (the "**Release**") and provided that such Release becomes effective and irrevocable no later than sixty (60) days following the termination date (such deadline, the "**Release Deadline**"). If the Release does not become effective and irrevocable by the Release Deadline, Executive will forfeit any rights to severance or benefits under this Agreement. In no event will severance payments or benefits be paid or provided until the Release becomes effective and irrevocable.

(b) Reserved.

(c) Section 409A.

(i) Notwithstanding anything to the contrary in this Agreement, no severance pay or benefits to be paid or provided to Executive, if any, pursuant to this Agreement that, when considered together with any other severance payments or separation benefits, are considered deferred compensation under Code Section 409A, and the final regulations and any guidance promulgated thereunder ("**Section 409A**") (together, the "**Deferred Payments**") will be paid or otherwise provided until Executive has a "separation from service" within the meaning of Section 409A. Similarly, no severance payable to Executive, if any, pursuant to this Agreement that otherwise would be exempt from Section 409A pursuant to Treasury Regulation Section 1.409A-1(b)(9) will be payable until Executive has a "separation from service" within the meaning of Section 409A. To the extent that any payment under Section 7(b) above, if made in accordance with the timing provided in Section 7(b) would result in any portion of such payment being subject to additional taxes to Executive under Section 409A (or any similar state law), such payment shall instead be made consistent with the timing set forth in Section 7(a) (if doing so would avoid such additional taxes being imposed on Executive).

(ii) Notwithstanding anything to the contrary in this Agreement, if Executive is a "specified employee" within the meaning of Section 409A at the time of Executive's termination (other than due to death), then the Deferred Payments that are payable within the first six (6) months following Executive's separation from service, will become payable on the first payroll date that occurs on or after the date six (6) months and one (1) day following the date of Executive's separation from service. All subsequent Deferred Payments, if any, will be payable in accordance with the payment schedule applicable to each payment or benefit. Notwithstanding anything herein to the contrary, if Executive dies following Executive's separation from service, but prior to the six (6) month anniversary of the separation from service, then any payments delayed in accordance with this paragraph will be payable in a lump sum as soon as administratively practicable after the date of Executive's death and all other Deferred Payments will be payable in accordance with the payment schedule applicable to each payment or benefit. Each payment and benefit payable under this Agreement is intended to constitute a separate payment for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

(iii) Any amount paid under this Agreement that satisfies the requirements of the "short-term deferral" rule set forth in Section 1.409A-1(b)(4) of the Treasury Regulations will not constitute Deferred Payments for purposes of clause (i) above.

(iv) Any amount paid under this Agreement that qualifies as a payment made as a result of an involuntary separation from service pursuant to Section 1.409A-1(b)(9)(iii) of the Treasury Regulations that does not exceed the Section 409A Limit (as defined below) will not constitute Deferred Payments for purposes of clause (i) above.

(v) The foregoing provisions are intended to comply with the requirements of Section 409A so that none of the severance payments and benefits to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities herein will be interpreted to so comply. The Company and Executive agree to work together in good faith to consider amendments to this Agreement and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to Executive under Section 409A. Executive agrees and acknowledges that the Company makes no representations or warranties with respect to the application of Section 409A and other tax consequences to any payments hereunder and, by the acceptance of any such payments, Executive agrees to accept the potential application of Section 409A and the other tax consequences of any payments made hereunder.

(d) Confidential Information Agreement. Executive's receipt of any payments or benefits under Section 6 will be subject to Executive continuing to comply with the terms of Confidential Information Agreement (as defined in Section 10). In the event Executive breaches the provisions of the Confidential Information Agreement, all continuing payments and benefits to which Executive may otherwise be entitled pursuant to Section 6(a) or (b) will immediately cease.

(e) No Duty to Mitigate. Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any earnings that Executive may receive from any other source reduce any such payment.

9. Definitions.

(a) Cause. For purposes of this Agreement, "**Cause**" is defined as (i) the willful failure, disregard, or refusal by Executive to perform the services hereunder or follow the reasonable instructions of the Board; *provided*, *however*, that any willful failure, disregard, or refusal by Executive to perform the services hereunder that can reasonably be cured shall not constitute Cause unless cure is not effected, as determined in good faith by the Board, within thirty (30) days after notice thereof is received by Executive from the Company; (ii) any willful or grossly negligent act by Executive having the effect of injuring, in a material way (whether financial or otherwise) as determined in good faith by the Board, the business or reputation of the Company or any of its subsidiaries or affiliates; (iii) Executive's conviction of, guilty plea, or plea of nolo contendere to any felony or a misdemeanor involving moral turpitude; (iv) the determination by the Company, after a reasonable and good faith investigation by the Company following a written allegation by an employee of the Company, that Executive engaged in some form of harassment prohibited by law (including, without limitation, age, sex, disability, or race discrimination) unless Executive's actions were specifically directed by the Board; or (v) material breach by Executive of any provision of this Agreement or any Confidential Information Agreement.

(b) Change of Control. For purposes of this Agreement, "**Change of Control**" means the occurrence of any of the following events:

(i) a change in the ownership of Aadi which occurs on the date that any one person (as defined in Section 13(d) and Section 14(d) of the Exchange Act), or more than one person acting as a group ("**Person**"), acquires ownership of the stock of Aadi that, together with the stock held by such Person, constitutes more than fifty percent (50%) of the total voting power of the stock of Aadi; provided, however, that for purposes of this subsection, the acquisition of additional stock by any one Person, who is considered to own more than fifty percent (50%) of the total voting power of the stock of Aadi will not be considered a Change of Control; provided, further, that any change in the ownership of the stock of Aadi as a result of a private financing of Aadi that is approved by the Board also will not be considered a Change of Control. Further, if the stockholders of Aadi immediately before such change in ownership continue to retain immediately after the change in ownership, in substantially the same proportions as their ownership of shares of Aadi's voting stock immediately prior to the change in ownership, direct or indirect beneficial ownership of fifty percent (50%) or more of the total voting power of the stock of Aadi or of the ultimate parent entity of Aadi, such event shall not be considered a Change of Control under this subsection (i). For this purpose, indirect beneficial ownership shall include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities which own Aadi, as the case may be, either directly or through one or more subsidiary corporations or other business entities; or

(ii) a change in the ownership of a substantial portion of Aadi's assets which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such person or persons) assets from Aadi that have a total gross fair market value equal to or more than fifty percent (50%) of the total gross fair market value of all of the assets of Aadi immediately prior to such acquisition or acquisitions; provided, however, that for purposes of this subsection (ii), the following will not constitute a change in the ownership of a substantial portion of Aadi's assets: (A) a transfer to an entity that is controlled by Aadi's stockholders immediately after the transfer, or (B) a transfer of assets by Aadi to: (1) a stockholder of Aadi (immediately before the asset transfer) in exchange for or with respect to Aadi's stock, (2) an entity, fifty percent (50%) or more of the total value or voting power of which is owned, directly or indirectly, by Aadi, (3) a Person, that owns, directly or indirectly, fifty percent (50%) or more of the total value or voting power of all the outstanding stock of Aadi, or (4) an entity, at least fifty percent (50%) of the total value or voting power of which is owned, directly or indirectly, by a Person described in this subsection (8)(b)(ii). For purposes of this subsection (ii), gross fair market value means the value of the assets of Aadi, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

For purposes of this definition, persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with Aadi.

Notwithstanding the foregoing, a transaction will not be deemed a Change of Control unless the transaction qualifies as a change in control event within the meaning of Section 409A, as it has been and may be amended from time to time, and any proposed or final Treasury Regulations and Internal Revenue Service guidance that has been promulgated or may be promulgated thereunder from time to time.

Further and for the avoidance of doubt, a transaction will not constitute a Change of Control if: (i) its sole purpose is to change the state of Aadi's incorporation, or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held Aadi's securities immediately before such transaction.

(c) Change of Control Period. For purposes of this Agreement, "**Change of Control Period**" means the period that begins three (3) months prior to a Change of Control and ends twelve (12) months following a Change of Control.

(d) Code. For purposes of this Agreement, "**Code**" means the Internal Revenue Code of 1986, as amended.

(e) Disability. For purposes of this Agreement, "**Disability**" means that Executive has been unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment for a period of ninety (90) consecutive days or more, or more than one hundred and eighty (180) days within any twelve (12)-month period, in each case, determined by the Board.

(f) Good Reason. For the purposes of this Agreement, "**Good Reason**" means Executive's resignation within thirty (30) days following the expiration of any Company cure period (discussed below) following the occurrence of one or more of the following, without Executive's express written consent: (i) a material breach of any provision of this Agreement by the Company (including, without limitation, any change in Executive's reporting requirements); (ii) any material reduction by the Company of Executive's duties, responsibilities, or authority which causes Executive's position to become materially of less responsibility or authority than Executive's position as of immediately following the Effective Date; it being understood that a change to Executive's title resulting in him no longer serving as Executive Chairman would constitute "Good Reason" under this Agreement; (iii) a material relocation of the Company's principal place of business of Executive outside of the Los Angeles Metropolitan area; or (iv) a material (more than 7%) diminution in Executive's base salary (other than in the context of salary or consideration reductions applied in identical percentages to all executive officers of the Company). Executive will not resign for Good Reason without first providing the Company with written notice of the acts or omissions constituting the grounds for "Good Reason" within ninety (90) days of the initial existence of the grounds for "Good Reason" and a reasonable cure period of not less than thirty (30) days following the date the Company receives such notice during which such condition must not have been cured.

(g) Section 409A Limit. For purposes of this Agreement, "**Section 409A Limit**" will mean two (2) times the lesser of: (i) Executive's annualized compensation based upon the annual rate of pay paid to Executive during Executive's taxable year preceding Executive's taxable year of Executive's separation from service as determined under Treasury Regulation Section 1.409A-1(b)(9)(iii)(A)(1) and any Internal Revenue Service guidance issued with respect thereto; or (ii) the maximum amount that may be taken into account under a qualified plan pursuant to Section 401(a)(17) of the Internal Revenue Code for the year in which Executive's separation from service occurred.

10. Limitation on Payments. In the event that the severance and other benefits provided for in this Agreement or otherwise payable to Executive (i) constitute "parachute payments" within the meaning of Section 280G of the Code and (ii) but for this Section 9, would be subject to the excise tax imposed by Section 4999 of the Code, then Executive's severance benefits will be either:

(a) delivered in full, or

(b) delivered as to such lesser extent which would result in no portion of such severance benefits being subject to the excise tax under Section 4999 of the Code,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999, results in the receipt by Executive on an after-tax basis, of the greatest amount of severance benefits, notwithstanding that all or some portion of such severance benefits may be taxable under Section 4999 of the Code. If a reduction in the severance and other benefits constituting "parachute payments" is necessary so that no portion of such severance benefits is subject to the excise tax under Section 4999 of the Code, the reduction shall occur in the following order: (1) reduction of the cash severance payments; (2) cancellation of accelerated vesting of equity awards; and (3) reduction of continued employee benefits. In the event that acceleration of vesting of equity award compensation is to be reduced, such acceleration of vesting shall be cancelled in the reverse order of the date of grant of Executive's equity awards.

A nationally recognized certified professional services firm selected by the Company, the Company's legal counsel or such other person or entity to which the parties mutually agree (the "**Firm**") shall perform the foregoing calculations related to the Excise Tax. The Company shall bear all expenses with respect to the determinations by the Firm required to be made hereunder. For purposes of making the calculations required by this Section, the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Code Sections 280G and 4999. The Company and Executive will furnish to the Firm such information and documents as the Firm may reasonably request in order to make a determination under this Section. The Firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and Executive within fifteen (15) calendar days after the date on which Executive's right to the severance benefits or other payments is triggered (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive. Any good faith determinations of the Firm made hereunder shall be final, binding, and conclusive upon the Company and Executive.

11. Confidential Information. The parties acknowledge and agree that Executive's Confidential Information and Invention Assignment Agreement with Aadi, LLC (a predecessor to the Company) dated December 19, 2016 (the "**Confidential Information Agreement**") shall continue to apply following the execution of this Agreement.

12. Legal Costs. The Company will reimburse Executive for reasonable legal fees and expenses directly relating to the preparation and negotiation of this Agreement up to an amount of $20,000 in the aggregate, within thirty (30) days of Executive's submission of reasonable documentation thereof.

13. Indemnification Agreement. The Indemnification Agreement previously entered into by and between the Company and Executive, dated on or around August 26, 2021 and in substantially the form attached as Exhibit 10.11 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 27, 2021 (the "**Indemnification Agreement**"), shall continue to remain in full force and effect.

14. Assignment. This Agreement will be binding upon and inure to the benefit of (a) the heirs, executors and legal representatives of Executive upon Executive's death and (b) any successor of the Company. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, "**successor**" means any person, firm, corporation or other business entity which at any time, whether by purchase, merger or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company. None of the rights of Executive to receive any form of compensation payable pursuant to this Agreement may be assigned or transferred except by will or the laws of descent and distribution. Any other attempted assignment, transfer, conveyance or other disposition of Executive's right to compensation or other benefits will be null and void.

15. Notices. All notices, requests, demands and other communications called for hereunder will be in writing and will be deemed given (i) on the date of delivery if delivered personally, (ii) one (1) day after being sent by a well-established commercial overnight service, or (iii) four (4) days after being mailed by registered or certified mail, return receipt requested, prepaid and addressed to the parties or their successors at the following addresses, or at such other addresses as the parties may later designate in writing:

If to the Company:

AADi Bioscience, Inc.
17383 Sunset Boulevard, Suite A250
Pacific Palisades, CA 90272
Attn: Board of Directors

If to Executive:

at the last residential address known by the Company.

16. Severability. In the event that any provision hereof becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement will continue in full force and effect without said provision.

17. Arbitration. Executive agrees that any and all controversies, claims, or disputes with anyone (including the Company and any employee, officer, director, stockholder or benefit plan of the Company in their capacity as such or otherwise) arising out of, relating to, or resulting from Executive's service to the Company, shall be subject to arbitration in accordance with the provisions of the Confidential Information Agreement.

18. Integration. This Agreement, along with the Confidential Information Agreement, the Equity Documents, the Indemnification Agreement and the plan and agreements governing your outstanding equity awards, represents the entire agreement and understanding between the parties as to the subject matter herein and supersedes all prior or contemporaneous agreements whether written or oral, including the Prior Agreement on and following the Effective Date. With respect to equity awards granted on or after the date of this Agreement, the acceleration of vesting provisions provided herein will apply to such equity awards except to the extent the applicable equity award agreement expressly supersedes this Agreement. This Agreement may be modified only by agreement of the parties by a written instrument executed by the parties that is designated as an amendment to this Agreement.

19. Waiver of Breach. The waiver of a breach of any term or provision of this Agreement, which must be in writing, will not operate as or be construed to be a waiver of any other previous or subsequent breach of this Agreement.

20. Headings. All captions and section headings used in this Agreement are for convenient reference only and do not form a part of this Agreement.

21. Tax Withholding. All payments made pursuant to this Agreement will be subject to withholding of applicable taxes.

22. Governing Law. This Agreement will be governed by the laws of the State of California (with the exception of its conflict of laws provisions).

23. Acknowledgment. Executive acknowledges that Executive has had the opportunity to discuss this matter with and obtain advice from Executive’s private attorney, has had sufficient time to, and has carefully read and fully understands all the provisions of this Agreement, and is knowingly and voluntarily entering into this Agreement.

24. Counterparts. This Agreement may be executed in counterparts, and each counterpart will have the same force and effect as an original and will constitute an effective, binding agreement on the part of each of the undersigned.

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by their duly authorized officers, as of the day and year first above written.

COMPANY:

AADI BIOSCIENCE, INC.

By: /s/ Caley Castelein Date: November 8, 2022

Name: Caley Castelein

Title: Chairman of the Board of Directors

EXECUTIVE:

/s/ Neil Desai Date: November 8, 2022
NEIL DESAI, PH.D.

[SIGNATURE PAGE TO EXECUTIVE EMPLOYMENT AGREEMENT]

Exhibit 10.17

AADI BIOSCIENCE, INC.

AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT

This Amended and Restated Executive Employment Agreement (the "**Agreement**") is entered into as of November 8, 2022 by and between Aadi Bioscience, Inc. ("**Aadi**"), and Brendan Delaney ("**Executive**"). This Agreement will be effective January 1, 2023 (the "**Effective Date**") and amends and restates the Employment Agreement by and between the Executive and the Company, dated September 14, 2021 (the "**Prior Agreement**"). Aadi, together with any other subsidiaries, including the entity employing you, shall be referred to in this letter as the "**Company**".

1. Duties and Scope of Employment.

(a) Positions and Duties. Effective as of the Effective Date, Executive will serve as the Company's President and Chief Executive Officer. Executive will render such business and professional services in the performance of Executive's duties, consistent with Executive's position within the Company, as will reasonably be assigned to Executive by the Board of Directors of Aadi (the "**Board**"). The period of Executive's employment under this Agreement is referred to herein as the "**Employment Term**."

(b) Board Membership. During the Employment Term, Executive will serve on the Board, subject to any required Board and stockholder approval.

(c) Obligations. During the Employment Term, Executive will perform Executive's duties faithfully and to the best of Executive's ability and will devote Executive's full business efforts and time to the Company. For the duration of the Employment Term, Executive agrees not to actively engage in any other employment, occupation or consulting activity for any direct or indirect remuneration without the prior approval of the Board; provided, however, that Executive may manage personal investments, participate in civic, charitable, educational and professional activities. In the event of any conflict between any policy of the Company and the terms of this Agreement, the terms of this Agreement shall govern and control.

(d) Principal Location of Services. Executive shall perform his duties during the Employment Term principally out of offices located in the New Jersey or New York Metropolitan area and shall undertake such travel within or outside of the United States as is necessary or advisable for the efficient operations of the Company.

2. At-Will Employment. The parties agree that Executive's employment with the Company will be "at-will" employment and may be terminated at any time with or without Cause or notice. Executive understands and agrees that neither Executive's job performance nor promotions, commendations, bonuses or the like from the Company give rise to or in any way serve as the basis for modification, amendment, or extension, by implication or otherwise, of Executive's employment with the Company. However, as described in this Agreement, Executive may be entitled to severance benefits depending on the circumstances of Executive's termination of employment with the Company.

3. Compensation.

(a) Base Salary. Effective as of the Effective Date and for the remainder of the Employment Term, the Company will pay Executive an annual salary of $624,000 as compensation for Executive's employment services to the Company (the "**Base Salary**"). The Base Salary will be paid periodically in accordance with the Company's normal payroll practices and be subject to the usual, required withholdings. Executive's salary will be subject to review at least annually and adjustments will be made based upon the Company's normal performance review practices.

(b) Target Bonus. Effective as of the Effective Date and for the remainder of the Employment Term, Executive will be eligible to receive an annual bonus of up to 60% of Executive's Base Salary upon achievement of performance objectives to be determined by the Board or its authorized committee (the "**Committee**") in its sole discretion, with reasonable input from Executive (the "**Target Bonus**"). For calendar year 2022, the achieved Target Bonus will be pro-rated for the portion of the calendar year that Executive was employed by the Company under the terms of this Agreement and the Target Bonus provided for under the Prior Agreement. The achieved portion of Executive's Target Bonus will be paid, less applicable withholdings, as soon as practicable after the Board or Committee determines that the Target Bonus has been earned, but in no event shall the Target Bonus be paid after the later of (i) the fifteenth (15^{th}) day of the third (3^{rd}) month following the close of the Company's fiscal year in which the Target Bonus is earned or (ii) March 15 following the calendar year in which the Target Bonus is earned.

(c) Stock Option. Subject to the approval of the Board or Committee, on the first trading day following the Effective Date Executive will be granted a nonstatutory stock option to purchase 150,000 shares of the Company's common stock at an exercise price per share equal to the fair market value of the Company's common stock on the date of grant, which will be the closing price of the Company's common stock as reported by the Nasdaq Stock Market on the first trading day following the Effective Date (the "**Option**"). Subject to the accelerated vesting provisions set forth herein, the Option will vest as to twenty-five percent (25%) of the shares subject to the Option one (1) year after the Effective Date, and as to 1/48th of the shares subject to the Option monthly thereafter on the same day of the month as the Effective Date (and if there is no corresponding day, the last day of the month), so that the Option will be fully vested and exercisable four (4) years from the Effective Date, subject to Executive continuing to provide services to the Company through the relevant vesting dates. Except as provided herein, the Option will be subject to the terms and conditions of an equity incentive plan and related stock option agreement approved by the Board or Committee, including vesting requirements (collectively, the "**Equity Documents**") and will be granted in accordance with the Company's equity grant policy. For the avoidance of doubt, the Option will be in addition to the option covering shares of Company common stock granted to Executive in connection with the Prior Agreement.

(d) Equity. During the Employment Term, Executive will be eligible to receive equity awards pursuant to any plans or arrangements the Company may have in effect from time to time. The Board or Committee will determine in its discretion whether Executive will be granted any equity awards and the terms of any equity award in accordance with the terms of any applicable plan or arrangement that may be in effect from time to time.

4. Employee Benefits. During the Employment Term, Executive will be entitled to participate in the employee benefit plans currently and hereafter maintained by the Company of general applicability to other senior executives of the Company. The Company reserves the right to cancel or change the benefit plans and programs it offers to its employees at any time. Executive shall also be entitled to four weeks of vacation, accruing annually, and participation in any 401(k) or employee benefit plan established by the Company, each as subject to the terms and conditions of such plans or programs adopted by the Company.

5. Expenses. The Company will reimburse Executive for reasonable travel, entertainment or other expenses incurred by Executive in the furtherance of or in connection with the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy as in effect from time to time.

6. Severance.

(a) Termination for other than Cause, Death or Disability Apart from a Change of Control. If, outside of the Change of Control Period, (i) the Company (or any parent or subsidiary or successor of the Company) terminates Executive's employment with the Company other than for Cause, death or Disability, or (ii) the Executive resigns from such employment for Good Reason, then, subject to Section 7, Executive will be entitled to receive:

(i) continuing payments of severance pay for a period of 18 months at a rate equal to (A) one hundred and fifty percent (150%) of Executive's Base Salary rate, as then in effect, *divided by* (B) 18. The severance will be paid, less applicable withholdings, in installments over the severance period described herein with the first payment to commence on the sixty-first (61st) day following Executive's termination of employment (and include any severance payments that otherwise would have been paid to Executive within the sixty (60) days following Executive's termination date), with any remaining payments paid in accordance with the Company's normal payroll practices for the remainder of the severance period following Executive's termination of employment (subject to any delay as may be required by Section 7(b)).

(ii) if Executive elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("**COBRA**") within the time period prescribed pursuant to COBRA for Executive and Executive's eligible dependents, then the Company will reimburse Executive for the COBRA premiums for such coverage (at the coverage levels in effect immediately prior to Executive's termination) until the earlier of (A) a period of eighteen (18) months from the date of termination or (B) the date upon which Executive and/or Executive's eligible dependents are no longer eligible for COBRA continuation coverage. The reimbursements will be made by the Company to Executive consistent with the Company's normal expense reimbursement policy. Notwithstanding the first sentence of this Section 6(a)(ii), if the Company determines in its sole discretion that it cannot provide the foregoing benefit without potentially violating, or being subject to an excise tax under, applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company will in lieu thereof provide to Executive a taxable monthly payment, payable on the last day of a given month (except as provided by the following sentence), in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue the group health coverage for Executive and/or Executive's eligible dependents in effect on the termination of employment date (which amount will be based on the premium for the first month of COBRA coverage), which payments will be made regardless of whether Executive and/or Executive's eligible dependents elect COBRA continuation coverage and will commence on the month following Executive's termination of employment and will end on the earlier of (x) the date upon which Executive obtains other employment with comparable health insurance coverage as that provided by Employer to Executive, or (y) the date the Company has paid an amount equal to eighteen (18) payments. Any such taxable monthly payments that otherwise would have been paid to Executive within the sixty (60) days following Executive's termination date instead will be paid on the sixty-first (61st) day following Executive's termination of employment, with any remaining payments paid as provided in the prior sentence (subject to any delay as may be required by Section 7(b)). For the avoidance of doubt, the taxable payments in lieu of COBRA reimbursements may be used for any purpose, including, but not limited to continuation coverage under COBRA, and will be subject to all applicable tax withholdings.

(b) Termination for other than Cause, Death or Disability or Resignation by Executive for Good Reason Related to a Change of Control. If, within the Change of Control Period (i) the Company (or any parent or subsidiary or successor of the Company) terminates Executive's employment with the Company other than for Cause, death or Disability, or (ii) the Executive resigns from such employment for Good Reason, then, subject to Section 8, Executive will be entitled to receive:

(i) a lump sum payment equal to one hundred and fifty percent (150%) of the sum of: (A) Executive's Base Salary, as then in effect, or if greater, at the level in effect immediately prior to the Change of Control, *plus* (B) Executive's Target Bonus in effect for the fiscal year in which Executive's termination of employment occurs. The severance will be paid, less applicable withholdings, on the sixty-first (61st) day following Executive's termination of employment in accordance with the Company's normal payroll practices (subject to any delay as may be required by Section 7(b)). For the avoidance of doubt, if (x) Executive incurred a termination of employment prior to a Change of Control that qualifies Executive for severance payments under Section 6(a)(i); and (y) a Change of Control occurs within the three (3)-month period following Executive's termination of employment that qualifies Executive for the superior benefits under this Section 6(b)(i), then Executive shall be entitled to a lump-sum payment of the amount calculated under this Section 6(b)(i), less amounts already paid under Section 6(a)(i).

(ii) if Executive elects continuation coverage pursuant to COBRA within the time period prescribed pursuant to COBRA for Executive and Executive's eligible dependents, then the Company will reimburse Executive for the COBRA premiums for such coverage (at the coverage levels in effect immediately prior to Executive's termination) until the earlier of (A) a period of eighteen (18) months from the date of termination or (B) the date upon which Executive and/or Executive's eligible dependents are no longer eligible for COBRA continuation coverage. The reimbursements will be subject to the same conditions, limitations, and restrictions as the COBRA benefits described in Section 6(a)(ii). For the avoidance of doubt, if (x) Executive incurred a termination of employment prior to a Change of Control that qualifies Executive for COBRA benefits under Section 6(a)(ii); and (y) a Change of Control occurs within the three (3)-month period following Executive's termination of employment that qualifies Executive for the benefits under this Section 6(b)(ii), then Executive's benefits under this Section 6(b)(ii) shall be offset by the benefits already provided to Executive under Section 6(b)(i); and

(iii) accelerated vesting as to one hundred percent (100%) of Executive's then-outstanding and unvested equity awards to acquire Company common stock.

(c) Termination for Cause, Death or Disability; Resignation without Good Reason. If Executive's employment with the Company (or any parent or subsidiary or successor of the Company) terminates voluntarily by Executive (except upon resignation for Good Reason), for Cause by the Company or due to Executive's death or Disability, then (i) all vesting will terminate immediately with respect to Executive's outstanding equity awards, (ii) all payments of compensation by the Company to Executive hereunder will terminate immediately (except as to amounts already earned), and (iii) Executive will only be eligible for severance benefits in accordance with the Company's established policies, if any, as then in effect.

(d) Termination for Any Reason. Upon termination of Executive's employment for any reason, Executive (or his estate) shall be entitled to receive (i) his Base Salary accrued through the date of termination, (ii) earned but unused vacation and paid time off as of the date of termination, (iii) reimbursement of expenses properly incurred prior to termination and properly documented in accordance with the Company's policy,

(iv) all benefits, including continuation and conversion rights, provided upon termination of employment under the Company's employee benefit plans and policies in accordance with the terms of such plans and policies, and (v) except in the case of termination for Cause or resignation without Good Reason, Executive's Target Bonus actually earned for the fiscal year ending prior to the date of termination to the extent not yet paid on the date of termination (collectively the "**Accrued Obligations**"). For avoidance of doubt, upon termination for Cause or resignation without Good Reason, Executive shall not be entitled to any payments or benefits other than the Accrued Obligation.

(e) Exclusive Remedy. In the event of a termination of Executive's employment with the Company (or any parent or subsidiary or successor of the Company), the provisions of this Section 7 are intended to be and are exclusive and in lieu of any other rights or remedies to which Executive or the Company may otherwise be entitled, whether at law, tort or contract, in equity, or under this Agreement, including any prior employment agreements entered into between the Company and Executive. Executive will be entitled to no severance or other benefits upon termination of employment with respect to acceleration of award vesting or severance pay other than those benefits expressly set forth in this Section 7.

7. Conditions to Receipt of Severance; No Duty to Mitigate.

(a) Separation Agreement and Release of Claims. The receipt of any severance pursuant to Section 6(a) or (b) will be subject to Executive signing and not revoking a separation agreement and release of claims in a form reasonably satisfactory to the Company (the "**Release**") and provided that such Release becomes effective and irrevocable no later than sixty (60) days following the termination date (such deadline, the "**Release Deadline**"). If the Release does not become effective and irrevocable by the Release Deadline, Executive will forfeit any rights to severance or benefits under this Agreement. In no event will severance payments or benefits be paid or provided until the Release becomes effective and irrevocable.

(b) Section 409A.

(i) Notwithstanding anything to the contrary in this Agreement, no severance pay or benefits to be paid or provided to Executive, if any, pursuant to this Agreement that, when considered together with any other severance payments or separation benefits, are considered deferred compensation under Code Section 409A, and the final regulations and any guidance promulgated thereunder ("**Section 409A**") (together, the "**Deferred Payments**") will be paid or otherwise provided until Executive has a "separation from service" within the meaning of Section 409A. Similarly, no severance payable to Executive, if any, pursuant to this Agreement that otherwise would be exempt from Section 409A pursuant to Treasury Regulation Section 1.409A-1(b)(9) will be payable until Executive has a "separation from service" within the meaning of Section 409A.

(ii) Notwithstanding anything to the contrary in this Agreement, if Executive is a "specified employee" within the meaning of Section 409A at the time of Executive's termination (other than due to death), then the Deferred Payments that are payable within the first six (6) months following Executive's separation from service, will become payable on the first payroll date that occurs on or after the date six (6) months and one (1) day following the date of Executive's separation from service. All subsequent Deferred Payments, if any, will be payable in accordance with the payment schedule applicable to each payment or benefit. Notwithstanding anything herein to the contrary, if Executive dies following Executive's separation from service, but prior to the six (6) month anniversary of the separation from service, then any payments delayed in accordance with this paragraph will be payable in a lump sum as soon as administratively practicable after the date of Executive's death and all other Deferred Payments will be payable in accordance with the payment schedule applicable to each payment or benefit. Each payment and benefit payable under this Agreement is intended to constitute a separate payment for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

(iii) Any amount paid under this Agreement that satisfies the requirements of the "short-term deferral" rule set forth in Section 1.409A-1(b)(4) of the Treasury Regulations will not constitute Deferred Payments for purposes of clause (i) above.

(iv) Any amount paid under this Agreement that qualifies as a payment made as a result of an involuntary separation from service pursuant to Section 1.409A-1(b)(9)(iii) of the Treasury Regulations that does not exceed the Section 409A Limit (as defined below) will not constitute Deferred Payments for purposes of clause (i) above.

(v) The foregoing provisions are intended to comply with the requirements of Section 409A so that none of the severance payments and benefits to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities herein will be interpreted to so comply. The Company and Executive agree to work together in good faith to consider amendments to this Agreement and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to Executive under Section 409A. Executive agrees and acknowledges that the Company makes no representations or warranties with respect to the application of Section 409A and other tax consequences to any payments hereunder and, by the acceptance of any such payments, Executive agrees to accept the potential application of Section 409A and the other tax consequences of any payments made hereunder.

(c) Confidential Information Agreement. Executive's receipt of any payments or benefits under Section 6 will be subject to Executive continuing to comply with the terms of Confidential Information Agreement (as defined in Section 10). In the event Executive breaches the provisions of the Confidential Information Agreement, all continuing payments and benefits to which Executive may otherwise be entitled pursuant to Section 6(a) or (b) will immediately cease.

(d) No Duty to Mitigate. Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any earnings that Executive may receive from any other source reduce any such payment.

8. Definitions.

(a) Cause. For purposes of this Agreement, "**Cause**" is defined as (i) the willful failure, disregard, or refusal by Executive to perform the services hereunder or follow the reasonable instructions of the Board; *provided*, *however*, that any willful failure, disregard, or refusal by Executive to perform the services hereunder shall not constitute Cause unless cure is not effected, as determined in good faith by the Board, within thirty (30) days after notice thereof is received by the Executive from the Company; (ii) any willful or grossly negligent act by the Executive having the effect of injuring, in a material way (whether financial or otherwise) as determined in good faith by the Board, the business or reputation of the Company or any of its subsidiaries or affiliates; (iii) Executive's conviction of, guilty plea, or plea of nolo contendere to any felony or a misdemeanor involving moral turpitude; (iv) the determination by the Company, after a reasonable and good faith investigation by the Company following a written allegation by an employee of the Company, that the Executive engaged in some form of harassment prohibited by law (including, without limitation, age, sex, disability, or race discrimination) unless Executive's actions were specifically directed by the Board; or (v) material breach by the Executive of any material provision of this Agreement or any Confidential Information Agreement.

(b) Change of Control. For purposes of this Agreement, "**Change of Control**" means the occurrence of any of the following events:

(i) a change in the ownership of the Company which occurs on the date that any one person (as defined in Section 13(d) and Section 14(d) of the Exchange Act), or more than one person acting as a group ("**Person**"), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than fifty percent (50%) of the total voting power of the stock of the Company; provided, however, that for purposes of this subsection, the acquisition of additional stock by any one Person, who is considered to own more than fifty percent (50%) of the total voting power of the stock of the Company will not be considered a Change in Control; provided, further, that any change in the ownership of the stock of the Company as a result of a private financing of the Company that is approved by the Board also will not be considered a Change of Control. Further, if the stockholders of the Company immediately before such change in ownership continue to retain immediately after the change in ownership, in substantially the same proportions as their ownership of shares of the Company's voting stock immediately prior to the change in ownership, direct or indirect beneficial ownership of fifty percent (50%) or more of the total voting power of the stock of the Company or of the ultimate parent entity of the Company, such event shall not be considered a Change of Control under this subsection (i). For this purpose, indirect beneficial ownership shall include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities which own the Company, as the case may be, either directly or through one or more subsidiary corporations or other business entities;

(ii) A change in the effective control of the Company which occurs on the date that a majority of members of the Board of Directors of the Company is replaced during any twelve (12) month period by Directors whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purposes of this subsection (ii), if any person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same person will not be considered a Change in Control; or

(iii) a change in the ownership of a substantial portion of the Company's assets which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such person or persons) assets from the Company that have a total gross fair market value equal to or more than fifty percent (50%) of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions; provided, however, that for purposes of this subsection (iii), the following will not constitute a change in the ownership of a substantial portion of the Company's assets: (A) a transfer to an entity that is controlled by the Company's stockholders immediately after the transfer, or (B) a transfer of assets by the Company to: (1) a stockholder of the Company (immediately before the asset transfer) in exchange for or with respect to the Company's stock, (2) an entity, fifty percent (50%) or more of the total value or voting power of which is owned, directly or indirectly, by the Company, (3) a Person, that owns, directly or indirectly, fifty percent (50%) or more of the total value or voting power of all the outstanding stock of the Company, or (4) an entity, at least fifty percent (50%) of the total value or voting power of which is owned, directly or indirectly, by a Person described in this subsection (8)(b)(ii). For purposes of this subsection (iii), gross fair market value means the value of the assets of the Company, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

For purposes of this definition, persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company.

Notwithstanding the foregoing, a transaction will not be deemed a Change in Control unless the transaction qualifies as a change in control event within the meaning of Section 409A, as it has been and may be amended from time to time, and any proposed or final Treasury Regulations and Internal Revenue Service guidance that has been promulgated or may be promulgated thereunder from time to time.

Further and for the avoidance of doubt, a transaction will not constitute a Change in Control if: (i) its sole purpose is to change the state of the Company's incorporation, or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

(c) Change of Control Period. For purposes of this Agreement, "**Change of Control Period**" means the period that begins three (3) months prior to a Change of Control and ends twelve (12) months following a Change of Control.

(d) Code. For purposes of this Agreement, "**Code**" means the Internal Revenue Code of 1986, as amended.

(e) Disability. For purposes of this Agreement, "**Disability**" means that Executive has been unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment for a period of ninety (90) consecutive days or more, or more than one hundred and eighty (180) days within any twelve (12)-month period, in each case, determined by the Board. This provision shall be subject to compliance with all federal, state and local disability laws.

(f) Good Reason. For the purposes of this Agreement, "**Good Reason**" means Executive's resignation within thirty (30) days following the expiration of any Company cure period (discussed below) following the occurrence of one or more of the following, without Executive's express written consent: (i) a material breach of any provision of this Agreement by the Company; (ii) any material reduction by the Company of Executive's duties, responsibilities, or authority which causes Executive's position to become materially of less responsibility or authority than Executive's position as of immediately following the Effective Date; (iii) a material relocation of the Company's principal place of business of Executive more than 50 miles from Executive's residence in New Jersey ; or (iv) a material (more than 7%) diminution in Executive's base salary (other than in the context of salary or consideration reductions applied in identical percentages to all executive officers of the Company). Executive will not resign for Good Reason without first providing the Company with written notice of the acts or omissions constituting the grounds for "Good Reason" within ninety (90) days of the initial existence of the grounds for "Good Reason" and a reasonable cure period of not less than thirty (30) days following the date the Company receives such notice during which such condition must not have been cured.

(g) Section 409A Limit. For purposes of this Agreement, "**Section 409A Limit**" will mean two (2) times the lesser of: (i) Executive's annualized compensation based upon the annual rate of pay paid to Executive during the Executive's taxable year preceding the Executive's taxable year of Executive's separation from service as determined under Treasury Regulation Section 1.409A-1(b)(9)(iii)(A)(1) and any Internal Revenue Service guidance issued with respect thereto; or (ii) the maximum amount that may be taken into account under a qualified plan pursuant to Section 401(a)(17) of the Internal Revenue Code for the year in which Executive's separation from service occurred.

9. Limitation on Payments. In the event that the severance and other benefits provided for in this Agreement or otherwise payable to Executive (i) constitute "parachute payments" within the meaning of Section 280G of the Code and (ii) but for this Section 9, would be subject to the excise tax imposed by Section 4999 of the Code, then Executive's severance benefits will be either:

(a) delivered in full, or

(b) delivered as to such lesser extent which would result in no portion of such severance benefits being subject to the excise tax under Section 4999 of the Code,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999, results in the receipt by Executive on an after-tax basis, of the greatest amount of severance benefits, notwithstanding that all or some portion of such severance benefits may be taxable under Section 4999 of the Code. If a reduction in the severance and other benefits constituting "parachute payments" is necessary so that no portion of such severance benefits is subject to the excise tax under Section 4999 of the Code, the reduction shall occur in the following order: (1) reduction of the cash severance payments; (2) cancellation of accelerated vesting of equity awards; and (3) reduction of continued employee benefits. In the event that acceleration of vesting of equity award compensation is to be reduced, such acceleration of vesting shall be cancelled in the reverse order of the date of grant of Executive's equity awards.

A nationally recognized certified professional services firm selected by the Company, the Company's legal counsel or such other person or entity to which the parties mutually agree (the "**Firm**") shall perform the foregoing calculations related to the Excise Tax. The Company shall bear all expenses with respect to the determinations by the Firm required to be made hereunder. For purposes of making the calculations required by this Section, the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Code Sections 280G and 4999. The Company and Executive will furnish to the Firm such information and documents as the Firm may reasonably request in order to make a determination under this Section. The Firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and Executive within fifteen (15) calendar days after the date on which Executive's right to the severance benefits or other payments is triggered (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive. Any good faith determinations of the Firm made hereunder shall be final, binding, and conclusive upon the Company and Executive.

10. Confidential Information. Executive agrees to continue to abide by the Company's Confidential Information and Invention Assignment Agreement (the "**Confidential Information Agreement**"), previously executed by Executive on or around September 14, 2021.

11. Indemnification Agreement. The Indemnification Agreement previously entered into by and between the Company and Executive, dated on or around September 14, 2021 and in substantially the form attached as Exhibit 10.11 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 27, 2021 (the "**Indemnification Agreement**"), shall continue to remain in full force and effect. In the event that the Company adopts a more favorable form of Indemnification Agreement, or amendments to the form of Indemnification Agreement, for other executives or Board members in the future, Executive shall be given the opportunity to enter into a new or amended Indemnification Agreement on the same terms.

12. Assignment. This Agreement will be binding upon and inure to the benefit of (a) the heirs, executors and legal representatives of Executive upon Executive's death and (b) any successor of the Company. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, "**successor**" means any person, firm, corporation or other business entity which at any time, whether by purchase, merger or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company. None of the rights of Executive to receive any form of compensation payable pursuant to this Agreement may be assigned or transferred except by will or the laws of descent and distribution. Any other attempted assignment, transfer, conveyance or other disposition of Executive's right to compensation or other benefits will be null and void.

13. Notices. All notices, requests, demands and other communications called for hereunder will be in writing and will be deemed given (i) on the date of delivery if delivered personally, (ii) one (1) day after being sent by a well established commercial overnight service, or (iii) four (4) days after being mailed by registered or certified

mail, return receipt requested, prepaid and addressed to the parties or their successors at the following addresses, or at such other addresses as the parties may later designate in writing:

If to the Company:

Aadi Bioscience, Inc.
17383 Sunset Boulevard, Suite A250
Pacific Palisades, CA 90272
Attn: Board of Directors

If to Executive:

at the last residential address known by the Company.

14. Severability. In the event that any provision hereof becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement will continue in full force and effect without said provision.

15. Arbitration. Executive agrees that any and all controversies, claims, or disputes with anyone (including the Company and any employee, officer, director, stockholder or benefit plan of the Company in their capacity as such or otherwise) arising out of, relating to, or resulting from Executive's service to the Company, shall be subject to arbitration in accordance with the provisions of the Confidential Information Agreement.

16. Integration. This Agreement, along with the Confidential Information Agreement, Equity Documents and Indemnification Agreement, represents the entire agreement and understanding between the parties as to the subject matter herein and supersedes all prior or contemporaneous agreements whether written or oral, including the Prior Agreement. With respect to equity awards granted on or after the date of this Agreement, the acceleration of vesting provisions provided herein will apply to such equity awards except to the extent the applicable equity award agreement expressly supersedes this Agreement. This Agreement may be modified only by agreement of the parties by a written instrument executed by the parties that is designated as an amendment to this Agreement.

17. Waiver of Breach. The waiver of a breach of any term or provision of this Agreement, which must be in writing, will not operate as or be construed to be a waiver of any other previous or subsequent breach of this Agreement.

18. Headings. All captions and section headings used in this Agreement are for convenient reference only and do not form a part of this Agreement.

19. Tax Withholding. All payments made pursuant to this Agreement will be subject to withholding of applicable taxes.

20. Governing Law. This Agreement will be governed by the laws of the State of New Jersey (with the exception of its conflict of laws provisions).

21. Acknowledgment. Executive acknowledges that Executive has had the opportunity to discuss this matter with and obtain advice from Executive's private attorney, has had sufficient time to, and has carefully read and fully understands all the provisions of this Agreement, and is knowingly and voluntarily entering into this Agreement.

22. Counterparts. This Agreement may be executed in counterparts, and each counterpart will have the same force and effect as an original and will constitute an effective, binding agreement on the part of each of the undersigned.

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by their duly authorized officers, as of the day and year first above written.

COMPANY:

AADI BIOSCIENCE, INC.

By: /s/ Caley Castelein Date: November 8, 2022

Name: Caley Castelein

Title: Chairman of the Board of Directors

EXECUTIVE:

/s/ Brendan Delaney Date: November 8, 2022

Brendan Delaney

[SIGNATURE PAGE TO EXECUTIVE EMPLOYMENT AGREEMENT]

Exhibit 10.21

AMENDMENT 01 to NEGOTIATED PURCHASE ORDER TERMS AND CONDITIONS FOR CLINICAL AND COMMERCIAL PRODUCT

This Amendment No. 01 to the Negotiated Purchase Order Terms and Conditions for Clinical and Commercial Product of January 13, 2022 (the **"Amendment"**) is made effective as of August 1, 2022 ("**Amendment Effective Date**") by and between Fresenius Kabi, LLC, a Delaware company having a principal place of business at Three Corporate Drive, Lake Zurich, IL 60047 ("**FRESENIUS KABI**"), and AADi Bioscience, Inc., a Delaware corporation having a principal address at 17383 Sunset Blvd., Suite A 250, Pacific Palisades, CA 90272 ("**AADI**" or "**Customer**"). AADI and the Company may hereafter be referred to collectively as the **"Parties"** and individually as a **"Party"**.

WHEREAS, FRESENIUS KABI and AADI are Parties to the Negotiated Purchase Order Terms and Conditions for Clinical and Commercial Product signed on January 13, 2022 ("**the Agreement**");

WHEREAS, the Parties mutually desire to amend, modify and restate certain terms and conditions of the Agreement.

NOW THEREFORE, in consideration of the premises and the mutual covenants herein contained, it is mutually agreed as follows:

1. DEFINITIONS

Unless otherwise defined herein, capitalized words in this Amendment shall have the meaning attributed to them in the Agreement.

2. AMENDMENTS

The Parties agree that, as of the Amendment Effective Date, the Agreement is amended as set forth in this Section 2.

2.1 The following sentence shall be added as the last sentence to the second paragraph on page 1 of the Agreement following the language "If FRESENIUS KABI cannot agree to the AADI's proposed delivery date, FRESENIUS KABI may decline the Purchase Order and the Parties shall negotiate in good faith a new delivery date":

"FRESENIUS KABI may elect not to manufacture Product for any confirmed purchase orders if any outstanding invoices payable by AADI exceed [***]. In such instance, the Parties shall agree on an alternative manufacturing dates as soon as the outstanding invoices have been settled by AADI."

2.2 The following sentences shall be added to the end of Section 12 (Payment) of the Agreement:

"Notwithstanding anything to the contrary in this Agreement, FRESENIUS KABI may invoice any Product (i) that has been released by AADI as agreed in the Quality Agreement but is not delivered to AADI within [***] calendar days after its release, or (ii) if the review at AADI to release Product is pending for more than [***] from the date on which FRESENIUS KABI has provided the relevant executed batch record, the certificate of analysis and the certificate of compliance without AADI's approval or request for comments or changes, or (iii) if all documentation has been provided by FRESENIUS KABI to AADI for release of Product but regulatory approval for a Product Change has not been received by the respective regulatory authority.

Such invoice shall be paid by AADI in US Dollars within [***] calendar days from the date of receipt of the applicable invoice. In the event the Parties agree in writing that Product is stored for an agreed period of time at FRESENIUS KABI after release, fees as described in Section 14 apply.

2.3 Section 14, shall be deleted and replaced by the following new clause:

"**14) Storage**: In the event that AADI fails to pick up any Product within [***] calendar days of FRESENIUS KABI's release of the Product or any Product subject to Section 12 as amended above by Section 2.2 of this Amendment, FRESENIUS KABI shall notify AADI and may thereafter arrange for storage of such Product at AADI's risk and expense. For Product stored at the manufacturing facility, FRESENIUS KABI shall charge AADI a storage fee of [***] per pallet for the first month, and [***] per pallet for each started month thereafter stored at 2-8°C or as otherwise agreed in the Quality Agreement. AADI acknowledges that if the number of stored pallets at any given time will exceed [***] pallets, FRESENIUS KABI may need to arrange for storage with a third party, which shall also be at AADI's risk and expense, or alternatively FRESENIUS KABI may delay further batch manufacture of Product."

2.4 The last sentence of Section 17 subsection c) shall be deleted and replaced by the following sentence:

"For clarity, FRESENIUS KABI is not responsible for any costs, or replacement, of Product or Supplied Material if [***].

2.5 Section 31 shall be deleted and replaced by the following new clause:

31) "**Term; Termination**: The term of this Agreement begins upon FRESENIUS KABI's acceptance of the purchase order and continues until March 31, 2024 (or such later date as may be agreed between the Parties) subject to the terms that survive expiration or termination of this Agreement (i.e., Sections 2, 4, 19, 21, and 26-31). Upon expiration or termination of this Agreement, no Party shall have any obligation to make any further payments to the other, except for amounts accrued prior to expiration or termination. Further, any purchase orders for Product confirmed by FRESENIUS KABI with a batch manufacturing date for Product prior to expiration or termination of the term of this Agreement shall be delivered by FRESENIUS KABI and shall be paid by AADI in full pursuant to this Agreement. Except as otherwise agreed upon by the Parties, AADI may terminate a purchase order for Products within [***] day of FRESENIUS KABI's confirmation of the purchase order. AADI may not terminate a confirmed purchase order for Products after such time."

2.6 Section 1. of Exhibit C ("Price") shall be deleted and replaced by the following new clause:

"1. Price

The table below identifies the Price per unit of Product that applies based on the total quantity of Product actually purchased by AADI for delivery during a given calendar year pursuant to this Agreement. The Price of the Product is calculated based on a batch-size of [***].

[***]

For clarity, [***]; with the exception that for the following purchase orders placed by AADI in 2022, the Price per unit of Product set forth in the Price Table at Section 1.A of Exhibit C shall apply:

1. [***]

Assumptions for Product Prices include but are not limited to:

[***]

Price for Product manufactured by FRESENIUS KABI after December 31, 2022 assumes AADI has submitted purchase orders for not less than [***] batches of either commercial and/or clinical Product to be manufactured in 2023, and that FRESENIUS KABI is timely provided with Supplied Materials to allow it to manufacture not less than [***] batches of Product, under this Agreement in the calendar year 2023 (as defined by the manufacturing date).

Each process-performance qualification batch for Product manufactured under the Prior NTCs in the FRESENIUS KABI facility in [***] with an upscaled batch size of [***] shall count as [***] batches towards the not less than [***] batch requirement. Costs for these process-performance qualification batches for Product with an upscaled batch size shall be quoted separately and agreed between the Parties in writing.

For clarity, FRESENIUS KABI shall increase the Price for Product manufactured under this Agreement in the calendar year 2023 if [***].

2. INTEGRATION

Except for the sections of the Agreement specifically amended hereunder, all terms and conditions of the Agreement remain and shall remain in full force and effect. This Amendment shall hereafter be incorporated into and deemed part of the Agreement and any future reference to the Agreement shall include the terms and conditions of this Amendment.

3. APPLICABLE LAW & JURISDICTION

This Amendment shall be governed by, and construed in accordance with, the laws which govern the Agreement, and the Parties submit to the jurisdiction and dispute resolution provisions as set forth in the Agreement.

[signature page follows immediately hereafter]

IN WITNESS WHEREOF, each Party is signing this Amendment on the date stated opposite that Party's signature.

AADi Bioscience, Inc.

By: _/s/ Brendan Delaney______________________ Date:__1/12/2023_______________
Name: Brendan Delaney
Title: Chief Executive Officer

Fresenius Kabi, LLC

By: _/s/ Michael Marinoff___________ Date:_1/17/2023__________
Name: Michael Marinoff
Title: Senior Director

Fresenius Kabi, LLC

By: __/s/ Saleem Farooqui______________ Date:_1/17/2023___________
Name: Saleem Farooqui
Title: EVP BU Gx Pharma & IV Fluids North America

SUNSET & PCH

OFFICE LEASE

This Office Lease (the "**Lease**"), dated as of the date set forth in Section 1 of the Summary of Basic Lease Information (the "**Summary**"), below, is made by and between BRE SUNSET COAST, LLC, a Delaware limited liability company("**Landlord**"), and AADI BIOSCIENCE, INC., a Delaware corporation ("**Tenant**").

SUMMARY OF BASIC LEASE INFORMATION

TERMS OF LEASE		DESCRIPTION
1.	Date:	April 19, 2019
2.	Premises	
2.1	Building:	Building A of 17383 Sunset Boulevard, Los Angeles, California 90272, containing approximately 61,296 rentable square feet of space ("**RSF**") and located at the corner of Sunset Boulevard and Pacific Coast Highway.
2.2	Premises:	Approximately 2,760 RSF on the 2nd floor of the Building and commonly known as Suite A250, as further set forth in **Exhibit A** to the Office Lease.
2.3	Project:	Sunset & PCH, consisting of three (3) buildings (Building A, B and C) containing a total of approximately 102,414 rentable square feet and other elements as described in Section 1.1 of the Lease.
3.	Lease Term (Article 2).	
3.1	Length of Term:	Two (2) years and four (4) months.
3.2	Lease Commencement Date:	May 1, 2019.
3.3	Lease Expiration Date:	August 31, 2021.

4. Base Rent (Article 3):

4.1 Amount Due:

Lease Year	Annual Base Rent	Monthly Installment of Base Rent	Monthly Rental Rate per RSF
1	$207,000.00	$17,250.00	$6.250
2	$214,245.00	$17,853.75	$6.469
3 (until Lease Expiration Date)	N/A	$18,478.63	$6.695

Note: Subject to Rent Abatement as provided in Section 3.2 of the Lease.

4.2 Rent Payment Address: c/o Lincoln Property Company
12180 Millennium, Suite 120
Playa Vista, CA 90094

5. Base Year (Article 4): Calendar year 2019.

6. Tenant's Share (Article 4): (i) 4.50% with respect to Direct Expenses allocated to only the Building; and (ii) 2.69% with respect to Direct Expenses allocated to the entire Project.

7. Permitted Use (Article 5): General office use, consistent with the character of a first class office building (the "Permitted Use").

8. Security Deposit (Article 21): $55,435.89 (subject to reduction as provided in Article 21).

9. Parking (Article 28): Tenant shall be allocated up to five (5) unreserved parking passes (the "**Allocated Passes**"), of which Tenant shall be required to lease, at all times during the Lease Term, at least three (3), unreserved parking passes (the "**Must-Take Passes**").

10. Address of Tenant (Section 29.18): 1343 Luna Vista Drive
Pacific Palisades, CA 90272
Attention: Chief Executive Officer

(Prior to Lease Commencement Date)

and

At the Premises
Attention: Chief Executive Officer
(After Lease Commencement Date)

11. Address of Landlord (Section 29.18): See Section 29.18 of the Lease.

12.	Broker(s) (Section 29.24):	NAI Capital and Cushman & Wakefield of California, Inc.

1. PREMISES, BUILDING, PROJECT, AND COMMON AREAS.

1.1 Premises, Building, Project and Common Areas.

1.1.1 **The Premises**. Landlord hereby leases to Tenant and Tenant hereby leases from Landlord the premises which are to be constructed by Landlord and are set forth in Section 2.2 of the Summary (the "**Premises**"). The outline of the Premises is set forth in **Exhibit A** attached hereto. The parties hereto hereby acknowledge that the purpose of **Exhibit A** is to show the approximate location of the Premises in the "Building," as that term is defined in Section 1.1.2, below, only, and such Exhibit is not meant to constitute an agreement, representation or warranty as to the construction of the Premises, the precise area thereof. Landlord shall not be obligated to provide or pay for any improvement work or services related to the improvement of the Premises, and Tenant agrees to accept the Premises in their currently existing, "as-is" condition. Neither Landlord nor any agent of Landlord has made any representation or warranty regarding the condition of the Premises, the Building or the Project or with respect to the suitability of any of the foregoing for the conduct of Tenant's business, except as specifically set forth in this Lease. The taking of possession of the Premises by Tenant shall conclusively establish that the Premises and the Building were at such time in good and sanitary order, condition and repair. Except when and where Tenant's right of access is specifically excluded as the result of (i) an emergency, (ii) a requirement by law, or (iii) a specific provision set forth in this Lease, Tenant shall have the right of ingress and egress to the Premises and the Project parking areas twenty-four (24) hours per day, seven (7) days per week, every day of the year during the Lease Term. Landlord shall deliver possession of the Premises to Tenant in good, vacant, broom clean condition, with all building systems in good working order, and in compliance with applicable laws to the extent required to allow the legal occupancy of the Premises. Landlord shall cause the Premises to have Building standard window blinds installed (and if such blinds are not currently in place, installation of the same shall occur within thirty (30) days after the Lease Commencement Date). Except in case of emergency or as otherwise provided in this Lease, Tenant shall have access to the Premises, Building and parking twenty-four (24) hours per day, seven (7) days per week.

1.1.2 **The Building and The Project**. The Premises are a part of the building set forth in Section 2.1 of the Summary (the "**Building**"). The Building is part of an office project known as "Sunset & PCH." The term "**Project**," as used in this Lease, shall mean (i) the Building, adjacent buildings in the Project, and the Common Areas, (ii) the land (which is improved with landscaping, parking facilities and other improvements) upon which the Building and the Common Areas are located, and (iii) at Landlord's discretion, any additional real property, areas, land, buildings or other improvements added thereto outside of the Project (provided that in such event Tenant's Share of the Project shall be appropriately adjusted).

1.1.3 **Common Areas**. Tenant shall have the non-exclusive right to use in common with other tenants in the Project, and subject to the rules and regulations referred to in Article 5 of this Lease, those portions of the Project which are provided, from time to time, for use in common by Landlord, Tenant and any other tenants of the Project (such areas, together with such other portions of the Project designated by Landlord, in its discretion, including certain areas designated for the exclusive use of certain tenants, or to be shared by Landlord and certain tenants, are collectively referred to herein as the "**Common Areas**"). The Common Areas shall consist of the "**Project Common Areas**" and the "**Building Common Areas**." The term "**Project Common Areas**," as used in this Lease, shall mean the portion of the Project designated as such by Landlord including the patios on the 2nd and 4th floors. The term "**Building Common Areas**," as used in this Lease, shall mean the portions of the Common Areas located within the Building designated as such by Landlord. The manner in which the Common Areas are maintained and operated shall be at the sole discretion of Landlord and the use thereof shall be subject to such rules, regulations and restrictions as Landlord may make from time to time. Landlord reserves the right to close temporarily, make alterations or additions to, or change the location of elements of the Project and the Common Areas, provided that no such changes shall unreasonably interfere with Tenant's use of or access to the Premises. Notwithstanding the foregoing, Landlord shall operate and maintain the Common Areas in a manner commensurate with "Comparable Buildings", as defined in <u>Section 2.2.2</u>, below.

1.1.4 **Premises Furniture**. Tenant shall accept the Premises with any existing furniture therein in its existing "as-is" condition. Tenant shall have the right to use such furniture during the Lease Term. At Tenant's option, Tenant shall be permitted to purchase such furniture for one dollar ($1), in which case Landlord and Tenant shall enter into a bill of sale acceptable to Tenant. If such furniture has not been purchased by Tenant in accordance with the foregoing, at the expiration of the Lease Term, at Landlord's option, Tenant shall either leave such furniture in place in the Premises, or shall remove and dispose of the same at Tenant's sole cost.

1.2 **Verification of Rentable Square Feet of Premises and Building**. For purposes of this Lease, "rentable square feet" and "usable square feet" of the Premises shall be deemed as set forth in Section 2.2 of the Summary and shall not be subject to remeasurement or modification.

2. LEASE TERM; OPTION TERM.

2.1 **Lease Term**. The terms and provisions of this Lease shall be effective as of the date of this Lease. The term of this Lease (the "**Lease Term**") shall be as set forth in Section 3.1 of the Summary, shall commence on the date set forth in Section 3.2 of the Summary (the "**Lease Commencement Date**"), and shall terminate on the date set forth in Section 3.3 of the Summary (the "**Lease Expiration Date**") unless this Lease is sooner terminated or extended as hereinafter provided. For purposes of this Lease, the term "**Lease Year**" shall mean each consecutive twelve (12) month period during the Lease Term. At any time during the Lease Term, Landlord may deliver to Tenant a notice in the form as set forth in **Exhibit C**, attached hereto, as a confirmation only of the information set forth therein, which Tenant shall execute and return to Landlord within five (5) days of receipt thereof. Landlord shall deliver the Premises to Tenant as soon as reasonably practicable following the full execution of this Lease. Upon such delivery, Tenant shall have the right to access and commence business in the Premises on all of the terms and conditions of this Lease (provided Tenant has provided insurance as required by the terms of Article 10, below), except that Tenant shall have no obligation to pay Base Rent for the Premises until the occurrence of the Lease Commencement Date.

2.2 **Option Term**.

2.2.1 **Option Right**. Landlord hereby grants the Tenant named in this Lease (the "**Original Tenant**"), one (1) option to extend the Lease Term for a period of three (3) years (the "**Option Term**"), which option shall be exercisable only by written notice delivered by Tenant to Landlord as provided below, provided that, as of the date of delivery of such notice, Tenant is not in default under this Lease, after expiration of any applicable notice and cure periods, and Tenant has not previously been in default under this Lease more than once, after expiration of any applicable notice and cure periods,. Upon the proper exercise of each such option to extend, and provided that, at Landlord's option, as of the end of the initial Lease Term, Tenant is not in default under this Lease, after expiration of any applicable notice and cure periods, and Tenant has not previously been in default under this Lease more than once, after expiration of any applicable notice and cure periods, the Lease Term, as it applies to the Premises, shall be extended for a period of three (3) years. The rights contained in this Section 2.2 shall be personal to the Original Tenant and may only be exercised by the Original Tenant (and not any assignee, sublessee or other transferee of Tenant's interest in this Lease) if the Original Tenant occupies the entire Premises.

2.2.2 **Option Rent**. The "Rent," as that term is defined in Article 3 of this Lease, payable by Tenant during the Option Term (the "**Option Rent**") shall be equal to one hundred percent (100%) of the "Fair Market Rent", as defined below, for the Premises effective as of the commencement of the Option Term. As used herein "**Fair Market Rent**" shall mean the rent (including additional rent and considering any "base year" or "expense stop" applicable thereto) at which tenants, as of the commencement of the Option Term, are leasing non-sublease, non-encumbered, non-equity space comparable in size, location and quality to the Premises for a term of five (5) years, which comparable space is located in the Building or Project, or in comparable first-class office buildings in the Pacific Palisades and Malibu submarkets, taking into consideration only the following concessions: (a) rental abatement concessions, if any, being granted such tenants in connection with such comparable space, and (b) tenant improvements or allowances provided or to be provided for such comparable space, taking into account, and deducting the value of, the existing improvements in the Premises, such value to be based upon the age, quality and layout of the improvements and the extent to which the same could be utilized by Tenant based upon the fact that the precise tenant improvements existing in the Premises are specifically suitable to Tenant.

2.2.3 **Exercise of Options**. The option contained in this Section 2.2 shall be exercised by Tenant, if at all, and only in the following manner: (i) Tenant shall deliver written notice to Landlord (the "**Interest Notice**") not more than fifteen (15) months nor less than twelve (12) months prior to the expiration of the initial Lease Term, stating that Tenant is interested in exercising its option; (ii) Landlord, after receipt of Tenant's notice, shall deliver notice (the "**Option Rent Notice**") to Tenant not less than thirty (30) days after receipt of the Interest Notice, setting forth the Option Rent; and (iii) if Tenant wishes to exercise such option, Tenant shall, on or before the date occurring thirty (30) days after Tenant's receipt of the Option Rent Notice, exercise the option by delivering written notice thereof to Landlord (the "**Exercise Notice**"). If Tenant timely delivers the Exercise Notice, the Lease Term shall be extended for the Option Term, and the Option Rent shall be as set forth in the Option Rent Notice. If Tenant fails to timely deliver the Exercise Notice, then Tenant shall have no further right to extend the Lease Term, and the Lease will expire at the end of the initial Lease Term. Upon and concurrent with Tenant's delivery of the Exercise Notice, Tenant may, at its option object to the Option Rent contained in the Option Rent Notice, in which case the parties shall follow the procedure, and the Option Rent shall be determined, as set forth in Section 2.2.4 below.

2.2.4 **Determination of Option Rent**. In the event Tenant timely and appropriately objects to the Option Rent, Landlord and Tenant shall attempt to agree upon the Option Rent using their best good-faith efforts. If Landlord and Tenant fail to reach agreement within ten (10) days following Tenant's objection to the Option Rent, (the "**Outside Agreement Date**"), then each party shall make a separate determination of the Option Rent, as the case may be, within five (5) days, and such determinations shall be submitted to arbitration in accordance with Sections 2.2.4.1 through 2.2.4.7 below.

2.2.4.1 Landlord and Tenant shall each appoint one arbitrator who shall by profession be a real estate broker, lawyer or appraiser who shall have been active over the five (5) year period ending on the date of such appointment in the leasing (or appraisal, as the case may be) of commercial office properties in the West Los Angeles, Santa Monica, Malibu, California area. The determination of the arbitrators shall be limited solely to the issue area of whether Landlord's or Tenant's submitted Option Rent, is the closest to the actual Option Rent as determined by the arbitrators, taking into account the requirements of Section 2.2.3 of this Lease. Each such arbitrator shall be appointed within fifteen (15) days after the applicable Outside Agreement Date.

2.2.4.2 The two arbitrators so appointed shall within ten (10) days of the date of the appointment of the last appointed arbitrator agree upon and appoint a third arbitrator who shall be qualified under the same criteria set forth hereinabove for qualification of the initial two arbitrators.

2.2.4.3 The three arbitrators shall within thirty (30) days of the appointment of the third arbitrator reach a decision as to whether the parties shall use Landlord's or Tenant's submitted Option Rent, and shall notify Landlord and Tenant thereof.

2.2.4.4 The decision of the majority of the three arbitrators shall be binding upon Landlord and Tenant.

2.2.4.5 If either Landlord or Tenant fails to appoint an arbitrator within fifteen (15) days after the applicable Outside Agreement Date, the arbitrator appointed by one of them shall reach a decision, notify Landlord and Tenant thereof, and such arbitrator's decision shall be binding upon Landlord and Tenant.

2.2.4.6 If the two arbitrators fail to agree upon and appoint a third arbitrator, or both parties fail to appoint an arbitrator, then the appointment of the third arbitrator or any arbitrator shall be dismissed and the matter to be decided shall be forthwith submitted to arbitration under the provisions of the American Arbitration Association, but subject to the instruction set forth in this Section 2.2.4.

2.2.4.7 The cost of arbitration shall be paid by Landlord and Tenant equally.

3. **BASE RENT**.

3.1 **Base Rent**. Tenant shall pay, without prior notice or demand, to Landlord or Landlord's agent at the address set forth in Section 4.2 of the Summary, or, at Landlord's option, at such other place as Landlord may from time to time designate in writing, by a check for currency which, at the time of payment, is legal tender for private or public debts in the United States of America, base rent ("**Base Rent**") as set forth in Section 4 of the Summary, payable in equal monthly installments as set forth in Section 4 of the Summary, in advance on or before the first day of each and every calendar month during the Lease Term, without any setoff or deduction whatsoever, except as expressly set forth herein. The Base Rent for the first full month of the Lease Term which occurs after the expiration of any free rent period shall be paid at the time of Tenant's execution of this Lease. If any Rent payment date (including the Lease Commencement Date) falls on a day of the month other than the first day of such month or if any payment of Rent is for a period which is shorter than one month, the Rent for any fractional month shall accrue on a daily basis for the period from the date such payment is due to the end of such calendar month or to the end of the Lease Term at a rate per day which is equal to 1/365 of the applicable annual Rent. All other payments or adjustments required to be made under the terms of this Lease that require proration on a time basis shall be prorated on the same basis.

3.2 **Base Rent Abatement**. Provided that Tenant is not then in default of this Lease beyond any applicable notice and cure period provided in this Lease, then during the four (4) full calendar month period from the second (2nd) through the fifth (5th) full months of the Lease Term (the "**Rent Abatement Period**"), Tenant shall not be obligated to pay any Base Rent otherwise attributable to the Premises during such Rent Abatement Period (the "**Rent Abatement**"). Landlord and Tenant acknowledge that the aggregate amount of the Rent Abatement equals $69,000.00 (i.e., $17,250.00 per month). Tenant acknowledges and agrees that the foregoing Rent Abatement has been granted to Tenant as additional consideration for entering into this Lease, and for agreeing to pay the Rent and performing the terms and conditions otherwise required under this Lease. If Tenant shall be in monetary Default under this Lease and shall fail to cure such default within the notice and cure period permitted for cure pursuant to this Lease, then the dollar amount of the unapplied portion of the Rent Abatement as of such default shall be converted to a credit to be applied to the Base Rent applicable at the end of the initial Lease Term (but prior to any extension of the Lease Term as provided in Section 2.2 above), and Tenant shall immediately be obligated to begin paying Base Rent for the Premises in full.

4. **ADDITIONAL RENT**.

4.1 **General Terms**. In addition to paying the Base Rent specified in Article 3 of this Lease, Tenant shall pay "Tenant's Share" of the annual "Direct Expenses," as those terms are defined in Sections 4.2.6 and 4.2.2 of this Lease, respectively, which are in excess of the amount of Direct Expenses applicable to the "Base Year," as that term is defined in Section 4.2.1, below; provided, however, that in no event shall any decrease in Direct Expenses for any Expense Year below Direct Expenses for the Base Year entitle Tenant to any decrease in Base Rent or any credit against sums due under this Lease. Such payments by Tenant, together with any and all other amounts payable by Tenant to Landlord pursuant to the terms of this Lease, are hereinafter collectively referred to as the "**Additional Rent**", and the Base Rent and the Additional Rent are herein collectively referred to as "**Rent**." All amounts due under this Article 4 as Additional Rent shall be payable for the same periods and in the same manner as the Base Rent. Without limitation on other obligations of Tenant which survive the expiration of the Lease Term, the obligations of Tenant to pay the Additional Rent provided for in this Article 4 shall survive the expiration of the Lease Term.

4.2 **Definitions of Key Terms Relating to Additional Rent**. As used in this Article 4, the following terms shall have the meanings hereinafter set forth:

4.2.1 "**Base Year**" shall mean the period set forth in Section 5 of the Summary.

4.2.2 "**Direct Expenses**" shall mean "Operating Expenses" and "Tax Expenses."

4.2.3 "**Expense Year**" shall mean each calendar year in which any portion of the Lease Term falls, through and including the calendar year in which the Lease Term expires, provided that Landlord, upon notice to Tenant, may change the Expense Year from time to time to any other twelve (12) consecutive month period, and, in the event of any such change, Tenant's Share of Direct Expenses shall be equitably adjusted for any Expense Year involved in any such change.

4.2.4 "**Operating Expenses**" shall mean all expenses, costs and amounts of every kind and nature which Landlord pays or accrues during any Expense Year because of or in connection with the ownership, management, maintenance, security, repair, replacement, restoration or operation of the Project, or any portion thereof. Without limiting the generality of the foregoing, Operating Expenses shall specifically include any and all of the following: (i) the cost of supplying all utilities, the cost of operating, repairing, maintaining, and renovating the utility, telephone, mechanical, sanitary, storm drainage, and elevator systems, and the cost of maintenance and service contracts in connection therewith; (ii) the cost of licenses, certificates, permits and inspections and the cost of contesting any governmental enactments which may affect Operating Expenses, and the costs incurred in connection with a transportation system management program or similar program; (iii) the cost of all insurance carried by Landlord in connection with the Project; (iv) the cost of landscaping, relamping, and all supplies, tools, equipment and materials used in the operation, repair and maintenance of the Project, or any portion thereof; (v) costs incurred in connection with the parking areas servicing the Project; (vi) fees and other costs, including management fees, consulting fees, legal fees and accounting fees, of all contractors and consultants in connection with the management, operation, maintenance and repair of the Project; (vii) payments under any equipment rental agreements and the fair rental value of any management office space; (viii) wages, salaries and other compensation and benefits, including taxes levied thereon, of all persons engaged in the operation, maintenance and security of the Project; (ix) payments, fees or charges under any easement, license, operating agreement, declaration, restrictive covenant, or any instrument pertaining to the sharing of costs by the Project, or any portion thereof; (x) operation, repair, maintenance and replacement of all systems and equipment and components thereof of the Building; (xi) the cost of janitorial, alarm, security and other services, replacement of wall and floor coverings, ceiling tiles and fixtures in common areas, maintenance and replacement of curbs and walkways, repair to roofs and re-roofing; (xii) amortization (including interest on the unamortized cost) of the cost of acquiring or the rental expense of personal property used in the maintenance, operation and repair of the Project, or any portion thereof; (xiii) the cost of capital improvements or other costs incurred in connection with the Project (A) which are intended to effect economies in the operation or maintenance of the Project, or any portion thereof, (B) that are required to comply with present or anticipated conservation programs, (C) which are replacements or modifications of nonstructural items located in the Common Areas required to keep the Common Areas in good order or condition, or (D) that are required under any governmental law or regulation; provided, however, that any capital expenditure shall be amortized with interest over its useful life as Landlord shall reasonably determine; (xiv) costs, fees, charges or assessments imposed by, or resulting from any mandate imposed on Landlord by, any federal, state or local government for fire and police protection, trash removal, community services, or other services which do not constitute "Tax Expenses" as that term is defined in Section 4.2.5, below; and (xv) payments under any easement, license, operating agreement, declaration, restrictive covenant, or instrument pertaining to the sharing of costs by the Building.

If Landlord is not furnishing any particular work or service (the cost of which, if performed by Landlord, would be included in Operating Expenses) to a tenant who has undertaken to perform such work or service in lieu of the performance thereof by Landlord, Operating Expenses shall be deemed to be increased by an amount equal to the additional Operating Expenses which would reasonably have been incurred during such period by Landlord if it had at its own expense furnished such work or service to such tenant. If the Project is not at least 95% occupied during all or a portion of the Base Year or any Expense Year, Landlord may elect to make an appropriate adjustment to the components of Operating Expenses for such year to determine the amount of Operating Expenses that would have been incurred had the Project been 95% occupied; and the amount so determined shall be deemed to have been the amount of Operating Expenses for such year. Operating Expenses for the Base Year shall include market-wide labor-rate increases due to extraordinary circumstances, including, but not limited to, boycotts and strikes, and utility rate increases due to extraordinary circumstances including, but not limited to, conservation surcharges, boycotts, embargoes or other shortages, or amortized costs relating to capital improvements (the "**Temporary Charges**"), provided that such Temporary Charges shall be deleted from the Operating Expenses for the Base Year at such time as they are no longer being incurred. In no event shall the component of Operating Expenses relating to electrical costs in any Expense Year be deemed to be less than the component of Operating Expenses relating to electrical costs which is included in the Base Year.

4.2.4.1 Notwithstanding the foregoing, for purposes of this Lease, Operating Expenses shall not include the following:

(a) brokerage commissions, space planning costs, finders' fees and attorneys' fees incurred by Landlord in connection with leasing or attempting to lease space within the Project;

(b) costs, including permit, license and inspection costs, incurred with respect to the installation of tenant improvements made for any tenants in the Project or incurred in renovating or otherwise improving, preparing, decorating, painting or redecorating vacant space for tenants or other occupants of the Project.

(c) interest, points, fees and principal payments on any mortgages encumbering the Project, and other debt costs, if any, except as specifically included in Sections 4.2.4(xi) and (xii) above;

(d) costs of correcting defects in the initial design or construction of the Building;

(e) advertising and promotional expenditures;

(f) costs of any items (including, but not limited to, costs incurred by Landlord with respect to goods, services and utilities sold and/or supplied to tenants and occupants of the Project, and/or for the repair of damage to the Project for items which are reimbursable under any contractor, manufacturer or supplier warranty) to the extent Landlord receives reimbursement from insurance or condemnation proceeds (provided that deductibles shall be included in Operating Expenses), or from a contractor, manufacturer, supplier or any other third party pursuant to any warranty or otherwise (other than reimbursement by tenants pursuant to the Operating Expenses pass-through provisions of their leases); such proceeds shall be credited to Operating Expenses in the year in which received;

(g) expenses in connection with services or other benefits for which Tenant is charged directly but which are provided to other tenants of the Project at no cost (or are separately reimbursed by or subject to reimbursement from such other tenants, whether or not collected);

(h) attorneys' fees and other costs and expenses incurred in connection with negotiations or disputes with present or prospective tenants or other occupants or prospective occupants of the Project (including costs incurred due to violations by tenants of the terms and conditions of their leases), or any other attorneys' fees incurred in connection with the Project (including, without limitation, any financing, sale or syndication of the Project), except (A) as specifically enumerated as an Operating Expense in this Lease, or (B) to the extent the expenditure of such attorneys' fees generally benefits the tenants of the Project, except as otherwise expressly limited herein;

(i) the wages and benefits of any employee who does not devote substantially all of his or her employed time to the operation and management of the Building or Project unless such wages and benefits are prorated to reflect time spent on operating and managing the Building and Project vis-à-vis time spent on matters unrelated to operating and managing the Building and Project;

(j) compensation (including benefits) of any employee of Landlord above the grade of project or building manager or engineer;

(k) costs and overhead and profit increment paid to Landlord or to subsidiaries or affiliates of Landlord for goods and/or services in or to the Project to the extent the same exceeds typical costs and overhead and profit increment of such goods and/or services rendered by qualified unaffiliated third parties on a competitive basis;

(l) any costs for which Landlord has been reimbursed (other than through the Operating Expenses pass-through provisions of other tenants' leases);

(m) costs of signs (other than building directories and signage for various equipment rooms and common areas) in or on the Project or any buildings located on the Project which identify other tenants;

(n) interest, penalties or other costs arising out of Landlord's failure to make timely payment of any of its obligations under this Lease, including, without limitation, Landlord's failure to make timely payment of any item that is included in Operating Expenses or Tax Expenses;

(o) any costs expressly excluded from Operating Expenses elsewhere in this Lease;

(p) any ground lease rental;

(q) costs incurred by Landlord due to the violation by Landlord of the terms and conditions of any lease of space within the Project;

(r) Landlord's general corporate overhead and administrative expenses, except for the property management fee;

(s) costs of acquisition of sculptures, painting and other objects of art;

(t) costs of cleanup, removal, investigation and/or remediation (collectively, "**Remediation Costs**") of any hazardous materials in, on or under the Project to the extent such hazardous materials are (1) in existence as of the Lease Commencement Date and in violation of applicable Laws in effect as of the Lease Commencement Date, or (2) introduced onto the Project after the Lease Commencement Date by Landlord or any of Landlord's agents, employees, contractors or tenants in violation of applicable Laws in effect at the date of introduction; and

(u) any Tax Expenses.

4.2.5 __**Taxes**__.

4.2.5.1 "**Tax Expenses**" shall mean all federal, state, county, or local governmental or municipal taxes, fees, charges or other impositions of every kind and nature, whether general, special, ordinary or extraordinary, (including, without limitation, real estate taxes, general and special assessments, transit taxes, leasehold taxes or taxes based upon the receipt of rent, including gross receipts or sales taxes applicable to the receipt of rent, unless required to be paid by Tenant, personal property taxes imposed upon the fixtures, machinery, equipment, apparatus, systems and equipment, appurtenances, furniture and other personal property used in connection with the Project, or any portion thereof), which shall be paid or accrued during any Expense Year (without regard to any different fiscal year used by such governmental or municipal authority) because of or in connection with the ownership, leasing and operation of the Project, or any portion thereof.

4.2.5.2 Tax Expenses shall include, without limitation: (i) Any tax on the rent, right to rent or other income from the Project, or any portion thereof, or as against the business of leasing the

Project, or any portion thereof; (ii) Any assessment, tax, fee, levy or charge in addition to, or in substitution, partially or totally, of any assessment, tax, fee, levy or charge previously included within the definition of real property tax, it being acknowledged by Tenant and Landlord that Proposition 13 was adopted by the voters of the State of California in the June 1978 election ("**Proposition 13**") and that assessments, taxes, fees, levies and charges may be imposed by governmental agencies for such services as fire protection, street, sidewalk and road maintenance, refuse removal and for other governmental services formerly provided without charge to property owners or occupants, and, in further recognition of the decrease in the level and quality of governmental services and amenities as a result of Proposition 13, Tax Expenses shall also include any governmental or private assessments or the Project's contribution towards a governmental or private cost-sharing agreement for the purpose of augmenting or improving the quality of services and amenities normally provided by governmental agencies; (iii) Any assessment, tax, fee, levy, or charge allocable to or measured by the area of the Premises or the Rent payable hereunder, including, without limitation, any business or gross income tax or excise tax with respect to the receipt of such rent, or upon or with respect to the possession, leasing, operating, management, maintenance, alteration, repair, use or occupancy by Tenant of the Premises, or any portion thereof; and (iv) Any assessment, tax, fee, levy or charge, upon this transaction or any document to which Tenant is a party, creating or transferring an interest or an estate in the Premises.

4.2.5.3 Any costs and expenses (including, without limitation, reasonable attorneys' fees) incurred in attempting to protest, reduce or minimize Tax Expenses shall be included in Tax Expenses in the Expense Year such expenses are paid. If Tax Expenses for any period during the Lease Term or any extension thereof are increased after payment thereof for any reason, including, without limitation, error or reassessment by applicable governmental or municipal authorities, Tenant shall pay Landlord upon demand Tenant's Share of any such increased Tax Expenses included by Landlord as Tax Expenses pursuant to the terms of this Lease. Notwithstanding anything to the contrary contained in this Section 4.2.5 (except as set forth in Section 4.2.5.1, above), there shall be excluded from Tax Expenses (i) all excess profits taxes, franchise taxes, gift taxes, capital stock taxes, inheritance and succession taxes, estate taxes, federal and state income taxes, and other taxes to the extent applicable to Landlord's general or net income (as opposed to rents, receipts or income attributable to operations at the Project), (ii) any items included as Operating Expenses, (iii) any penalties or interest imposed as a result of a failure to pay Tax Expenses when due, unless such failure is caused by Tenant's failure to make its payments of Tax Expenses when due, and (iv) any items paid by Tenant under Section 4.5 of this Lease.

4.2.5.4 Notwithstanding anything to the contrary set forth in this Lease, the amount of Tax Expenses for the Base Year and any Expense Year shall be calculated without taking into account any decreases in real estate taxes obtained in connection with Proposition 8, and, therefore, the Tax Expenses in the Base Year and/or an Expense Year may be greater than those actually incurred by Landlord, but shall, nonetheless, be the Tax Expenses due under this Lease; provided that (i) any costs and expenses incurred by Landlord in securing any Proposition 8 reduction shall not be included in Direct Expenses for purposes of this Lease, and (ii) tax refunds under Proposition 8 shall not be deducted from Tax Expenses, but rather shall be the sole property of Landlord. Landlord and Tenant acknowledge that this Section 4.2.5.4 is not intended to in any way affect (A) the inclusion in Tax Expenses of the statutory two percent (2.0%) annual increase in Tax Expenses (as such statutory increase may be modified by subsequent legislation), or (B) the inclusion or exclusion of Tax Expenses pursuant to the terms of Proposition 13, which shall be governed pursuant to the terms of Sections 4.2.5.1 through 4.2.5.3, above.

4.2.6 "**Tenant's Share**" shall mean the percentage set forth in Section 6 of the Summary.

4.3 **<u>Allocation of Direct Expenses</u>**. The parties acknowledge that the Building is part of a multi-building commercial project consisting of the Building and the adjacent buildings and that certain of the costs and expenses incurred in connection with the Project (i.e. the Direct Expenses), as reasonably and equitably determined by Landlord, shall be shared among the Building and such other buildings, while certain other costs and expenses which are solely attributable to the Building or any such other buildings, as applicable, shall be allocated directly to the Building or any such other buildings, respectively. Accordingly, as set forth in Sections 4.1 and 4.2, above and as determined by Landlord on an equitable basis, some Direct Expenses shall be allocated to the Project as a whole, and some Direct Expenses shall be allocated only to the Building, and Tenant's Share shall be calculated for each such category of Direct Expenses.

4.4 **Calculation and Payment of Additional Rent**. If for any Expense Year after the Base Year ending or commencing within the Lease Term, Tenant's Share of Direct Expenses for such Expense Year exceeds Tenant's Share of Direct Expenses applicable to the Base Year, then Tenant shall pay to Landlord, in the manner set forth in Section 4.4.1, below, and as Additional Rent, an amount equal to the excess (the "**Excess**").

4.4.1 **Statement of Actual Direct Expenses and Payment by Tenant**. Landlord shall endeavor to give to Tenant following the end of each Expense Year, a statement (the "**Statement**") which shall state the Direct Expenses incurred or accrued for such preceding Expense Year, and which shall indicate the amount of the Excess. Upon receipt of the Statement for each Expense Year commencing or ending during the Lease Term, if an Excess is present, Tenant shall pay, with its next installment of Base Rent due, the full amount of the Excess for such Expense Year, less the amounts, if any, paid during such Expense Year as "Estimated Excess," as that term is defined in Section 4.4.2, below. The failure of Landlord to timely furnish the Statement for any Expense Year shall not prejudice Landlord or Tenant from enforcing its rights under this Article 4. Even though the Lease Term has expired and Tenant has vacated the Premises, when the final determination is made of Tenant's Share of Direct Expenses for the Expense Year in which this Lease terminates, if an Excess if present, Tenant shall immediately pay to Landlord such amount. The provisions of this Section 4.4.1 shall survive the expiration or earlier termination of the Lease Term.

4.4.2 **Statement of Estimated Direct Expenses**. In addition, Landlord shall endeavor to give Tenant a yearly expense estimate statement (the "**Estimate Statement**") which shall set forth Landlord's reasonable estimate (the "**Estimate**") of what the total amount of Direct Expenses for the then-current Expense Year shall be and the estimated excess (the "**Estimated Excess**") as calculated by comparing the Direct Expenses for such Expense Year, which shall be based upon the Estimate, to the amount of Direct Expenses for the Base Year. The failure of Landlord to timely furnish the Estimate Statement for any Expense Year shall not preclude Landlord from enforcing its rights to collect any Estimated Excess under this Article 4, nor shall Landlord be prohibited from revising any Estimate Statement or Estimated Excess theretofore delivered to the extent necessary. Thereafter, Tenant shall pay, with its next installment of Base Rent due, a fraction of the Estimated Excess for the then-current Expense Year (reduced by any amounts paid pursuant to the next to last sentence of this Section 4.4.2). Such fraction shall have as its numerator the number of months which have elapsed in such current Expense Year, including the month of such payment, and twelve (12) as its denominator. Until a new Estimate Statement is furnished (which Landlord shall have the right to deliver to Tenant at any time), Tenant shall pay monthly, with the monthly Base Rent installments, an amount equal to one-twelfth (1/12) of the total Estimated Excess set forth in the previous Estimate Statement delivered by Landlord to Tenant.

4.5 **Taxes and Other Charges for Which Tenant Is Directly Responsible**. Tenant shall be liable for and shall pay before delinquency, taxes levied against Tenant's equipment, furniture, fixtures and any other personal property located in or about the Premises. If any such taxes on Tenant's equipment, furniture, fixtures and any other personal property are levied against Landlord or Landlord's property or if the assessed value of Landlord's property is increased by the inclusion therein of a value placed upon such equipment, furniture, fixtures or any other personal property and if Landlord pays the taxes based upon such increased assessment, which Landlord shall have the right to do regardless of the validity thereof but only under proper protest if requested by Tenant, Tenant shall upon demand repay to Landlord the taxes so levied against Landlord or the proportion of such taxes resulting from such increase in the assessment, as the case may be. Notwithstanding any contrary provision herein, Tenant shall pay prior to delinquency any (i) rent tax or sales tax, service tax, transfer tax or value added tax, or any other applicable tax on the rent or services herein or otherwise respecting this Lease, (ii) taxes assessed upon or with respect to the possession, leasing, operation, management, maintenance, alteration, repair, use or occupancy by Tenant of the Premises or any portion of the Project, including the Project parking facility; or (iii) taxes assessed upon this transaction or any document to which Tenant is a party creating or transferring an interest or an estate in the Premises.

5. **USE OF PREMISES**. Tenant shall use the Premises solely for the Permitted Use set forth in Section 7 of the Summary and Tenant shall not use or permit the Premises or the Project to be used for any other purpose or purposes whatsoever without the prior written consent of Landlord, which may be withheld in Landlord's sole discretion. The uses prohibited under this Lease shall include, without limitation, use of the Premises or a portion thereof for (i) offices of any agency or bureau of the United States or any state or political subdivision thereof; (ii) offices or agencies of any foreign governmental or political subdivision thereof; (iii) offices of any health care professionals or service organization; (iv) schools or other training facilities which are not ancillary to corporate, executive or professional office use; (v) retail or restaurant uses; or (vi) communications firms such as radio and/or television stations. Tenant further covenants and agrees that Tenant shall not use, or suffer or permit any person or persons to use, the Premises or any part thereof for any use or purpose contrary to the provisions of the Rules and Regulations set forth in **Exhibit D**, attached hereto, or in violation of the laws of the United States of America, the State of California, or the ordinances, regulations or requirements of the local municipal or county governing body or other lawful authorities having jurisdiction over the Project) including, without limitation, any such laws, ordinances, regulations or requirements relating to hazardous materials or substances, as those terms are defined by applicable laws now or hereafter in effect. Tenant shall comply with all recorded covenants, conditions, and restrictions now or hereafter affecting the Project.

6. **SERVICES AND UTILITIES**.

6.1 **Standard Tenant Services**. Landlord shall provide the following services on all days (unless otherwise stated below) during the Lease Term.

6.1.1 Subject to limitations imposed by all governmental rules, regulations and guidelines applicable thereto, Landlord shall provide heating and air conditioning ("**HVAC**") when necessary for normal comfort for normal office use in the Premises from 8:00 A.M. to 6:00 P.M. Monday through Friday, and on Saturdays (by request, as more particularly set forth, below) from 9:00 A.M. to 1:00 P.M. (collectively, the "**Building Hours**"), except for the date of observation of New Year's Day, Presidents' Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, Christmas Day and, at Landlord's discretion, other locally or nationally recognized holidays (collectively, the "**Holidays**"). If Tenant desires to use heat, ventilation or air conditioning on any given Saturday, Tenant shall give Landlord such prior notice, if any, as Landlord shall from time to time establish as appropriate, of Tenant's desired use in order to supply such utilities.

6.1.2 Landlord shall provide adequate electrical wiring service capacity to the Premises for Tenant's lighting fixtures and incidental use equipment, provided that (i) the connected electrical load of the incidental use equipment does not exceed an average of three (3) watts per rentable square foot of the Premises during Building Hours, calculated on a monthly basis, and the electricity so furnished for incidental use equipment will be at a nominal one hundred twenty (120) volts and no electrical circuit for the supply of such incidental use equipment will require a current capacity exceeding twenty (20) amperes, and (ii) the connected electrical load of Tenant's lighting fixtures does not exceed an average of one (1) watt per rentable square foot of the Premises during Building Hours, calculated on a monthly basis, and the electricity so furnished for Tenant's lighting will be at a nominal two hundred seventy-seven (277) volts, which electrical usage shall be subject to applicable laws and regulations, including Title 24. Subject to the foregoing limitations regarding the electrical service capacity to be provided by Landlord, Landlord shall only provide electricity for Tenant's lighting fixtures during the Building Hours, excluding Holidays. Tenant will design Tenant's electrical system serving any equipment producing nonlinear electrical loads to accommodate such nonlinear electrical loads, including, but not limited to, oversizing neutral conductors, derating transformers and/or providing power-line filters. Engineering plans shall include a calculation of Tenant's fully connected electrical design load with and without demand factors and shall indicate the number of watts of unmetered and submetered loads. Tenant shall bear the cost of replacement of lamps, starters and ballasts for non-Building standard lighting fixtures within the Premises.

6.1.3 Landlord shall provide city water from the regular Building outlets for drinking, lavatory and toilet purposes in the Building Common Areas.

6.1.4 Landlord shall provide janitorial services to the Premises, except the date of observation of the Holidays, in and about the Premises and window washing services in a manner consistent with other comparable buildings in the vicinity of the Building.

6.1.5 Landlord shall provide nonexclusive, non-attended automatic passenger elevator service during the Building Hours, and shall have one elevator available at all other times.

6.1.6 Landlord shall provide nonexclusive freight elevator service subject to scheduling by Landlord.

6.1.7 Landlord shall maintain fire / life-safety systems for the Common Areas of the Project to the extent required by applicable laws to allow the legal occupancy of the Premises.

Tenant shall cooperate fully with Landlord at all times and abide by all regulations and requirements that Landlord may reasonably prescribe for the proper functioning and protection of the HVAC, electrical, mechanical and plumbing systems.

6.2 **Overstandard Tenant Use**. Tenant shall not, without Landlord's prior written consent, use heat-generating machines, equipment, or lighting other than Building standard lights in the Premises, which may affect the temperature otherwise maintained by the air conditioning system or increase the water normally furnished for the Premises by Landlord pursuant to the terms of Section 6.1 of this Lease. If such consent is given, Landlord shall have the right to install supplementary air conditioning units or other facilities in the Premises, including supplementary or additional metering devices, and the cost thereof, including the cost of installation, operation and maintenance, increased wear and tear on existing equipment and other similar charges, shall be paid by Tenant to Landlord upon billing by Landlord. If Tenant uses water, electricity, heat or air conditioning in excess of that supplied by Landlord pursuant to Section 6.1 of this Lease, Tenant shall pay to Landlord, upon billing, the cost of such excess consumption, the cost of the installation, operation, and maintenance of equipment which is installed in order to supply such excess consumption, and the cost of the increased wear and tear on existing equipment caused by such excess consumption; and Landlord may install devices to separately meter any increased use and in such event Tenant shall pay the increased cost directly to Landlord, on demand, at the rates charged by the public utility company furnishing the same, including the cost of such additional metering devices. Tenant's use of electricity shall never exceed the capacity of the feeders to the Project or the risers or wiring installation. If Tenant desires to use heat, ventilation or air conditioning during hours other than those for which Landlord is obligated to supply such utilities pursuant to the terms of Section 6.1 of this Lease, Tenant shall give Landlord such prior notice, if any, as Landlord shall from time to time establish as appropriate, of Tenant's desired use in order to supply such utilities, and Landlord shall supply such utilities to Tenant at such hourly cost to Tenant (which shall be treated as Additional Rent) as Landlord shall from time to time establish.

6.3 **Interruption of Use**. Tenant agrees that Landlord shall not be liable for damages, by abatement of Rent or otherwise, for failure to furnish or delay in furnishing any service (including telephone, telecommunication, and electrical services), or for any diminution in the quality or quantity thereof, when such failure or delay or diminution is occasioned, in whole or in part, by breakage, repairs, replacements, or improvements, by any strike, lockout or other labor trouble, by inability to secure electricity, gas, water, or other fuel at the Building or Project after reasonable effort to do so, by any riot or other dangerous condition, emergency, accident or casualty whatsoever, by act or default of Tenant or other parties, or by any other cause; and such failures or delays or diminution shall never be deemed to constitute an eviction or disturbance of Tenant's use and possession of the Premises or, except as provided in Section 6.5, below, relieve Tenant from paying Rent or performing any of its obligations under this Lease. Furthermore, Landlord shall not be liable under any circumstances for a loss of, or injury to, property or for injury to, or interference with, Tenant's business, including, without limitation, loss of profits, however occurring, through or in connection with or incidental to a failure to furnish any of the services or utilities as set forth in this

Article 6. Landlord may comply with voluntary controls or guidelines promulgated by any governmental entity relating to the use or conservation of energy, water, gas, light or electricity or the reduction of automobile or other emissions without creating any liability of Landlord to Tenant under this Lease, provided that the Premises are not thereby rendered untenantable.

6.4 **Failure of Services or Access**. In the event that Tenant is prevented from using, and does not use, the Premises or any portion thereof, as a result of (i) any repair, maintenance or alteration performed by Landlord, or which Landlord failed to perform, after the Lease Commencement Date and required by the Lease, which materially interferes with Tenant's use of the Premises, or (ii) any failure to provide services, utilities or access to the Premises (either such set of circumstances as set forth in items (i) or (ii), above, to be known as an "**Abatement Event**"), then Tenant shall give Landlord notice of such Abatement Event, and if such Abatement Event continues for five (5) consecutive business days after Landlord's receipt of any such notice (the "**Eligibility Period**"), then the Base Rent and Tenant's Share of Building Direct Expenses and Tenant's obligation to pay for parking shall be abated or reduced, as the case may be, after expiration of the Eligibility Period for such time that Tenant continues to be so prevented from using, and does not use, the Premises or a portion thereof, in the proportion that the rentable area of the portion of the Premises that Tenant is prevented from using, and does not use, bears to the total rentable area of the Premises; provided, however, in the event that Tenant is prevented from using, and does not use, a portion of the Premises for a period of time in excess of the Eligibility Period and the remaining portion of the Premises is not sufficient to allow Tenant to effectively conduct its business therein, and if Tenant does not conduct its business from such remaining portion, then for such time after expiration of the Eligibility Period during which Tenant is so prevented from effectively conducting its business therein, the Base Rent and Tenant's Share of Building Direct Expenses and Tenant's obligation to pay for parking for the entire Premises shall be abated for such time as Tenant continues to be so prevented from using, and does not use, the Premises. If, however, Tenant reoccupies any portion of the Premises during such period, the rent allocable to such reoccupied portion, based on the proportion that the rentable area of such reoccupied portion of the Premises bears to the total rentable area of the Premises, shall be payable by Tenant from the date Tenant reoccupies such portion of the Premises. Such right to abate Base Rent and Tenant's Share of Building Direct Expenses shall be Tenant's sole and exclusive rental abatement remedy at law or in equity for an Abatement Event.

7. REPAIRS. Subject to Articles 11 and 13 and this Article 7, Tenant shall, at Tenant's own expense, pursuant to the terms of this Lease, including without limitation Article 8 hereof, keep the Premises, including all improvements, fixtures and furnishings therein, in good order, repair and condition at all times during the Lease Term. In addition, subject to the terms of Article 11, below, Tenant shall, at Tenant's own expense, but under the supervision and subject to the prior approval of Landlord, and within any reasonable period of time specified by Landlord, pursuant to the terms of this Lease, including without limitation Article 8 hereof, promptly and adequately repair all damage to the Premises and replace or repair all damaged, broken, or worn fixtures and appurtenances, except for damage caused by casualty, ordinary wear and tear, casualty, condemnation or beyond the reasonable control of Tenant; provided however, that, at Landlord's option, or if Tenant fails to make such repairs, Landlord may, but need not, make such repairs and replacements, and Tenant shall pay Landlord the cost thereof, including a percentage of the cost thereof (to be uniformly established for the Building and/or the Project) sufficient to reimburse Landlord for all overhead, general conditions, fees and other costs or expenses arising from Landlord's involvement with such repairs and replacements forthwith upon being billed for same. Landlord may, but shall not be required to, enter the Premises at all reasonable times to make such repairs, alterations, improvements or additions to the Premises or to the Project or to any equipment located in the Project as Landlord shall desire or deem necessary or as Landlord may be required to do by governmental or quasi-governmental authority or court order or decree. Landlord shall repair and maintain in good order, condition and repair, the structural portions of the Project (including, without limitation, foundations, exterior walls, bearing walls and support beams), the exterior windows of the Project, the roof of the Project, the Building systems and Building equipment and the Common Areas of the Project; provided, however, to the extent such Landlord-required maintenance and repairs are required to be performed as a result of the negligence or willful misconduct or breach of this Lease by Tenant, its agents, employees or invitees, Tenant shall pay to Landlord as additional rent, the reasonable cost of such maintenance and repairs. Tenant hereby waives any and all rights under and benefits of subsection 1 of Section 1932 and Sections 1941 and 1942 of the California Civil Code or under any similar law, statute, or ordinance now or hereafter in effect.

8. ADDITIONS AND ALTERATIONS.

8.1 **Landlord's Consent to Alterations**. Tenant may not make any improvements, alterations, additions or changes to the Premises or any mechanical, plumbing or HVAC facilities or systems pertaining to the Premises (collectively, the "**Alterations**") without first procuring the prior written consent of Landlord to such Alterations, which consent shall be requested by Tenant not less than thirty (30) days prior to the commencement thereof, and which consent shall not be unreasonably withheld by Landlord, provided it shall be deemed reasonable for Landlord to withhold its consent to any Alteration which adversely affects the structural portions or the systems or equipment of the Building or is visible from the exterior of the Building. For the avoidance of doubt, Alterations shall not include ordinary decoration or hanging of artwork.

8.2 **Manner of Construction**. Landlord may impose, as a condition of its consent to any and all Alterations or repairs of the Premises or about the Premises, such requirements as Landlord in its sole discretion may deem desirable, including, but not limited to, the requirement that Tenant utilize for such purposes only contractors, subcontractors, materials, mechanics and materialmen selected by Tenant from a list provided and approved by Landlord, the requirement that upon Landlord's request, Tenant shall, at Tenant's expense, remove such Alterations upon the expiration or any early termination of the Lease Term, the requirement that all Alterations conform in terms of quality and style to the building's standards established by Landlord, and the requirement that all Alterations comply with Landlord's most recent Construction and Greening Policies/Plans as provided to Tenant from Landlord. If such Alterations will involve the use of or disturb hazardous materials or substances existing in the Premises, Tenant shall comply with Landlord's rules and regulations concerning such hazardous materials or substances. Tenant shall construct such Alterations and perform such repairs in a good and workmanlike manner, in conformance with any and all applicable federal, state, county or municipal laws, rules and regulations and pursuant to a valid building permit, issued by the City of Los Angeles, all in conformance with Landlord's construction rules and regulations. In the event Tenant performs any Alterations in the Premises which require or give rise to governmentally required changes to the "Base Building," as that term is defined below, then Landlord shall, at Tenant's expense, make such changes to the Base Building. The "**Base Building**" shall include the structural portions of the Building, and the public restrooms and the systems and equipment located in the internal core of the Building on the floor or floors on which the Premises are located. In performing the work of any such Alterations, Tenant shall have the work performed in such manner so as not to obstruct access to the Project or any portion thereof, by any other tenant of the Project, and so as not to obstruct the business of Landlord or other tenants in the Project. Tenant shall not use (and upon notice from Landlord shall cease using) contractors, services, workmen, labor, materials or equipment that, in Landlord's reasonable judgment, would disturb labor harmony with the workforce or trades engaged in performing other work, labor or services in or about the Building or the Common Areas. In addition to Tenant's obligations under Article 9 of this Lease, upon completion of any Alterations, Tenant agrees to cause a Notice of Completion to be recorded in the office of the Recorder of the County of Los Angeles in accordance with Section 3093 of the Civil Code of the State of California or any successor statute, and Tenant shall deliver to the Project management office a reproducible copy of the "as built" drawings of the Alterations as well as all permits, approvals and other documents issued by any governmental agency in connection with the Alterations.

8.3 **Payment for Improvements**. If payment is made directly to contractors, Tenant shall comply with Landlord's requirements for final lien releases and waivers in connection with Tenant's payment for work to contractors. Whether or not Tenant orders any work directly from Landlord, Tenant shall pay to Landlord a percentage of the cost of such work sufficient to compensate Landlord for all overhead, general conditions, fees and other costs and expenses arising from Landlord's involvement with such work.

8.4 **Construction Insurance**. In addition to the requirements of Article 10 of this Lease, in the event that Tenant makes any Alterations, prior to the commencement of such Alterations, Tenant shall provide Landlord with evidence that Tenant carries "Builder's All Risk" insurance in an amount approved by

Landlord covering the construction of such Alterations, and such other insurance as Landlord may require, it being understood and agreed that all of such Alterations shall be insured by Tenant pursuant to Article 10 of this Lease immediately upon completion thereof. In addition, Landlord may, in its discretion, require Tenant to obtain a lien and completion bond or some alternate form of security satisfactory to Landlord in an amount sufficient to ensure the lien-free completion of such Alterations and naming Landlord as a co-obligee.

8.5 **Landlord's Property**. All Alterations, improvements, fixtures, equipment and/or appurtenances which may be installed or placed in or about the Premises, from time to time, shall be at the sole cost of Tenant and shall be and become the property of Landlord, except that Tenant may remove any Alterations, improvements, fixtures and/or equipment which Tenant can substantiate to Landlord have not been paid for with any Tenant improvement allowance funds provided to Tenant by Landlord, provided Tenant repairs any damage to the Premises and Building caused by such removal and returns the affected portion of the Premises to a building standard tenant improved condition as determined by Landlord. Furthermore, Landlord may, by written notice to Tenant prior to the end of the Lease Term, or given following any earlier termination of this Lease, require Tenant, at Tenant's expense, to remove any Alterations or improvements in the Premises, and to repair any damage to the Premises and Building caused by such removal and returns the affected portion of the Premises to a building standard tenant improved condition as determined by Landlord. If Tenant fails to complete such removal and/or to repair any damage caused by the removal of any Alterations or improvements in the Premises, and return the affected portion of the Premises to a building standard tenant improved condition as determined by Landlord, then at Landlord's option, either (A) Tenant shall be deemed to be holding over in the Premises and Rent shall continue to accrue in accordance with the terms of Article 16, below, until such work shall be completed, or (B) Landlord may do so and may charge the cost thereof to Tenant. Tenant hereby protects, defends, indemnifies and holds Landlord harmless from any liability, cost, obligation, expense or claim of lien in any manner relating to the installation, placement, removal or financing of any such Alterations, improvements, fixtures and/or equipment in, on or about the Premises, which obligations of Tenant shall survive the expiration or earlier termination of this Lease.

9. COVENANT AGAINST LIENS. Tenant shall keep the Project and Premises free from any liens or encumbrances arising out of the work performed, materials furnished or obligations incurred by or on behalf of Tenant, and shall protect, defend, indemnify and hold Landlord harmless from and against any claims, liabilities, judgments or costs (including, without limitation, reasonable attorneys' fees and costs) arising out of same or in connection therewith. Tenant shall give Landlord notice at least twenty (20) days prior to the commencement of any such work on the Premises (or such additional time as may be necessary under applicable laws) to afford Landlord the opportunity of posting and recording appropriate notices of non-responsibility. Tenant shall remove any such lien or encumbrance by bond or otherwise within five (5) days after notice by Landlord, and if Tenant shall fail to do so, Landlord may pay the amount necessary to remove such lien or encumbrance, without being responsible for investigating the validity thereof. The amount so paid shall be deemed Additional Rent under this Lease payable upon demand, without limitation as to other remedies available to Landlord under this Lease. Nothing contained in this Lease shall authorize Tenant to do any act which shall subject Landlord's title to the Building or Premises to any liens or encumbrances whether claimed by operation of law or express or implied contract. Any claim to a lien or encumbrance upon the Building or Premises arising in connection with any such work or respecting the Premises not performed by or at the request of Landlord shall be null and void, or at Landlord's option shall attach only against Tenant's interest in the Premises and shall in all respects be subordinate to Landlord's title to the Project, Building and Premises.

10. INSURANCE.

10.1 **Indemnification and Waiver**. Except to the extent caused by Landlord's negligence or willful misconduct, Tenant hereby assumes all risk of damage to property or injury to persons in, upon or about the Premises from any cause whatsoever and agrees that Landlord, its partners, subpartners and their respective officers, agents, servants, employees, and independent contractors (collectively, "**Landlord Parties**") shall not be liable for, and are hereby released from any responsibility for, any damage either to person or property or resulting from the loss of use thereof, which damage is sustained by Tenant or by other persons claiming through Tenant. Tenant shall indemnify, defend, protect, and hold harmless the Landlord Parties from any and all loss, cost, damage, expense and liability (including without limitation court costs and reasonable attorneys' fees) incurred in connection with or arising from any cause in, on or about the Premises, any violation of any of the requirements, ordinances, statutes, regulations or other laws, including, without limitation, any environmental laws, any acts, omissions or negligence of Tenant or of any person claiming by, through or under Tenant, or of the contractors, agents, servants, employees, invitees, guests or licensees of Tenant or any such person, in, on or about the Project or any breach of the terms of this Lease, either prior to, during, or after the expiration of the Lease Term, provided that the terms of the foregoing indemnity shall not apply to the negligence or willful misconduct of Landlord. Should Landlord be named as a defendant in any suit brought against Tenant in connection with or arising out of Tenant's occupancy of the Premises, Tenant shall pay to Landlord its costs and expenses incurred in such suit, including without limitation, its actual professional fees such as appraisers', accountants' and attorneys' fees. Further, Tenant's agreement to indemnify Landlord pursuant to this Section 10.1 is not intended and shall not relieve any insurance carrier of its obligations under policies required to be carried by Tenant pursuant to the provisions of this Lease, to the extent such policies cover the matters subject to Tenant's indemnification obligations; nor shall they supersede any inconsistent agreement of the parties set forth in any other provision of this Lease. The provisions of this Section 10.1 shall survive the expiration or sooner termination of this Lease with respect to any claims or liability arising in connection with any event occurring prior to such expiration or termination.

10.2 **Landlord's Insurance**. Landlord shall carry commercial general liability insurance with respect to the Building during the Lease Term, and shall further insure the Building and the Project during the Lease Term (for the full replacement value to the extent such coverage is reasonably available) against loss or damage due to fire and other casualties covered within the classification of fire and extended coverage, vandalism coverage and malicious mischief, sprinkler leakage, water damage and special extended coverage, and such policy shall include a customary rental loss endorsement. Such coverage shall be in such amounts, from such companies, and on such other terms and conditions, as Landlord may from time to time reasonably determine. Additionally, at the option of Landlord, or as required by any lender, such insurance coverage may include the risks of earthquakes and/or flood damage, terrorist acts and additional hazards, and one or more loss payee endorsements in favor of the holders of any mortgages or deeds of trust encumbering the interest of Landlord in the Building or the ground or underlying lessors of the Building, or any portion thereof. Landlord may meet any of the foregoing requirements through primary coverage combined with umbrella coverage and may include a reasonable self-insured retention. Tenant shall, at Tenant's expense, comply with all insurance company requirements pertaining to the use of the Premises. If Tenant's conduct or use of the Premises causes any increase in the premium for such insurance policies then Tenant shall reimburse Landlord for any such increase. Tenant, at Tenant's expense, shall comply with all rules, orders, regulations or requirements of the American Insurance Association (formerly the National Board of Fire Underwriters) and with any similar body.

10.3 **Tenant's Insurance**. Tenant shall maintain the following coverages in the following amounts.

10.3.1 Commercial General Liability Insurance covering the insured against claims of bodily injury, personal injury and property damage (including loss of use thereof) arising out of Tenant's operations, and contractual liabilities (covering the performance by Tenant of its indemnity agreements) including a Broad Form endorsement covering the insuring provisions of this Lease and the performance by Tenant of the indemnity agreements set forth in Section 10.1 of this Lease, for limits of liability not less than:

Bodily Injury and Property Damage Liability	\$2,000,000 each occurrence \$2,000,000 annual aggregate
Personal Injury Liability	\$2,000,000 each occurrence \$2,000,000 annual aggregate 0% Insured's participation

10.3.2 Physical Damage Insurance covering (i) all office furniture, business and trade fixtures, office equipment, free-standing cabinet work, movable partitions, merchandise and all other items of Tenant's property on the Premises installed by, for, or at the expense of Tenant, (ii) the improvements which exist in the Premises as of the Lease Commencement Date (excluding the Base Building) (the "**Original Improvements**"), and (iii) all other improvements, alterations and additions to the Premises. Such insurance shall be written on an "all risks" of physical loss or damage basis, for the full replacement cost value (subject to reasonable deductible amounts) new without deduction for depreciation of the covered items and in amounts that meet any co-insurance clauses of the policies of insurance and shall include coverage for damage or other loss caused by fire or other peril including, but not limited to, vandalism and malicious mischief, theft, water damage of any type, including sprinkler leakage, bursting or stoppage of pipes, and explosion, and providing business interruption coverage for a period of one year.

10.3.3 Worker's Compensation and Employer's Liability or other similar insurance pursuant to all applicable state and local statutes and regulations.

10.4 **Form of Policies**. The minimum limits of policies of insurance required of Tenant under this Lease shall in no event limit the liability of Tenant under this Lease. Such insurance shall (i) name Landlord, Landlord's lender, and any other party the Landlord so specifies, as an additional insured, including Landlord's managing agent, if any; (ii) specifically cover the liability assumed by Tenant under this Lease, including, but not limited to, Tenant's obligations under Section 10.1 of this Lease; (iii) be issued by an insurance company having a rating of not less than A-X in Best's Insurance Guide or which is otherwise acceptable to Landlord and licensed to do business in the State of California; (iv) be primary insurance as to all claims thereunder and provide that any insurance carried by Landlord is excess and is non-contributing with any insurance requirement of Tenant; (v) be in form and content reasonably acceptable to Landlord; and (vi) provide that said insurance shall not be canceled or coverage changed unless thirty (30) days' prior written notice shall have been given to Landlord and any mortgagee of Landlord. Tenant shall deliver said policy or policies or certificates thereof to Landlord on or before the Lease Commencement Date and at least thirty (30) days before the expiration dates thereof. In the event Tenant shall fail to procure such insurance, or to deliver such policies or certificate, Landlord may, at its option, procure such policies for the account of Tenant, and the cost thereof shall be paid to Landlord within five (5) days after delivery to Tenant of bills therefor.

10.5 **Subrogation**. Landlord and Tenant intend that their respective property loss risks shall be borne by reasonable insurance carriers to the extent above provided, and Landlord and Tenant hereby agree to look solely to, and seek recovery only from, their respective insurance carriers in the event of a property loss to the extent that such coverage is agreed to be provided hereunder. Notwithstanding anything herein to the contrary, the parties each hereby waive all rights and claims against each other for, and release each other from, any loss which results from a risk insurable under policies of property damage insurance or which is actually insured against at the time of such loss, and waive all rights of subrogation of their respective insurers, provided such waiver of subrogation shall not affect the right to the insured to recover thereunder. The parties agree that their respective insurance policies are now, or shall be, endorsed such that the waiver of subrogation shall not affect the right of the insured to recover thereunder. All of Landlord's and Tenant's repair and indemnity obligations under this Lease shall be subject to the waiver and release contained in this paragraph.

10.6 **Additional Insurance Obligations**. Tenant shall carry and maintain during the entire Lease Term, at Tenant's sole cost and expense, increased amounts of the insurance required to be carried by Tenant pursuant to this Article 10 and such other reasonable types of insurance coverage and in such reasonable amounts covering the Premises and Tenant's operations therein, as may be reasonably requested by Landlord.

11. DAMAGE AND DESTRUCTION.

11.1 **Repair of Damage to Premises by Landlord**. Tenant shall promptly notify Landlord of any damage to the Premises resulting from fire or any other casualty. If the Premises or any Common Areas serving or providing access to the Premises shall be damaged by fire or other casualty, Landlord shall promptly and diligently, subject to reasonable delays for insurance adjustment or other matters beyond Landlord's reasonable control, and subject to all other terms of this Article 11, restore the Base Building and such Common Areas. Such restoration shall be to substantially the same condition of the Base Building and the Common Areas prior to the casualty, except for modifications required by zoning and building codes and other laws or by the holder of a mortgage on the Building or Project or any other modifications to the Common Areas deemed desirable by Landlord, provided that access to the Premises and any common restrooms serving the Premises shall not be materially impaired. Upon the occurrence of any damage to the Premises, upon notice (the "**Landlord Repair Notice**") to Tenant from Landlord, Tenant shall assign to Landlord (or to any party designated by Landlord) all insurance proceeds payable to Tenant under Tenant's insurance required under Section 10.3 of this Lease, and Landlord shall repair any injury or damage to the Original Improvements installed in the Premises and shall return such Original Improvements to their original condition; provided that if the cost of such repair by Landlord exceeds the amount of insurance proceeds received by Landlord from Tenant's insurance carrier, as assigned by Tenant, the cost of such repairs shall be paid by Tenant to Landlord prior to Landlord's commencement of repair of the damage. In the event that Landlord does not deliver the Landlord Repair Notice within sixty (60) days following the date the casualty becomes known to Landlord, Tenant shall, at its sole cost and expense, repair any injury or damage to the Original Improvements installed in the Premises and shall return such Original Improvements to their original condition. Whether or not Landlord delivers a Landlord Repair Notice, prior to the commencement of construction, Tenant shall submit to Landlord, for Landlord's review and approval, all plans, specifications and working drawings relating thereto, and Landlord shall select the contractors to perform such improvement work. Landlord shall not be liable for any inconvenience or annoyance to Tenant or its visitors, or injury to Tenant's business resulting in any way from such damage or the repair thereof; provided however, that if such fire or other casualty shall have damaged the Premises or Common Areas necessary to Tenant's occupancy, Landlord shall allow Tenant a proportionate abatement of Rent to the extent Landlord is reimbursed from the proceeds of rental interruption insurance purchased by Landlord as part of Operating Expenses, during the time and to the extent the Premises are unfit for occupancy for the purposes permitted under this Lease, and not occupied by Tenant as a result thereof; provided, further, however, that if the damage or destruction is due to the negligence or willful misconduct of Tenant or any of its agents, employees, contractors, invitees or guests, Tenant shall be responsible for any reasonable, applicable insurance deductible (which shall be payable to Landlord upon demand). In the event that Landlord shall not deliver the Landlord Repair Notice, Tenant's right to rent abatement pursuant to the preceding sentence shall terminate as of the date which is reasonably determined by Landlord to be the date Tenant should have completed repairs to the Premises assuming Tenant used reasonable due diligence in connection therewith.

11.2 **Landlord's Option to Repair**. Notwithstanding the terms of Section 11.1 of this Lease, Landlord may elect not to rebuild and/or restore the Premises, Building and/or Project, and instead terminate this Lease, by notifying Tenant in writing of such termination within sixty (60) days after the date of discovery of the damage, such notice to include a termination date giving Tenant sixty (60) days to vacate the Premises, but Landlord may so elect only if the Building or Project shall be damaged by fire or other casualty or cause, whether or not the Premises are affected, and one or more of the following conditions is present: (i) in Landlord's reasonable judgment, repairs cannot reasonably be completed within ninety (90) days after the date of discovery of the damage (when such repairs are made without the payment of overtime or other premiums); (ii) the holder of any mortgage on the Building or Project or ground lessor with respect to the Building or Project shall require that the insurance proceeds or any portion thereof be used to retire the mortgage debt, or shall terminate the ground lease, as the case may be; (iii) the damage is not fully covered by Landlord's insurance policies; or (iv) Landlord decides to rebuild the Building or Common Areas so that they will be substantially different structurally or architecturally; or (v) the damage occurs during the last twelve (12) months of the Lease Term. Additionally, if Landlord does not elect to terminate the Lease as provided in this Section 11.2, and either (a) the damage occurs during the last twelve (12) months of the Lease Term, or (b) repairs cannot reasonably be completed within one hundred eighty (180) days after being commenced, then in either such case Tenant shall have the right to terminate this Lease by written notice to Landlord given within forty-five (45) days after the date of such damage.

11.3 **Waiver of Statutory Provisions**. The provisions of this Lease, including this Article 11, constitute an express agreement between Landlord and Tenant with respect to any and all damage to, or destruction of, all or any part of the Premises, the Building or the Project, and any statute or regulation of the State of California, including, without limitation, Sections 1932(2) and 1933(4) of the California Civil Code, with respect to any rights or obligations concerning damage or destruction in the absence of an express agreement between the parties, and any other statute or regulation, now or hereafter in effect, shall have no application to this Lease or any damage or destruction to all or any part of the Premises, the Building or the Project.

12. **NONWAIVER**. No provision of this Lease shall be deemed waived by either party hereto unless expressly waived in a writing signed thereby. The waiver by either party hereto of any breach of any term, covenant or condition herein contained shall not be deemed to be a waiver of any subsequent breach of same or any other term, covenant or condition herein contained. The subsequent acceptance of Rent hereunder by Landlord shall not be deemed to be a waiver of any preceding breach by Tenant of any term, covenant or condition of this Lease, other than the failure of Tenant to pay the particular Rent so accepted, regardless of Landlord's knowledge of such preceding breach at the time of acceptance of such Rent. No acceptance of a lesser amount than the Rent herein stipulated shall be deemed a waiver of Landlord's right to receive the full amount due, nor shall any endorsement or statement on any check or payment or any letter accompanying such check or payment be deemed an accord and satisfaction, and Landlord may accept such check or payment without prejudice to Landlord's right to recover the full amount due. No receipt of monies by Landlord from Tenant after the termination of this Lease shall in any way alter the length of the Lease Term or of Tenant's right of possession hereunder, or after the giving of any notice shall reinstate, continue or extend the Lease Term or affect any notice given Tenant prior to the receipt of such monies, it being agreed that after the service of notice or the commencement of a suit, or after final judgment for possession of the Premises, Landlord may receive and collect any Rent due, and the payment of said Rent shall not waive or affect said notice, suit or judgment.

13. **CONDEMNATION**. If the whole or any part of the Premises, Building or Project shall be taken by power of eminent domain or condemned by any competent authority for any public or quasi-public use or purpose, or if any adjacent property or street shall be so taken or condemned, or reconfigured or vacated by such authority in such manner as to require the use, reconstruction or remodeling of any part of the Premises, Building or Project, or if Landlord shall grant a deed or other instrument in lieu of such taking by eminent domain or condemnation, Landlord shall have the option to terminate this Lease effective as of the date possession is required to be surrendered to the authority. Tenant shall not because of such taking assert any claim against Landlord or the authority for any compensation because of such taking and Landlord shall be entitled to the entire award or payment in connection therewith. All Rent shall be apportioned as of the date of such termination. If any part of the Premises shall be taken, and this Lease shall not be so terminated, the Rent shall be proportionately abated. Tenant hereby waives any and all rights it might otherwise have pursuant to Section 1265.130 of The California Code of Civil Procedure. Notwithstanding anything to the contrary contained in this Article 13, in the event of a temporary taking of all or any portion of the Premises for a period of one hundred and eighty (180) days or less, then this Lease shall not terminate but the Base Rent and the Additional Rent shall be abated for the period of such taking in proportion to the ratio that the amount of rentable square feet of the Premises taken bears to the total rentable square feet of the Premises. Landlord shall be entitled to receive the entire award made in connection with any such temporary taking.

14. **ASSIGNMENT AND SUBLETTING**.

14.1 **Transfers**. Tenant shall not, without the prior written consent of Landlord, assign, mortgage, pledge, hypothecate, encumber, or permit any lien to attach to, or otherwise transfer, this Lease or any interest hereunder, permit any assignment, or other transfer of this Lease or any interest hereunder by operation of law, sublet the Premises or any part thereof, or enter into any license or concession agreements or otherwise permit the occupancy or use of the Premises or any part thereof by any persons other than Tenant and its employees and contractors (all of the foregoing are hereinafter sometimes referred to collectively as "**Transfers**" and any person to whom any Transfer is made or sought to be made is hereinafter sometimes referred to as a "**Transferee**"). If Tenant desires Landlord's consent to any Transfer, Tenant shall notify Landlord in writing, which notice (the "**Transfer Notice**") shall include (i) the proposed effective date of the Transfer, which shall not be less than thirty (30) days nor more than one hundred eighty (180) days after the date of delivery of the Transfer Notice, (ii) a description of the portion of the Premises to be transferred (the "**Subject Space**"), (iii) all of the terms of the proposed Transfer and the consideration therefor, including calculation of the "Transfer Premium", as that term is defined in Section 14.3 below, in connection with such Transfer, the name and address of the proposed Transferee, and an executed copy of all documentation effectuating the proposed Transfer, including all operative documents to evidence such Transfer and all agreements incidental or related to such Transfer, provided that Landlord shall have the right to require Tenant to utilize Landlord's standard consent documents in connection with the documentation of such Transfer, (iv) current financial statements of the proposed Transferee certified by an officer, partner or owner thereof, business credit and personal references and history of the proposed Transferee and any other information reasonably required by Landlord which will enable Landlord to determine the financial responsibility, character, and reputation of the proposed Transferee, nature of such Transferee's business and proposed use of the Subject Space. Any Transfer made without Landlord's prior written consent shall, at Landlord's option, be null, void and of no effect, and shall, at Landlord's option, constitute a default by Tenant under this Lease. Whether or not Landlord consents to any proposed Transfer, Tenant shall pay Landlord's review and processing fees, as well as any reasonable professional fees (including, without limitation, attorneys', accountants', architects', engineers' and consultants' fees) incurred by Landlord, within thirty (30) days after written request by Landlord; provided, however, that in no event shall Tenant be required to pay any such fees in excess of $2,500 in the aggregate, per request.

14.2 **Landlord's Consent**. Landlord shall not unreasonably withhold, condition or delay its consent to any proposed Transfer of the Subject Space to the Transferee on the terms specified in the Transfer Notice. Without limitation as to other reasonable grounds for withholding consent, the parties hereby agree that it shall be reasonable under this Lease and under any applicable law for Landlord to withhold consent to any proposed Transfer where one or more of the following apply:

14.2.1 The Transferee is of a character or reputation or engaged in a business which is not consistent with the quality of the Building or the Project, or would be a significantly less prestigious occupant of the Building than Tenant;

14.2.2 The Transferee intends to use the Subject Space for purposes which are not permitted under this Lease;

14.2.3 The Transferee is either a governmental agency or instrumentality thereof;

14.2.4 The Transferee is not a party of reasonable financial worth and/or financial stability in light of the responsibilities to be undertaken in connection with the Transfer on the date consent is requested;

14.2.5 The proposed Transfer would cause a violation of another lease for space in the Project, or would give an occupant of the Project a right to cancel its lease;

14.2.6 The terms of the proposed Transfer will allow the Transferee to exercise a right of renewal, right of expansion, right of first offer, or other similar right held by Tenant; or

14.2.7 Either the proposed Transferee, or any person or entity which directly or indirectly, controls, is controlled by, or is under common control with, the proposed Transferee, (i) occupies space in the Project at the time of the request for consent, or (ii) is negotiating with Landlord to lease space in the Project at such time, or (iii) has negotiated with Landlord during the twelve (12)-month period immediately preceding the Transfer Notice; or

14.2.8 The Transferee does not intend to occupy the entire Premises and conduct its business therefrom for a substantial portion of the term of the Transfer.

If Landlord consents to any Transfer pursuant to the terms of this Section 14.2 (and does not exercise any recapture rights Landlord may have under Section 14.4 of this Lease), Tenant may within six (6) months after Landlord's consent, but not later than the expiration of said six-month period, enter into such Transfer of the Premises or portion thereof, upon substantially the same terms and conditions as are set forth in the Transfer Notice furnished by Tenant to Landlord pursuant to Section 14.1 of this Lease, provided that if there are any changes in the terms and conditions from those specified in the Transfer Notice (i) such that Landlord would initially have been entitled to refuse its consent to such Transfer under this Section 14.2, or (ii) which would cause the proposed Transfer to be materially more favorable to the Transferee than the terms set forth in Tenant's original Transfer Notice, Tenant shall again submit the Transfer to Landlord for its approval and other action under this Article 14 (including Landlord's right of recapture, if any, under Section 14.4 of this Lease). Notwithstanding anything to the contrary in this Lease, Tenant hereby waives all other remedies, including, without limitation, any right at law or equity to terminate this Lease, on its own behalf and, to the extent permitted under all applicable laws, on behalf of the proposed Transferee, in connection with any claims by Tenant or such Proposed Transferee that Landlord has unreasonably withheld or delayed its consent under Section 14.2 or otherwise has breached or acted unreasonably under this Article 14.

14.3 **Transfer Premium**. If Landlord consents to a Transfer, as a condition thereto which the parties hereby agree is reasonable, Tenant shall pay to Landlord fifty percent (50%) of any "Transfer Premium," as that term is defined in this Section 14.3, received by Tenant from such Transferee. "**Transfer Premium**" shall mean all rent, additional rent or other consideration paid to Tenant by such Transferee in connection with the Transfer in excess of the Rent and Additional Rent payable by Tenant under this Lease during the term of the Transfer on a per rentable square foot basis if less than all of the Premises is transferred, after deducting the reasonable expenses incurred by Tenant for (i) any free base rent reasonably provided to the Transferee, and (ii) any brokerage commissions, legal fees or improvement allowances paid by Tenant in connection with the Transfer. "Transfer Premium" shall also include, but not be limited to, key money, bonus money or other cash consideration paid by Transferee to Tenant in connection with such Transfer, and any payment in excess of fair market value for services rendered by Tenant to Transferee or for assets, fixtures, inventory, equipment, or furniture transferred by Tenant to Transferee in connection with such Transfer. In the calculations of the Rent (as it relates to the Transfer Premium calculated under this Section 14.3), the Rent paid during each annual period for the Subject Space shall be computed after adjusting such rent to the actual effective rent to be paid, taking into consideration any and all leasehold concessions granted in connection therewith, including, but not limited to, any rent credit and tenant improvement allowance. For purposes of calculating any such effective rent all such concessions shall be amortized on a straight-line basis over the relevant term.

14.4 **Landlord's Option as to Subject Space**. Notwithstanding anything to the contrary contained in this Article 14, if Tenant proposes to Transfer all or substantially all of the Premises for all or substantially all of the remaining Lease Term, Landlord shall have the option, by giving written notice to Tenant within thirty (30) days after receipt of any Transfer Notice, to recapture the Subject Space. Such recapture notice shall cancel and terminate this Lease with respect to the Subject Space as of the date stated in the Transfer Notice as the effective date of the proposed Transfer until the last day of the term of the Transfer as set forth in the Transfer Notice (or at Landlord's option, shall cause the Transfer to be made to Landlord or its agent, in which case the parties shall execute the Transfer documentation promptly thereafter). In the event of a recapture by Landlord, if this Lease shall be canceled with respect to less than the entire Premises, the Rent reserved herein shall be prorated on the basis of the number of rentable square feet retained by Tenant in proportion to the number of rentable square feet contained in the Premises, and this Lease as so amended shall continue thereafter in full force and effect, and upon request of either party, the parties shall execute written confirmation of the same. If Landlord declines, or fails to elect in a timely manner to recapture the Subject Space under this Section 14.4, then, provided Landlord has consented to the proposed Transfer, Tenant shall be entitled to proceed to transfer the Subject Space to the proposed Transferee, subject to provisions of this Article 14.

14.5 **Effect of Transfer**. If Landlord consents to a Transfer, (i) the terms and conditions of this Lease shall in no way be deemed to have been waived or modified, (ii) such consent shall not be deemed consent to any further Transfer by either Tenant or a Transferee, (iii) Tenant shall deliver to Landlord, promptly after execution, an original executed copy of all documentation pertaining to the Transfer in form reasonably acceptable to Landlord, (iv) Tenant shall furnish upon Landlord's request a complete statement, certified by an independent certified public accountant, or Tenant's chief financial officer, setting forth in detail the computation of any Transfer Premium Tenant has derived and shall derive from such Transfer, and (v) no Transfer relating to this Lease or agreement entered into with respect thereto, whether with or without Landlord's consent, shall relieve Tenant or any guarantor of the Lease from any liability under this Lease, including, without limitation, in connection with the Subject Space. Landlord or its authorized representatives shall have the right at all reasonable times to audit the books, records and papers of Tenant relating to any Transfer, and shall have the right to make copies thereof. If the Transfer Premium respecting any Transfer shall be found understated, Tenant shall, within thirty (30) days after demand, pay the deficiency, and if understated by more than two percent (2%), Tenant shall pay Landlord's costs of such audit.

14.6 **Occurrence of Default**. Any Transfer hereunder shall be subordinate and subject to the provisions of this Lease, and if this Lease shall be terminated during the term of any Transfer, Landlord shall have the right to: (i) treat such Transfer as cancelled and repossess the Subject Space by any lawful means, or (ii) require that such Transferee attorn to and recognize Landlord as its landlord under any such Transfer. If Tenant shall be in default beyond applicable notice and cure periods under this Lease, Landlord is hereby irrevocably authorized to direct any Transferee to make all payments under or in connection with the Transfer directly to Landlord (which Landlord shall apply towards Tenant's obligations under this Lease) until such default is cured. Such Transferee shall rely on any representation by Landlord that Tenant is in default hereunder, without any need for confirmation thereof by Tenant. Upon any assignment, the assignee shall assume in writing all obligations and covenants of Tenant thereafter to be performed or observed under this Lease. No collection or acceptance of rent by Landlord from any Transferee shall be deemed a waiver of any provision of this Article 14 or the approval of any Transferee or a release of Tenant from any obligation under this Lease, whether theretofore or thereafter accruing. In no event shall Landlord's enforcement of any provision of this Lease against any Transferee be deemed a waiver of Landlord's right to enforce any term of this Lease against Tenant or any other person. If Tenant's obligations hereunder have been guaranteed, Landlord's consent to any Transfer shall not be effective unless the guarantor also consents to such Transfer.

14.7 **Non-Transfers**. Notwithstanding anything to the contrary contained in this Article 14, neither (i) an assignment to a transferee of all or substantially all of the assets of Tenant, (ii) an assignment of the Premises to a transferee which is the resulting entity of a merger or consolidation of Tenant with another entity, nor (iii) an assignment or subletting of all or a portion of the Premises to an affiliate of Tenant (an entity which is controlled by, controls, or is under common control with, Tenant), shall be deemed a Transfer under Article 14 of this Lease provided that (A) Tenant notifies Landlord of any such assignment or sublease and promptly supplies Landlord with any documents or information reasonably requested by Landlord regarding such transfer or transferee as set forth in items (i) through (iii) above, (B) the resulting transferee shall have a tangible net worth, as determined by generally accepted accounting principles, that is at least equal to the greater of Tenant's net worth at the date of this Lease, or Tenant's net worth immediately prior to such transfer, and (C) that such assignment or sublease is not a subterfuge by Tenant to avoid its obligations under this Lease. "**Control**," as used in this Section 14.8, shall mean the ownership, directly or indirectly, of at least fifty-one percent (51%) of the voting securities of, or possession of the right to vote, in the ordinary direction of its affairs, of at least fifty-one percent (51%) of the voting interest in, any person or entity.

15. SURRENDER OF PREMISES; OWNERSHIP AND REMOVAL OF TRADE FIXTURES.

15.1 **Surrender of Premises**. No act or thing done by Landlord or any agent or employee of Landlord during the Lease Term shall be deemed to constitute an acceptance by Landlord of a surrender of the Premises unless such intent is specifically acknowledged in writing by Landlord. The delivery of keys to the Premises to Landlord or any agent or employee of Landlord shall not constitute a surrender of the Premises or effect a termination of this Lease, whether or not the keys are thereafter retained by Landlord, and notwithstanding such delivery Tenant shall be entitled to the return of such keys at any reasonable time upon request until this Lease shall have been properly terminated. The voluntary or other surrender of this

Lease by Tenant, whether accepted by Landlord or not, or a mutual termination hereof, shall not work a merger, and at the option of Landlord shall operate as an assignment to Landlord of all subleases or subtenancies affecting the Premises or terminate any or all such sublessees or subtenancies.

15.2 **Removal of Tenant Property by Tenant**. Upon the expiration of the Lease Term, or upon any earlier termination of this Lease, Tenant shall, subject to the provisions of this Article 15, quit and surrender possession of the Premises to Landlord in as good order and condition as when Tenant took possession and as thereafter improved by Landlord and/or Tenant, reasonable wear and tear, casualties, condemnation hazardous materials (other than those released or emitted by Tenant), alterations or other interior improvements which it is permitted to surrender at the termination of this Lease and repairs which are specifically made the responsibility of Landlord hereunder excepted. Upon such expiration or termination, Tenant shall, without expense to Landlord, remove or cause to be removed from the Premises all debris and rubbish, and such items of furniture, equipment, business and trade fixtures, free-standing cabinet work, movable partitions and other articles of personal property owned by Tenant or installed or placed by Tenant at its expense in the Premises, and such similar articles of any other persons claiming under Tenant, as Landlord may, in its sole discretion, require to be removed, and Tenant shall repair at its own expense all damage to the Premises and Building resulting from such removal.

16. HOLDING OVER. If Tenant holds over after the expiration of the Lease Term or earlier termination thereof, with or without the express or implied consent of Landlord, such tenancy shall be from month-to-month only, and shall not constitute a renewal hereof or an extension for any further term, and in such case Rent shall be payable at a monthly rate equal to 150% of the greater of (i) the Rent applicable during the last rental period of the Lease Term under this Lease, and (ii) the then-current market rent for the Premises (as determined by Landlord). Such month-to-month tenancy shall be subject to every other applicable term, covenant and agreement contained herein. For purposes of this Article 16, a holding over shall include Tenant's remaining in the Premises after the expiration or earlier termination of the Lease Term, as required pursuant to the terms of Section 8.5, above, to remove any Alterations located within the Premises. Nothing contained in this Article 16 shall be construed as consent by Landlord to any holding over by Tenant, and Landlord expressly reserves the right to require Tenant to surrender possession of the Premises to Landlord as provided in this Lease upon the expiration or other termination of this Lease. The provisions of this Article 16 shall not be deemed to limit or constitute a waiver of any other rights or remedies of Landlord provided herein or at law. If Tenant fails to surrender the Premises upon the termination or expiration of this Lease, in addition to any other liabilities to Landlord accruing therefrom, Tenant shall protect, defend, indemnify and hold Landlord harmless from all loss, costs (including reasonable attorneys' fees) and liability resulting from such failure, including, without limiting the generality of the foregoing, any claims made by any succeeding tenant founded upon such failure to surrender and any lost profits to Landlord resulting therefrom.

17. ESTOPPEL CERTIFICATES. Within ten (10) days following a request in writing by Landlord, Tenant shall execute, acknowledge and deliver to Landlord an estoppel certificate, which, as submitted by Landlord, shall be substantially in the form of **Exhibit E**, attached hereto (or such other form as may be required by any prospective mortgagee or purchaser of the Project, or any portion thereof), indicating therein any exceptions thereto that may exist at that time, and shall also contain any other information reasonably requested by Landlord or Landlord's mortgagee or prospective mortgagee. Any such certificate may be relied upon by any prospective mortgagee or purchaser of all or any portion of the Project. Tenant shall execute and deliver whatever other instruments may be reasonably required for such purposes. At any time during the Lease Term, Landlord may require Tenant to provide Landlord with a current financial statement and financial statements of the two (2) years prior to the current financial statement year, provided that Tenant may require Landlord to enter into a commercially reasonable and customary confidentiality agreement in connection with the provision of such financial information. Such statements shall be prepared in accordance with generally accepted accounting principles and, if such is the normal practice of Tenant, shall be audited by an independent certified public accountant. Failure of Tenant to timely execute, acknowledge and deliver such estoppel certificate or other instruments shall constitute an acceptance of the Premises and an acknowledgment by Tenant that statements included in the estoppel certificate are true and correct, without exception.

18. <u>SUBORDINATION</u>. This Lease shall be subject and subordinate to all present and future ground or underlying leases of the Building or Project and to the lien of any mortgage, trust deed or other encumbrances now or hereafter in force against the Building or Project or any part thereof, if any, and to all renewals, extensions, modifications, consolidations and replacements thereof, and to all advances made or hereafter to be made upon the security of such mortgages or trust deeds, unless the holders of such mortgages, trust deeds or other encumbrances, or the lessors under such ground lease or underlying leases, require in writing that this Lease be superior thereto. Tenant covenants and agrees in the event any proceedings are brought for the foreclosure of any such mortgage or deed in lieu thereof (or if any ground lease is terminated), to attorn, without any deductions or set-offs whatsoever, to the lienholder or purchaser or any successors thereto upon any such foreclosure sale or deed in lieu thereof (or to the ground lessor), if so requested to do so by such purchaser or lienholder or ground lessor, and to recognize such purchaser or lienholder or ground lessor as the lessor under this Lease, provided such lienholder or purchaser or ground lessor shall agree to accept this Lease and not disturb Tenant's occupancy, so long as Tenant timely pays the rent and observes and performs the terms, covenants and conditions of this Lease to be observed and performed by Tenant. Landlord's interest herein may be assigned as security at any time to any lienholder. Tenant shall, within five (5) days of request by Landlord, execute such further instruments or assurances as Landlord may reasonably deem necessary to evidence or confirm the subordination or superiority of this Lease to any such mortgages, trust deeds, ground leases or underlying leases. Tenant waives the provisions of any current or future statute, rule or law which may give or purport to give Tenant any right or election to terminate or otherwise adversely affect this Lease and the obligations of the Tenant hereunder in the event of any foreclosure proceeding or sale.

19. <u>DEFAULTS; REMEDIES</u>.

19.1 **<u>Events of Default</u>**. The occurrence of any of the following shall constitute a default of this Lease by Tenant:

19.1.1 Any failure by Tenant to pay any Rent or any other charge required to be paid under this Lease, or any part thereof, when due unless such failure is cured within five (5) days after written notice; or

19.1.2 Except where a specific time period is otherwise set forth for Tenant's performance in this Lease, in which event the failure to perform by Tenant within such time period shall be a default by Tenant under this Section 19.1.2, any failure by Tenant to observe or perform any other provision, covenant or condition of this Lease to be observed or performed by Tenant where such failure continues for ten (10) business days after written notice thereof from Landlord to Tenant; provided that if the nature of such default is such that the same cannot reasonably be cured within a ten (10) business day period, Tenant shall not be deemed to be in default if it diligently commences such cure within such period and thereafter diligently proceeds to rectify and cure such default, but in no event exceeding a period of time in excess of ninety (90) days after written notice thereof from Landlord to Tenant; or

19.1.3 To the extent permitted by law, a general assignment by Tenant or any guarantor of this Lease for the benefit of creditors, or the taking of any corporate action in furtherance of bankruptcy or dissolution whether or not there exists any proceeding under an insolvency or bankruptcy law, or the filing by or against Tenant or any guarantor of any proceeding under an insolvency or bankruptcy law, unless in the case of a proceeding filed against Tenant or any guarantor the same is dismissed within sixty (60) days, or the appointment of a trustee or receiver to take possession of all or substantially all of the assets of Tenant or any guarantor, unless possession is restored to Tenant or such guarantor within thirty (30) days, or any execution or other judicially authorized seizure of all or substantially all of Tenant's assets located upon the Premises or of Tenant's interest in this Lease, unless such seizure is discharged within thirty (30) days; or

19.1.4 Abandonment or vacation of all or a substantial portion of the Premises by Tenant; or

19.1.5 The failure by Tenant to observe or perform according to the provisions of Articles 5, 14, 17 or 18 of this Lease where such failure continues for more than five (5) business days after written notice from Landlord; or

19.1.6 Tenant's failure to occupy the Premises within ten (10) business days after the Lease Commencement Date.

The notice periods provided herein are in lieu of, and not in addition to, any notice periods provided by law.

19.2 **Remedies Upon Default**. Upon the occurrence of any event of default by Tenant, Landlord shall have, in addition to any other remedies available to Landlord at law or in equity (all of which remedies shall be distinct, separate and cumulative), the option to pursue any one or more of the following remedies, each and all of which shall be cumulative and nonexclusive, without any notice or demand whatsoever.

19.2.1 Terminate this Lease, in which event Tenant shall immediately surrender the Premises to Landlord, and if Tenant fails to do so, Landlord may, without prejudice to any other remedy which it may have for possession or arrearages in rent, enter upon and take possession of the Premises and expel or remove Tenant and any other person who may be occupying the Premises or any part thereof, without being liable for prosecution or any claim or damages therefor; and Landlord may recover from Tenant the following: (i) the worth at the time of any unpaid rent which has been earned at the time of such termination; plus (ii) the worth at the time of award of the amount by which the unpaid rent which would have been earned after termination until the time of award exceeds the amount of such rental loss that Tenant proves could have been reasonably avoided; plus (iii) the worth at the time of award of the amount by which the unpaid rent for the balance of the Lease Term after the time of award exceeds the amount of such rental loss that Tenant proves could have been reasonably avoided; plus (iv) any other amount necessary to compensate Landlord for all the detriment proximately caused by Tenant's failure to perform its obligations under this Lease or which in the ordinary course of things would be likely to result therefrom, specifically including but not limited to, brokerage commissions and advertising expenses incurred, expenses of remodeling the Premises or any portion thereof for a new tenant, whether for the same or a different use, and any special concessions made to obtain a new tenant; and (v) at Landlord's election, such other amounts in addition to or in lieu of the foregoing as may be permitted from time to time by applicable law.

The term "rent" as used in this Section 19.2 shall be deemed to be and to mean all sums of every nature required to be paid by Tenant pursuant to the terms of this Lease, whether to Landlord or to others. As used in Paragraphs 19.2.1(i) and (ii), above, the "worth at the time of award" shall be computed by allowing interest at the rate set forth in Article 25 of this Lease, but in no case greater than the maximum amount of such interest permitted by law. As used in Paragraph 19.2.1(iii) above, the "worth at the time of award" shall be computed by discounting such amount at the discount rate of the Federal Reserve Bank of San Francisco at the time of award plus one percent (1%).

19.2.2 Landlord shall have the remedy described in California Civil Code Section 1951.4 (lessor may continue lease in effect after lessee's breach and abandonment and recover rent as it becomes due, if lessee has the right to sublet or assign, subject only to reasonable limitations). Accordingly, if Landlord does not elect to terminate this Lease on account of any default by Tenant, Landlord may, from time to time, without terminating this Lease, enforce all of its rights and remedies under this Lease, including the right to recover all rent as it becomes due.

19.3 **Subleases of Tenant**. Whether or not Landlord elects to terminate this Lease on account of any default by Tenant, as set forth in this Article 19, Landlord shall have the right to terminate any and all subleases, licenses, concessions or other consensual arrangements for possession entered into by Tenant and affecting the Premises or may, in Landlord's sole discretion, succeed to Tenant's interest in such subleases, licenses, concessions or arrangements. In the event of Landlord's election to succeed to Tenant's interest in any such subleases, licenses, concessions or arrangements, Tenant shall, as of the date of notice by Landlord of such election, have no further right to or interest in the rent or other consideration receivable thereunder.

19.4 **Efforts to Relet**. No re-entry or repossession, repairs, maintenance, changes, alterations and additions, reletting, appointment of a receiver to protect Landlord's interests hereunder, or any other action or omission by Landlord shall be construed as an election by Landlord to terminate this Lease or Tenant's right to possession, or to accept a surrender of the Premises, nor shall same operate to release Tenant in whole or in part from any of Tenant's obligations hereunder, unless express written notice of such intention is sent by Landlord to Tenant. Tenant hereby irrevocably waives any right otherwise available under any law to redeem or reinstate this Lease.

20. COVENANT OF QUIET ENJOYMENT. Landlord covenants that Tenant, on paying the Rent, charges for services and other payments herein reserved and on keeping, observing and performing all the other terms, covenants, conditions, provisions and agreements herein contained on the part of Tenant to be kept, observed and performed, shall, during the Lease Term, peaceably and quietly have, hold and enjoy the Premises subject to the terms, covenants, conditions, provisions and agreements hereof without interference by any persons lawfully claiming by or through Landlord. The foregoing covenant is in lieu of any other covenant express or implied.

21. SECURITY DEPOSIT. Concurrent with Tenant's execution of this Lease, Tenant shall deposit with Landlord a security deposit (the "**Security Deposit**") in the amount set forth in Section 8 of the Summary, as security for the faithful performance by Tenant of all of its obligations under this Lease. If Tenant defaults with respect to any provisions of this Lease, including, but not limited to, the provisions relating to the payment of Rent, the removal of property and the repair of resultant damage, Landlord may, without notice to Tenant, but shall not be required to apply all or any part of the Security Deposit for the payment of any Rent or any other sum in default and Tenant shall, upon demand therefor, restore the Security Deposit to its original amount. Any unapplied portion of the Security Deposit shall be returned to Tenant, or, at Landlord's option, to the last assignee of Tenant's interest hereunder, within sixty (60) days following the expiration of the Lease Term. Tenant shall not be entitled to any interest on the Security Deposit. Tenant hereby waives the provisions of Section 1950.7 of the California Civil Code, or any successor statute.

If Tenant has not previously been in default of the Lease, after expiration of any applicable notice and cure period, then as of the last day of the tenth (10th) month of the Lease Term the amount of the required Security Deposit shall be reduced by $18,478.63, to equal $36,957.26, and Landlord shall credit the amount of such reduction to the next Rent coming due under the Lease.

22. SUBSTITUTION OF OTHER PREMISES. Landlord shall have the right to move Tenant to other space in the Project substantially similar to the Premises, and all terms hereof shall apply to the new space with equal force. In such event, Landlord shall give Tenant prior notice, shall provide Tenant, at Landlord's sole cost and expense, with tenant improvements at least equal in quality to those in the Premises and shall move Tenant's effects to the new space at Landlord's sole cost and expense at such time and in such manner as to inconvenience Tenant as little as reasonably practicable. Simultaneously with such relocation of the Premises, the parties shall immediately execute an amendment to this Lease stating the relocation of the Premises.

23. SIGNS.

23.1 **Multi-Tenant Floors**. If other tenants occupy space on the floor on which the Premises is located, Tenant's identifying signage shall be provided by Landlord, at Landlord's sole cost, and such signage shall be comparable to that used by Landlord for other similar floors in the Building and shall comply with Landlord's Building standard signage program.

23.2 **Prohibited Signage and Other Items**. Any signs, notices, logos, pictures, names or advertisements which are installed and that have not been separately approved by Landlord may be removed without notice by Landlord at the sole expense of Tenant. Tenant may not install any signs on the exterior or roof of the Project or the Common Areas. Any signs, window coverings, or blinds (even if the same are located behind the Landlord-approved window coverings for the Building), or other items visible from the exterior of the Premises or Building, shall be subject to the prior approval of Landlord, in its sole discretion.

23.3 **Building Directory**. A building directory will be located in the lobby of the Building. Landlord shall, at Landlord's sole cost and expense, install Tenant's name and/or logo in such building directory at the rate of one and four-tenths (1.4) strips per each 1,000 rentable square feet of the Premises.

24. COMPLIANCE WITH LAW. Tenant shall not do anything or suffer anything to be done in or about the Premises or the Project which will in any way conflict with any law, statute, ordinance or other governmental rule, regulation or requirement now in force or which may hereafter be enacted or promulgated. At its sole cost and expense, Tenant shall promptly comply with all such governmental measures. Should any standard or regulation now or hereafter be imposed on Landlord or Tenant by a state, federal or local governmental body charged with the establishment, regulation and enforcement of occupational, health or safety standards for employers, employees, landlords or tenants, then Tenant agrees, at its sole cost and expense, to comply promptly with such standards or regulations. Tenant shall be responsible, at its sole cost and expense, to make all alterations to the Premises as are required to comply with the governmental rules, regulations, requirements or standards described in this Article 24. The judgment of any court of competent jurisdiction or the admission of Tenant in any judicial action, regardless of whether Landlord is a party thereto, that Tenant has violated any of said governmental measures, shall be conclusive of that fact as between Landlord and Tenant. Notwithstanding the foregoing or any other provision of this Lease, however, Tenant shall not be responsible for compliance with any laws, regulations, or the like requiring (a) structural repairs or modifications; or (b) repairs or modifications to the building systems or equipment; or (c) installation of new building systems or equipment, such as fire detection or suppression equipment, unless such repairs, modifications, or installations shall (i) be due to Tenant's particular manner of use of the Premises (as opposed to office use generally), or (ii) be due to any Alterations performed by or on behalf of Tenant in the Premises.

For purposes of Section 1938(a) of the California Civil Code, Landlord hereby discloses to Tenant, and Tenant hereby acknowledges, that the Premises have not undergone inspection by a Certified Access Specialist (CASp). As required by Section 1938(e) of the California Civil Code, Landlord hereby states as follows: "A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises." In furtherance of the foregoing, Landlord and Tenant hereby agree as follows: (a) any CASp inspection requested by Tenant shall be conducted, at Tenant's sole cost and expense, by a CASp designated by Landlord, subject to Landlord's reasonable rules and requirements; (b) Tenant, at its sole cost and expense, shall be responsible for making any improvements or repairs within the Premises to correct violations of construction-related accessibility standards; and (c) if anything done by or for Tenant in its use or occupancy of the Premises shall require any improvements or repairs to the Building or Project (outside the Premises) to correct violations of construction-related accessibility standards, then Tenant shall reimburse Landlord upon demand, as Additional Rent, for the cost to Landlord of performing such improvements or repairs.

25. LATE CHARGES. If any installment of Rent or any other sum due from Tenant shall not be received by Landlord or Landlord's designee within five (5) business days after said amount is due, then Tenant shall pay to Landlord a late charge equal to five percent (5%) of the overdue amount plus any attorneys' fees incurred by Landlord by reason of Tenant's failure to pay Rent and/or other charges when due hereunder. The late charge shall be deemed Additional Rent and the right to require it shall be in addition to all of Landlord's other rights and remedies hereunder or at law and shall not be construed as liquidated damages or as limiting Landlord's remedies in any manner. In addition to the late charge described above, any Rent or other amounts owing hereunder which are not paid within ten (10) days after the date they are due shall bear interest from the date when due until paid at a rate per annum equal to the lesser of (i) the annual "Bank Prime Loan" rate cited in the Federal Reserve Statistical Release Publication G.13(415), published on the first Tuesday of each calendar month (or such other comparable index as Landlord and Tenant shall reasonably agree upon if such rate ceases to be published) plus four (4) percentage points, and (ii) the highest rate permitted by applicable law.

26. LANDLORD'S RIGHT TO CURE DEFAULT; PAYMENTS BY TENANT.

26.1 **Landlord's Cure**. All covenants and agreements to be kept or performed by Tenant under this Lease shall be performed by Tenant at Tenant's sole cost and expense and without any reduction of Rent, except to the extent, if any, otherwise expressly provided herein. If Tenant shall fail to perform any obligation under this Lease, and such failure shall continue in excess of the time allowed under Section 19.1.2, above, unless a specific time period is otherwise stated in this Lease, Landlord may, but shall not be obligated to, make any such payment or perform any such act on Tenant's part without waiving its rights based upon any default of Tenant and without releasing Tenant from any obligations hereunder.

26.2 **Tenant's Reimbursement**. Except as may be specifically provided to the contrary in this Lease, Tenant shall pay to Landlord, upon delivery by Landlord to Tenant of statements therefor: (i) sums equal to reasonable expenditures reasonably made and obligations incurred by Landlord in connection with the remedying by Landlord of Tenant's defaults pursuant to the provisions of Section 26.1; (ii) sums equal to all losses, costs, liabilities, damages and expenses referred to in Article 10 of this Lease; and (iii) sums equal to all expenditures made and obligations incurred by Landlord in collecting or attempting to collect the Rent or in enforcing or attempting to enforce any rights of Landlord under this Lease or pursuant to law, including, without limitation, all legal fees and other amounts so expended. Tenant's obligations under this Section 26.2 shall survive the expiration or sooner termination of the Lease Term.

27. ENTRY BY LANDLORD. Landlord reserves the right at all reasonable times and upon reasonable notice to Tenant (except in the case of an emergency) to enter the Premises to (i) inspect them; (ii) show the Premises to prospective purchasers, mortgagees or tenants, or to current or prospective mortgagees, ground or underlying lessors or insurers; (iii) post notices of nonresponsibility; or (iv) alter, improve or repair the Premises or the Building, or for structural alterations, repairs or improvements to the Building or the Building's systems and equipment. Notwithstanding anything to the contrary contained in this Article 27, Landlord may enter the Premises at any time to (A) perform services required of Landlord, including janitorial service; (B) take possession due to any breach of this Lease in the manner provided herein; and (C) perform any covenants of Tenant which Tenant fails to perform. Landlord may make any such entries without the abatement of Rent and may take such reasonable steps as required to accomplish the stated purposes. Tenant hereby waives any claims for damages or for any injuries or inconvenience to or interference with Tenant's business, lost profits, any loss of occupancy or quiet enjoyment of the Premises, and any other loss occasioned thereby. For each of the above purposes, Landlord shall at all times have a key with which to unlock all the doors in the Premises, excluding Tenant's vaults, safes and special security areas designated in advance by Tenant. In an emergency, Landlord shall have the right to use any means that Landlord may deem proper to open the doors in and to the Premises. Any entry into the Premises by Landlord in the manner hereinbefore described shall not be deemed to be a forcible or unlawful entry into, or a detainer of, the Premises, or an actual or constructive eviction of Tenant from any portion of the Premises. No provision of this Lease shall be construed as obligating Landlord to perform any repairs, alterations or decorations except as otherwise expressly agreed to be performed by Landlord herein.

28. TENANT PARKING

28.1 **Tenant Parking Passes**. Tenant shall rent from Landlord, commencing on the Lease Commencement Date, up to the amount of parking passes set forth in Section 9 of the Summary, on a monthly basis throughout the Lease Term, which parking passes shall pertain to the Project parking facility. Tenant shall pay to Landlord for automobile parking passes on a monthly basis the prevailing rate charged from time to time at the location of such parking passes (provided that the parking rates charged at the Project shall not increase by more than 4% per year, on a cumulative and compounding basis). In addition, Tenant shall be responsible for the full amount of any taxes imposed by any governmental authority in connection with the renting of such parking passes by Tenant or the use of the parking facility by Tenant. Tenant's continued right to use the parking passes is conditioned upon Tenant abiding by all rules and regulations which are prescribed from time to time for the orderly operation and use of the parking facility where the parking passes are located, including any sticker or other identification system established by Landlord, Tenant's cooperation in seeing that Tenant's employees and visitors also comply with such rules and regulations and Tenant not being in default under this Lease.

28.2 **Other Terms**. Landlord specifically reserves the right to change the size, configuration, design, layout and all other aspects of the Project parking facility at any time and Tenant acknowledges and agrees that Landlord may, without incurring any liability to Tenant and without any abatement of Rent under this Lease, from time to time, close-off or restrict access to the Project parking facility for purposes of permitting or facilitating any such construction, alteration or improvements. Landlord may delegate its responsibilities hereunder to a parking operator in which case such parking operator shall have all the rights of control attributed hereby to the Landlord. The parking passes rented by Tenant pursuant to this Article 28 are provided to Tenant solely for use by Tenant's own personnel and such passes may not be transferred, assigned, subleased or otherwise alienated by Tenant without Landlord's prior approval. Tenant may validate visitor parking by such method or methods as the Landlord may establish, at the validation rate from time to time generally applicable to visitor parking.

28.3 **Parking Procedures**. The parking passes initially will not be separately identified; however Landlord reserves the right in its sole and absolute discretion to separately identify by signs or other markings the area to which Tenant's parking passes relate. Landlord shall have no obligation to monitor the use of such parking facility, nor shall Landlord be responsible for any loss or damage to any vehicle or other property or for any injury to any person. Tenant's parking passes shall be used only for parking of automobiles no larger than full size passenger automobiles, sport utility vehicles or pick-up trucks. Tenant shall comply with all rules and regulations which may be adopted by Landlord from time to time with respect to parking and/or the parking facilities servicing the Project. Tenant shall not at any time use more parking passes than the number so allocated to Tenant or park its vehicles or the vehicles of others in any portion of the Project parking facility not designated by Landlord as a non-exclusive parking area. Tenant shall not have the exclusive right to use any specific parking space. If Landlord grants to any other tenant the exclusive right to use any particular parking space(s), Tenant shall not use such spaces. All trucks (other than pick-up trucks) and delivery vehicles shall be (i) parked at the loading dock of the Building, (ii) loaded and unloaded in a manner which does not interfere with the businesses of other occupants of the Project, and (iii) permitted to remain on the Project only so long as is reasonably necessary to complete loading and unloading. In the event Landlord elects in its sole and absolute discretion or is required by any law to limit or control parking, whether by validation of parking tickets or any other method of assessment, Tenant agrees to participate in such validation or assessment program under such reasonable rules and regulations as are from time to time established by Landlord.

29. MISCELLANEOUS PROVISIONS.

29.1 **Captions**. The captions of Articles and Sections are for convenience only and shall not be deemed to limit, construe, affect or alter the meaning of such Articles and Sections.

29.2 **Binding Effect**. Subject to all other provisions of this Lease, each of the covenants, conditions and provisions of this Lease shall extend to and shall, as the case may require, bind or inure to the benefit not only of Landlord and of Tenant, but also of their respective heirs, personal representatives, successors or assigns, provided this clause shall not permit any assignment by Tenant contrary to the provisions of Article 14 of this Lease.

29.3 **No Air Rights**. No rights to any view or to light or air over any property, whether belonging to Landlord or any other person, are granted to Tenant by this Lease. If at any time any windows of the Premises are temporarily darkened or the light or view therefrom is obstructed by reason of any repairs, improvements, maintenance or cleaning in or about the Project, the same shall be without liability to Landlord and without any reduction or diminution of Tenant's obligations under this Lease.

29.4 **Transfer of Landlord's Interest**. Tenant acknowledges that Landlord has the right to transfer all or any portion of its interest in the Project or Building and in this Lease, and Tenant agrees that in the event of any such transfer, Landlord shall automatically be released from all liability under this Lease and Tenant agrees to look solely to such transferee for the performance of Landlord's obligations hereunder after the date of transfer and such transferee shall be deemed to have fully assumed and be liable for all obligations of this Lease to be performed by Landlord, including the return of any Security Deposit, and Tenant shall attorn to such transferee. Tenant further acknowledges that Landlord may assign its interest in this Lease to a mortgage lender as additional security and agrees that such an assignment shall not release Landlord from its obligations hereunder and that Tenant shall continue to look to Landlord for the performance of its obligations hereunder.

29.5 **Prohibition Against Recording**. Neither this Lease, nor any memorandum, affidavit or other writing with respect thereto, shall be recorded by Tenant or by anyone acting through, under or on behalf of Tenant.

29.6 **Relationship of Parties**. Nothing contained in this Lease shall be deemed or construed by the parties hereto or by any third party to create the relationship of principal and agent, partnership, joint venturer or any association between Landlord and Tenant.

29.7 **Application of Payments**. Landlord shall have the right to apply payments received from Tenant pursuant to this Lease, regardless of Tenant's designation of such payments, to satisfy any obligations of Tenant hereunder, in such order and amounts as Landlord, in its sole discretion, may elect.

29.8 **Time of Essence**. Time is of the essence with respect to the performance of every provision of this Lease in which time of performance is a factor.

29.9 **Partial Invalidity**. If any term, provision or condition contained in this Lease shall, to any extent, be invalid or unenforceable, the remainder of this Lease, or the application of such term, provision or condition to persons or circumstances other than those with respect to which it is invalid or unenforceable, shall not be affected thereby, and each and every other term, provision and condition of this Lease shall be valid and enforceable to the fullest extent possible permitted by law.

29.10 **No Warranty**. In executing and delivering this Lease, Tenant has not relied on any representations, including, but not limited to, any representation as to the amount of any item comprising Additional Rent or the amount of the Additional Rent in the aggregate or that Landlord is furnishing the same services to other tenants, at all, on the same level or on the same basis, or any warranty or any statement of Landlord which is not set forth herein or in one or more of the exhibits attached hereto.

29.11 **Landlord Exculpation**. The liability of Landlord or the Landlord Parties to Tenant for any default by Landlord under this Lease or arising in connection herewith or with Landlord's operation, management, leasing, repair, renovation, alteration or any other matter relating to the Project or the Premises shall be limited solely and exclusively to an amount which is equal to the lesser of (a) the interest of Landlord in the Building or (b) the equity interest Landlord would have in the Building if the Building were encumbered by third-party debt in an amount equal to eighty percent (80%) of the value of the Building (as such value is determined by Landlord). Neither Landlord, nor any of the Landlord Parties shall have any personal liability therefor, and Tenant hereby expressly waives and releases such personal liability on behalf of itself and all persons claiming by, through or under Tenant. The limitations of liability contained in this Section 29.11 shall inure to the benefit of Landlord's and the Landlord Parties' present and future partners, beneficiaries, officers, directors, trustees, shareholders, agents and employees, and their respective partners, heirs, successors and assigns. Under no circumstances shall any present or future partner of Landlord (if Landlord is a partnership), or trustee or beneficiary (if Landlord or any partner of Landlord is a trust), have any liability for the performance of Landlord's obligations under this Lease. Notwithstanding any contrary provision herein, neither Landlord nor the Landlord Parties shall be liable under any circumstances for injury or damage to, or interference with, Tenant's business, including but not limited to, loss of profits, loss of rents or other revenues, loss of business opportunity, loss of goodwill or loss of use, in each case, however occurring.

29.12 **Entire Agreement**. It is understood and acknowledged that there are no oral agreements between the parties hereto affecting this Lease and this Lease constitutes the parties' entire agreement with respect to the leasing of the Premises and supersedes and cancels any and all previous negotiations, arrangements, brochures, agreements and understandings, if any, between the parties hereto or displayed by Landlord to Tenant with respect to the subject matter thereof, and none thereof shall be used to interpret or construe this Lease. None of the terms, covenants, conditions or provisions of this Lease can be modified, deleted or added to except in writing signed by the parties hereto.

29.13 **Right to Lease**. Landlord reserves the absolute right to effect such other tenancies in the Project as Landlord in the exercise of its sole business judgment shall determine to best promote the interests of the Building or Project. Tenant does not rely on the fact, nor does Landlord represent, that any specific tenant or type or number of tenants shall, during the Lease Term, occupy any space in the Building or Project.

29.14 **Force Majeure**. Any prevention, delay or stoppage due to strikes, lockouts, labor disputes, acts of God, inability to obtain services, labor, or materials or reasonable substitutes therefor, governmental actions, civil commotions, fire or other casualty, and other causes beyond the reasonable control of the party obligated to perform, except with respect to the obligations imposed with regard to Rent and other charges to be paid by Tenant pursuant to this Lease and except as to Tenant's obligations under Articles 5 and 24 of this Lease (collectively, a "**Force Majeure**"), notwithstanding anything to the contrary contained in this Lease, shall excuse the performance of such party for a period equal to any such prevention, delay or stoppage and, therefore, if this Lease specifies a time period for performance of an obligation of either party, that time period shall be extended by the period of any delay in such party's performance caused by a Force Majeure.

29.15 **Waiver of Redemption by Tenant**. Tenant hereby waives, for Tenant and for all those claiming under Tenant, any and all rights now or hereafter existing to redeem by order or judgment of any court or by any legal process or writ, Tenant's right of occupancy of the Premises after any termination of this Lease.

29.16 **Notices**. All notices, demands, statements, designations, approvals or other communications (collectively, "**Notices**") given or required to be given by either party to the other hereunder or by law shall be in writing, shall be (A) sent by United States certified or registered mail, postage prepaid, return receipt requested ("**Mail**"), (B) transmitted by telecopy, if such telecopy is promptly followed by a Notice sent by Mail, (C) delivered by a nationally recognized overnight courier, or (D) delivered personally. Any Notice shall be sent, transmitted, or delivered, as the case may be, to Tenant at the appropriate address set forth in Section 10 of the Summary, or to such other place as Tenant may from time to time designate in a Notice to Landlord, or to Landlord at the addresses set forth below, or to such other places as Landlord may from time to time designate in a Notice to Tenant. Any Notice will be deemed given (i) three (3) days after the date it is posted if sent by Mail, (ii) the date the telecopy is transmitted, (iii) the date the overnight courier delivery is made, or (iv) the date personal delivery is made or attempted to be made. If Tenant is notified of the identity and address of Landlord's mortgagee or ground or underlying lessor, Tenant shall give to such mortgagee or ground or underlying lessor written notice of any default by Landlord under the terms of this Lease by registered or certified mail, and such mortgagee or ground or underlying lessor shall be given a reasonable opportunity to cure such default prior to Tenant's exercising any remedy available to Tenant. As of the date of this Lease, any Notices to Landlord must be sent, transmitted, or delivered, as the case may be, to the following addresses:

BRE SUNSET COAST, LLC
c/o Brickman Associates
712 5th Avenue, 6th Floor
New York, NY 10019
Attention: Mike Esquenazi
Telephone: (212) 541-5500
Facsimile: (212) 980-5961
E-mail: mesquenazi@brickmanre.com

and

Allen Matkins Leck Gamble & Mallory LLP
1901 Avenue of the Stars, Suite 1800
Los Angeles, California 90067
Attention: Eric J. Shelby, Esq.

29.17 **Joint and Several**. If there is more than one Tenant, the obligations imposed upon Tenant under this Lease shall be joint and several.

29.18 **Authority**. If Tenant is a corporation, trust or partnership, Tenant hereby represents and warrants that Tenant is a duly formed and existing entity qualified to do business in California and that Tenant has full right and authority to execute and deliver this Lease and that each person signing on behalf of Tenant is authorized to do so. In such event, Tenant shall, within ten (10) days after execution of this Lease, deliver to Landlord satisfactory evidence of such authority and, if a corporation, upon demand by Landlord, also deliver to Landlord satisfactory evidence of (i) good standing in Tenant's state of incorporation and (ii) qualification to do business in California.

29.19 **Attorneys' Fees**. In the event that either Landlord or Tenant should bring suit for the possession of the Premises, for the recovery of any sum due under this Lease, or because of the breach of any provision of this Lease or for any other relief against the other, then all costs and expenses, including reasonable attorneys' fees, incurred by the prevailing party therein shall be paid by the other party, which obligation on the part of the other party shall be deemed to have accrued on the date of the commencement of such action and shall be enforceable whether or not the action is prosecuted to judgment.

29.20 **Governing Law; WAIVER OF TRIAL BY JURY**. This Lease shall be construed and enforced in accordance with the laws of the State of California. IN ANY ACTION OR PROCEEDING ARISING HEREFROM, LANDLORD AND TENANT HEREBY CONSENT TO (I) THE JURISDICTION OF ANY COMPETENT COURT WITHIN THE STATE OF CALIFORNIA, (II) SERVICE OF PROCESS BY ANY MEANS AUTHORIZED BY CALIFORNIA LAW, AND (III) IN THE INTEREST OF SAVING TIME AND EXPENSE, TRIAL WITHOUT A JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM BROUGHT BY EITHER OF THE PARTIES HERETO AGAINST THE OTHER OR THEIR SUCCESSORS IN RESPECT OF ANY MATTER ARISING OUT OF OR IN CONNECTION WITH THIS LEASE, THE RELATIONSHIP OF LANDLORD AND TENANT, TENANT'S USE OR OCCUPANCY OF THE PREMISES, AND/OR ANY CLAIM FOR INJURY OR DAMAGE, OR ANY EMERGENCY OR STATUTORY REMEDY. IN THE EVENT LANDLORD COMMENCES ANY SUMMARY PROCEEDINGS OR ACTION FOR NONPAYMENT OF BASE RENT OR ADDITIONAL RENT, TENANT SHALL NOT INTERPOSE ANY COUNTERCLAIM OF ANY NATURE OR DESCRIPTION (UNLESS SUCH COUNTERCLAIM SHALL BE MANDATORY) IN ANY SUCH PROCEEDING OR ACTION, BUT SHALL BE RELEGATED TO AN INDEPENDENT ACTION AT LAW.

29.21 **Submission of Lease**. Submission of this instrument for examination or signature by Tenant does not constitute a reservation of, option for or option to lease, and it is not effective as a lease or otherwise until execution and delivery by both Landlord and Tenant.

29.22 **Brokers**. Landlord and Tenant hereby warrant to each other that they have had no dealings with any real estate broker or agent in connection with the negotiation of this Lease, excepting only the real estate brokers or agents specified in Section 12 of the Summary (the "**Brokers**"), and that they know of no other real estate broker or agent who is entitled to a commission in connection with this Lease. Each party agrees to indemnify and defend the other party against and hold the other party harmless from any and all claims, demands, losses, liabilities, lawsuits, judgments, costs and expenses (including without limitation reasonable attorneys' fees) with respect to any leasing commission or equivalent compensation alleged to be owing on account of any dealings with any real estate broker or agent, other than the Brokers, occurring by, through, or under the indemnifying party.

29.23 **Independent Covenants**. This Lease shall be construed as though the covenants herein between Landlord and Tenant are independent and not dependent and Tenant hereby expressly waives the benefit of any statute to the contrary and agrees that if Landlord fails to perform its obligations set forth herein, Tenant shall not be entitled to make any repairs or perform any acts hereunder at Landlord's expense or to any setoff of the Rent or other amounts owing hereunder against Landlord.

29.24 **Project or Building Name and Signage**. Landlord shall have the right at any time to change the name of the Project or Building and to install, affix and maintain any and all signs on the exterior and on the interior of the Project or Building as Landlord may, in Landlord's sole discretion, desire. Tenant shall not use the name of the Project or Building or use pictures or illustrations of the Project or Building in advertising or other publicity or for any purpose other than as the address of the business to be conducted by Tenant in the Premises, without the prior written consent of Landlord.

29.25 **Counterparts**. This Lease may be executed in counterparts with the same effect as if both parties hereto had executed the same document. Both counterparts shall be construed together and shall constitute a single lease.

29.26 **Confidentiality**. Tenant acknowledges that the content of this Lease and any related documents are confidential information. Tenant shall keep such confidential information strictly confidential and shall not disclose such confidential information to any person or entity other than Tenant's financial, legal, and space planning consultants.

29.27 **Transportation Management**. Tenant shall fully comply with all present or future programs intended to manage parking, transportation or traffic in and around the Building, and in connection therewith, Tenant shall take responsible action for the transportation planning and management of all employees located at the Premises by working directly with Landlord, any governmental transportation management organization or any other transportation-related committees or entities.

29.28 **Building Renovations**. It is specifically understood and agreed that Landlord has made no representation or warranty to Tenant and has no obligation and has made no promises to alter, remodel, improve, renovate, repair or decorate the Premises, Building, or any part thereof and that no representations respecting the condition of the Premises or the Building have been made by Landlord to Tenant except as specifically set forth herein. However, Tenant hereby acknowledges that Landlord is currently renovating or may during the Lease Term renovate, improve, alter, or modify (collectively, the "**Renovations**") the Project, the Building and/or the Premises including without limitation the parking structure, common areas, systems and equipment, roof, and structural portions of the same, which Renovations may include, without limitation, (i) installing sprinklers in the Building common areas and tenant spaces, (ii) modifying the common areas and tenant spaces to comply with applicable laws and regulations, including regulations relating to the physically disabled, seismic conditions, and building safety and security, and (iii) installing new floor covering, lighting, and wall coverings in the Building common areas, and in connection with any Renovations, Landlord may, among other things, erect scaffolding or other necessary structures in the Building, limit or eliminate access to portions of the Project, including portions of the common areas, or perform work in the Building, which work may create noise, dust or leave debris in the Building. Tenant hereby agrees that such Renovations and Landlord's actions in connection with such Renovations shall in no way constitute a constructive eviction of Tenant nor, except as provided in Section 6.4, above, entitle Tenant to any abatement of Rent. Landlord shall have no responsibility or for any reason be liable to Tenant for any direct or indirect injury to or interference with Tenant's business arising from the Renovations, nor shall Tenant be entitled to any compensation or damages from Landlord for loss of the use of the whole or any part of the Premises or of Tenant's personal property or improvements resulting from the Renovations or Landlord's actions in connection with such Renovations, or for any inconvenience or annoyance occasioned by such Renovations or Landlord's actions.

29.29 **No Violation**. Tenant hereby warrants and represents that neither its execution of nor performance under this Lease shall cause Tenant to be in violation of any agreement, instrument, contract, law, rule or regulation by which Tenant is bound, and Tenant shall protect, defend, indemnify and hold Landlord harmless against any claims, demands, losses, damages, liabilities, costs and expenses, including, without limitation, reasonable attorneys' fees and costs, arising from Tenant's breach of this warranty and representation.

29.30 **Communications and Computer Lines**. Tenant may install, maintain, replace, remove or use any communications or computer wires and cables (collectively, the "**Lines**") at the Project in or serving the Premises, provided that (i) Tenant shall obtain Landlord's prior written consent, use an experienced and qualified contractor approved in writing by Landlord, and comply with all of the other provisions of Articles 7 and 8 of this Lease, (ii) an acceptable number of spare Lines and space for additional Lines shall be maintained for existing and future occupants of the Project, as determined in Landlord's reasonable opinion, (iii) the Lines therefor (including riser cables) shall be appropriately insulated to prevent excessive electromagnetic fields or radiation, and shall be surrounded by a protective conduit reasonably acceptable to Landlord, (iv) any new or existing Lines servicing the Premises shall comply with all applicable governmental laws and regulations, (v) as a condition to permitting the installation of new Lines, Landlord may require that Tenant remove existing Lines located in or serving the Premises and repair any damage in connection with such removal, and (vi) Tenant shall pay all costs in connection therewith. Landlord reserves the right to require that Tenant remove any Lines located in or serving the Premises which are installed in violation of these provisions, or which are at any time in violation of any laws or represent a dangerous or potentially dangerous condition. Notwithstanding the foregoing, Landlord reserves the right to require that all work performed in the telephone riser of the Building be performed by Landlord's designated riser management contractor.

29.31 **Construction of Project and Other Improvements**. Tenant acknowledges that portions of the Project and/or the Other Improvements may be under construction following Tenant's occupancy of the Premises, and that such construction may result in levels of noise, dust, obstruction of access, etc. which are in excess of that present in a fully constructed project. Tenant hereby waives any and all rent offsets or claims of constructive eviction which may arise in connection with such construction.

29.32 **Counterparts**. This Lease may be executed in counterparts with the same effect as if all parties hereto had executed the same document. All counterparts shall be construed together and shall constitute a single document.

[Signatures on next page.]

IN WITNESS WHEREOF, Landlord and Tenant have caused this Lease to be executed the day and date first above written.

"LANDLORD"

BRE SUNSET COAST, LLC,
a Delaware limited liability company

By: ____________________

Its: Chief Financial Officer

"TENANT"

AADI BIOSCIENCE, INC.,
a Delaware corporation

By: ____________________

Its: CEO

By: ____________________

Its: ____________________

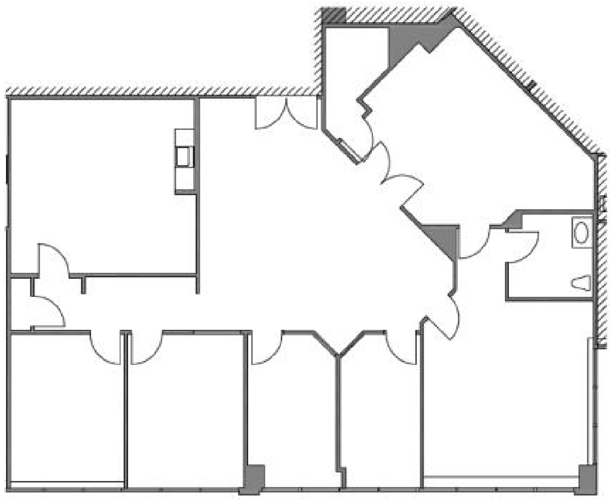
EXHIBIT A

SUNSET & PCH

OUTLINE OF PREMISES

FLOOR PLAN

Suite A250
2,760 RSF



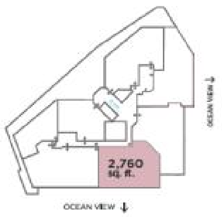


EXHIBIT B

SUNSET & PCH

INTENTIONALLY OMITTED

EXHIBIT C

SUNSET & PCH

NOTICE OF LEASE TERM DATES

To: ______________________
____
____
____

Re: Office Lease dated ___________, 20__ between ___________________, a ____________________ ("Landlord"), and ______________________, a _____________________ ("Tenant") concerning Suite ______ on floor(s) __________ of the office building located at ____________________________, ______________________, California.

Gentlemen:

In accordance with the Office Lease (the "Lease"), we wish to advise you and/or confirm as follows:

1. The Lease Term shall commence on or has commenced on _____________ for a term of _________________ ending on _________________.

2. Rent commenced to accrue on _________________, in the amount of _______________.

3. If the Lease Commencement Date is other than the first day of the month, the first billing will contain a pro rata adjustment. Each billing thereafter, with the exception of the final billing, shall be for the full amount of the monthly installment as provided for in the Lease.

4. Your rent checks should be made payable to _________________ at __________________.

5. The exact number of rentable/usable square feet within the Premises is ___________ square feet.

6. Tenant's Share as adjusted based upon the exact number of usable square feet within the Premises is ________%.

"Landlord":

______________________________________,
a ______________________________________

By: ______________________________________
Its: ______________________________________

Agreed to and Accepted
as of _________________, 20___.

"Tenant":

______________________________________,
a ______________________________________

By: ______________________________________
Its: ______________________________________

EXHIBIT D

SUNSET & PCH

RULES AND REGULATIONS

Tenant shall faithfully observe and comply with the following Rules and Regulations. Landlord shall not be responsible to Tenant for the nonperformance of any of said Rules and Regulations by or otherwise with respect to the acts or omissions of any other tenants or occupants of the Project. In the event of any conflict between the Rules and Regulations and the other provisions of this Lease, the latter shall control.

1. Tenant shall not alter any lock or install any new or additional locks or bolts on any doors or windows of the Premises without obtaining Landlord's prior written consent. Tenant shall bear the cost of any lock changes or repairs required by Tenant. Two keys will be furnished by Landlord for the Premises, and any additional keys required by Tenant must be obtained from Landlord at a reasonable cost to be established by Landlord. Upon the termination of this Lease, Tenant shall restore to Landlord all keys of stores, offices, and toilet rooms, either furnished to, or otherwise procured by, Tenant and in the event of the loss of keys so furnished, Tenant shall pay to Landlord the cost of replacing same or of changing the lock or locks opened by such lost key if Landlord shall deem it necessary to make such changes.

2. All doors opening to public corridors shall be kept closed at all times except for normal ingress and egress to the Premises.

3. Landlord reserves the right to close and keep locked all entrance and exit doors of the Building during such hours as are customary for comparable buildings in the Los Angeles County, California area. Tenant, its employees and agents must be sure that the doors to the Building are securely closed and locked when leaving the Premises if it is after the normal hours of business for the Building. Any tenant, its employees, agents or any other persons entering or leaving the Building at any time when it is so locked, or any time when it is considered to be after normal business hours for the Building, may be required to sign the Building register. Access to the Building may be refused unless the person seeking access has proper identification or has a previously arranged pass for access to the Building. Landlord will furnish passes to persons for whom Tenant requests same in writing. Tenant shall be responsible for all persons for whom Tenant requests passes and shall be liable to Landlord for all acts of such persons. The Landlord and his agents shall in no case be liable for damages for any error with regard to the admission to or exclusion from the Building of any person. In case of invasion, mob, riot, public excitement, or other commotion, Landlord reserves the right to prevent access to the Building or the Project during the continuance thereof by any means it deems appropriate for the safety and protection of life and property.

4. No furniture, freight or equipment of any kind shall be brought into the Building without prior notice to Landlord. All moving activity into or out of the Building shall be scheduled with Landlord and done only at such time and in such manner as Landlord designates. Landlord shall have the right to prescribe the weight, size and position of all safes and other heavy property brought into the Building and also the times and manner of moving the same in and out of the Building. Safes and other heavy objects shall, if considered necessary by Landlord, stand on supports of such thickness as is necessary to properly distribute the weight. Landlord will not be responsible for loss of or damage to any such safe or property in any case. Any damage to any part of the Building, its contents, occupants or visitors by moving or maintaining any such safe or other property shall be the sole responsibility and expense of Tenant.

5. No furniture, packages, supplies, equipment or merchandise will be received in the Building or carried up or down in the elevators, except between such hours, in such specific elevator and by such personnel as shall be designated by Landlord.

6. The requirements of Tenant will be attended to only upon application at the management office for the Project or at such office location designated by Landlord. Employees of Landlord shall not

perform any work or do anything outside their regular duties unless under special instructions from Landlord.

7. No sign, advertisement, notice or handbill shall be exhibited, distributed, painted or affixed by Tenant on any part of the Premises or the Building without the prior written consent of the Landlord. Tenant shall not disturb, solicit, peddle, or canvass any occupant of the Project and shall cooperate with Landlord and its agents of Landlord to prevent same.

8. The toilet rooms, urinals, wash bowls and other apparatus shall not be used for any purpose other than that for which they were constructed, and no foreign substance of any kind whatsoever shall be thrown therein. The expense of any breakage, stoppage or damage resulting from the violation of this rule shall be borne by the tenant who, or whose servants, employees, agents, visitors or licensees shall have caused same.

9. Tenant shall not overload the floor of the Premises, nor mark, drive nails or screws, or drill into the partitions, woodwork or drywall or in any way deface the Premises or any part thereof without Landlord's prior written consent. Tenant shall not purchase spring water, ice, towel, linen, maintenance or other like services from any person or persons not approved by Landlord.

10. Except for vending machines intended for the sole use of Tenant's employees and invitees, no vending machine or machines other than fractional horsepower office machines shall be installed, maintained or operated upon the Premises without the written consent of Landlord.

11. Tenant shall not use or keep in or on the Premises, the Building, or the Project any kerosene, gasoline, explosive material, corrosive material, material capable of emitting toxic fumes, or other inflammable or combustible fluid chemical, substitute or material. Tenant shall provide material safety data sheets for any Hazardous Material used or kept on the Premises.

12. Tenant shall not without the prior written consent of Landlord use any method of heating or air conditioning other than that supplied by Landlord.

13. Tenant shall not use, keep or permit to be used or kept, any foul or noxious gas or substance in or on the Premises, or permit or allow the Premises to be occupied or used in a manner offensive or objectionable to Landlord or other occupants of the Project by reason of noise, odors, or vibrations, or interfere with other tenants or those having business therein, whether by the use of any musical instrument, radio, phonograph, or in any other way. Tenant shall not throw anything out of doors, windows or skylights or down passageways.

14. Tenant shall not bring into or keep within the Project, the Building or the Premises any animals, birds, aquariums, or, except in areas designated by Landlord, bicycles or other vehicles.

15. No cooking shall be done or permitted on the Premises, nor shall the Premises be used for the storage of merchandise, for lodging or for any improper, objectionable or immoral purposes. Notwithstanding the foregoing, Underwriters' laboratory-approved equipment and microwave ovens may be used in the Premises for heating food and brewing coffee, tea, hot chocolate and similar beverages for employees and visitors, provided that such use is in accordance with all applicable federal, state, county and city laws, codes, ordinances, rules and regulations.

16. The Premises shall not be used for manufacturing or for the storage of merchandise except as such storage may be incidental to the use of the Premises provided for in the Summary. Tenant shall not occupy or permit any portion of the Premises to be occupied as an office for a messenger-type operation or dispatch office, public stenographer or typist, or for the manufacture or sale of liquor, narcotics, or tobacco in any form, or as a medical office, or as a barber or manicure shop, or as an employment bureau without the express prior written consent of Landlord. Tenant shall not engage or pay any employees on the

Premises except those actually working for such tenant on the Premises nor advertise for laborers giving an address at the Premises.

17. Landlord reserves the right to exclude or expel from the Project any person who, in the judgment of Landlord, is intoxicated or under the influence of liquor or drugs, or who shall in any manner do any act in violation of any of these Rules and Regulations.

18. Tenant, its employees and agents shall not loiter in or on the entrances, corridors, sidewalks, lobbies, courts, halls, stairways, elevators, vestibules or any Common Areas for the purpose of smoking tobacco products or for any other purpose, nor in any way obstruct such areas, and shall use them only as a means of ingress and egress for the Premises.

19. Tenant shall not waste electricity, water or air conditioning and agrees to cooperate fully with Landlord to ensure the most effective operation of the Building's heating and air conditioning system, and shall refrain from attempting to adjust any controls. Tenant shall participate in recycling programs undertaken by Landlord including, but not limited to, general office materials (paper products, glass, plastic, aluminum cans), lamps, E-waste, used batteries and used printer cartridges).

20. Tenant shall store all its trash and garbage within the interior of the Premises. No material shall be placed in the trash boxes or receptacles if such material is of such nature that it may not be disposed of in the ordinary and customary manner of removing and disposing of trash and garbage in Los Angeles County, California without violation of any law or ordinance governing such disposal. All trash, garbage and refuse disposal shall be made only through entry-ways and elevators provided for such purposes at such times as Landlord shall designate. If the Premises is or becomes infested with vermin as a result of the use or any misuse or neglect of the Premises by Tenant, its agents, servants, employees, contractors, visitors or licensees, Tenant shall forthwith, at Tenant's expense, cause the Premises to be exterminated from time to time to the satisfaction of Landlord and shall employ such licensed exterminators as shall be approved in writing in advance by Landlord.

21. Tenant shall comply with all safety, fire protection and evacuation procedures and regulations established by Landlord or any governmental agency.

22. Any persons employed by Tenant to do janitorial work shall be subject to the prior written approval of Landlord, and while in the Building and outside of the Premises, shall be subject to and under the control and direction of the Building manager (but not as an agent or servant of such manager or of Landlord), and Tenant shall be responsible for all acts of such persons.

23. No awnings or other projection shall be attached to the outside walls of the Building without the prior written consent of Landlord, and no curtains, blinds, shades or screens shall be attached to or hung in, or used in connection with, any window or door of the Premises other than Landlord standard drapes. All electrical ceiling fixtures hung in the Premises or spaces along the perimeter of the Building must be fluorescent and/or of a quality, type, design and a warm white bulb color approved in advance in writing by Landlord. Neither the interior nor exterior of any windows shall be coated or otherwise sunscreened without the prior written consent of Landlord. Tenant shall be responsible for any damage to the window film on the exterior windows of the Premises and shall promptly repair any such damage at Tenant's sole cost and expense. Tenant shall keep its window coverings closed during any period of the day when the sun is shining directly on the windows of the Premises. Prior to leaving the Premises for the day, Tenant shall draw or lower window coverings and extinguish all lights. Tenant shall abide by Landlord's regulations concerning the opening and closing of window coverings which are attached to the windows in the Premises, if any, which have a view of any interior portion of the Building or Building Common Areas.

24. The sashes, sash doors, skylights, windows, and doors that reflect or admit light and air into the halls, passageways or other public places in the Building shall not be covered or obstructed by Tenant, nor shall any bottles, parcels or other articles be placed on the windowsills.

25. Tenant must comply with requests by the Landlord concerning the informing of their employees of items of importance to the Landlord.

26. Tenant must comply with all applicable "**NO-SMOKING**" or similar ordinances. If Tenant is required under the ordinance to adopt a written smoking policy, a copy of said policy shall be on file in the office of the Building.

27. Tenant hereby acknowledges that Landlord shall have no obligation to provide guard service or other security measures for the benefit of the Premises, the Building or the Project. Tenant hereby assumes all responsibility for the protection of Tenant and its agents, employees, contractors, invitees and guests, and the property thereof, from acts of third parties, including keeping doors locked and other means of entry to the Premises closed, whether or not Landlord, at its option, elects to provide security protection for the Project or any portion thereof. Tenant further assumes the risk that any safety and security devices, services and programs which Landlord elects, in its sole discretion, to provide may not be effective, or may malfunction or be circumvented by an unauthorized third party, and Tenant shall, in addition to its other insurance obligations under this Lease, obtain its own insurance coverage to the extent Tenant desires protection against losses related to such occurrences. Tenant shall cooperate in any reasonable safety or security program developed by Landlord or required by law.

28. All office equipment of any electrical or mechanical nature shall be placed by Tenant in the Premises in settings approved by Landlord, to absorb or prevent any vibration, noise and annoyance.

29. Tenant shall not use in any space or in the public halls of the Building, any hand trucks except those equipped with rubber tires and rubber side guards.

30. No tenant shall use or permit the use of any portion of the Premises for living quarters, sleeping apartments or lodging rooms.

31. Tenant shall install and maintain, at Tenant's sole cost and expense, an adequate, visibly marked and properly operational fire extinguisher next to any duplicating or photocopying machines or similar heat producing equipment, which may or may not contain combustible material, in the Premises.

32. All vendors, service providers or other agents of Tenant providing services to Tenant in the Premises or the Building shall provide proof of insurance as required in Landlord's sole discretion.

Landlord reserves the right at any time to change or rescind any one or more of these Rules and Regulations, or to make such other and further reasonable Rules and Regulations as in Landlord's judgment may from time to time be necessary for the management, safety, care and cleanliness of the Premises, Building, the Common Areas and the Project, and for the preservation of good order therein, as well as for the convenience of other occupants and tenants therein. Landlord may waive any one or more of these Rules and Regulations for the benefit of any particular tenants, but no such waiver by Landlord shall be construed as a waiver of such Rules and Regulations in favor of any other tenant, nor prevent Landlord from thereafter enforcing any such Rules or Regulations against any or all tenants of the Project. Tenant shall be deemed to have read these Rules and Regulations and to have agreed to abide by them as a condition of its occupancy of the Premises.

EXHIBIT E

SUNSET & PCH

FORM OF TENANT'S ESTOPPEL CERTIFICATE

The undersigned as Tenant under that certain Office Lease (the "Lease") made and entered into as of ___________, 20___ by and between _______________ as Landlord, and the undersigned as Tenant, for Premises on the ______________ floor(s) of the office building located at ______________, ________________________, California ____________, certifies as follows:

1. Attached hereto as Exhibit A is a true and correct copy of the Lease and all amendments and modifications thereto. The documents contained in Exhibit A represent the entire agreement between the parties as to the Premises.

2. The undersigned currently occupies the Premises described in the Lease, the Lease Term commenced on __________, and the Lease Term expires on ___________, and the undersigned has no option to terminate or cancel the Lease or to purchase all or any part of the Premises, the Building and/or the Project.

3. Base Rent became payable on ____________.

4. The Lease is in full force and effect and has not been modified, supplemented or amended in any way except as provided in **Exhibit A**.

5. Tenant has not transferred, assigned, or sublet any portion of the Premises nor entered into any license or concession agreements with respect thereto except as follows:

6. Tenant shall not modify the documents contained in Exhibit A without the prior written consent of Landlord's mortgagee.

7. All monthly installments of Base Rent, all Additional Rent and all monthly installments of estimated Additional Rent have been paid when due through ___________. The current monthly installment of Base Rent is $_____________________.

8. All conditions of the Lease to be performed by Landlord necessary to the enforceability of the Lease have been satisfied and Landlord is not in default thereunder. In addition, the undersigned has not delivered any notice to Landlord regarding a default by Landlord thereunder.

9. No rental has been paid more than thirty (30) days in advance and no security has been deposited with Landlord except as provided in the Lease.

10. As of the date hereof, there are no existing defenses or offsets, or, to the undersigned's knowledge, claims or any basis for a claim, that the undersigned has against Landlord.

11. If Tenant is a corporation or partnership, each individual executing this Estoppel Certificate on behalf of Tenant hereby represents and warrants that Tenant is a duly formed and existing entity qualified to do business in California and that Tenant has full right and authority to execute and deliver this Estoppel Certificate and that each person signing on behalf of Tenant is authorized to do so.

12. There are no actions pending against the undersigned under the bankruptcy or similar laws of the United States or any state.

13. Other than in compliance with all applicable laws and incidental to the ordinary course of the use of the Premises, the undersigned has not used or stored any hazardous substances in the Premises.

14. To the undersigned's knowledge, all tenant improvement work to be performed by Landlord under the Lease has been completed in accordance with the Lease and has been accepted by the undersigned and all reimbursements and allowances due to the undersigned under the Lease in connection with any tenant improvement work have been paid in full.

The undersigned acknowledges that this Estoppel Certificate may be delivered to Landlord or to a prospective mortgagee or prospective purchaser, and acknowledges that said prospective mortgagee or prospective purchaser will be relying upon the statements contained herein in making the loan or acquiring the property of which the Premises are a part and that receipt by it of this certificate is a condition of making such loan or acquiring such property.

Executed at ______________ on the ____ day of ___________, 20__.

"Tenant":

____,
a ____

By: ____
Its: ______________________________________

By: ____
Its: ______________________________________

OFFICE LEASE

SUNSET & PCH

BRE SUNSET COAST, LLC,

a Delaware limited liability company,

as Landlord,

and

AADI BIOSCIENCE, INC.,

a Delaware corporation,

as Tenant.

TABLE OF CONTENTS

Page

EXHIBITS

INDEX

Page(s)

Page(s)

Exhibit 21.1

Subsidiaries of Aadi Bioscience, Inc.

Name of Subsidiary	**Jurisdiction of Incorporation or Organization**
Aadi Subsidiary, Inc.	Delaware

Consent of Independent Registered Public Accounting Firm

Aadi Bioscience, Inc.

Pacific Palisades, California

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-268021, 333-259785, 333-255129, 333-223113, 333-217320 and 333-229087) and Form S-8 (Nos. 333-262639, 333-259787, 333-220057, 333-224189, 333-229089, 333-230114 and 333-237210) of Aadi Bioscience, Inc., of our report dated March 28, 2023, relating to the consolidated financial statements, which appears in this Annual Report on Form 10-K.

/s/ BDO USA, LLP

San Diego, California

March 28, 2023

Exhibit 31

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Scott Giacobello, certify that:

1. I have reviewed this annual report on Form 10-K of Aadi Bioscience, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) 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.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2023	By:	*/s/ Scott Giacobello*
		Scott Giacobello
		Interim Chief Executive Officer and President, and Chief Financial Officer (Principal Executive Officer and Principal Financial Officer)

Exhibit 32

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

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

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

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 28, 2023

By: */s/ Scott Giacobello*

Scott Giacobello
Interim Chief Executive Officer and President, and Chief Financial Officer
(Principal Executive Officer and
Principal Financial Officer)