UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

OR

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

Commission File Number 001-39488

Apexigen, Inc.

(Exact name of registrant as specified in its Charter)

Delaware	**85-1260244**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
75 Shoreway Road, Suite C San Carlos, CA	**94070**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 931-6236

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**APGN**	**The Nasdaq Stock Market LLC**
Warrants, each whole warrant exercisable for one share of Common Stock at an exercise price of $11.50 per share	**APGNW**	**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 ☐ No ☒

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the registrant's Common Stock held by non-affiliates as of June 30, 2022 was $203,552,461. Shares of the registrant's common stock held by each executive officer, director and by each other person that may be deemed to be an affiliate have been excluded from this calculation. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

The number of shares of registrant's Common Stock outstanding as of February 17, 2023 was 24,641,723.

Table of Contents

		Page
Special Note Regarding Forward-Looking Statements		1
PART I		
Item 1.	Business	3
Item 1A.	Risk Factors	31
Item 1B.	Unresolved Staff Comments	82
Item 2.	Properties	82
Item 3.	Legal Proceedings	82
Item 4.	Mine Safety Disclosures	82
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	83
Item 6.	[Reserved]	84
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	85
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	94
Item 8.	Financial Statements and Supplementary Data	95
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	121
Item 9A.	Controls and Procedures	121
Item 9B.	Other Information	121
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	121
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	122
Item 11.	Executive Compensation	127
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	132
Item 13.	Certain Relationships and Related Transactions, and Director Independence	133
Item 14.	Principal Accounting Fees and Services	136
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	137
Item 16.	Form 10-K Summary	139

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, timing, and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “would,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential,” or “continue” or the negative of these terms or other similar expressions. Forward-looking statements contained in this report include, but are not limited to, statements about:

- our expectations regarding the length of time that our existing capital resources will be sufficient to enable us to fund our planned operations, including our ability to continue as a going concern;
- our public securities’ potential liquidity and trading;
- our ability to maintain the listing of our public securities on the Nasdaq Stock Market;
- our projected financial performance and market opportunity;
- estimates of our expenses, capital requirements, and need for additional financing;
- the anticipated benefits of cost-reduction efforts;
- our expectations regarding the anticipated benefits of the Business Combination (as defined in our notes to consolidated financial statements in this Annual Report);
- the outcome of any legal proceedings that may be instituted against us related to the Business Combination;
- the efficacy of immuno-oncology therapeutics in the treatment of cancer;
- the timing and focus of our current and future clinical trials, and the reporting of data from those trials;
- the ability of our clinical trials to demonstrate safety and efficacy, and other positive results, of our product candidates;
- the anticipated beneficial characteristics, safety, efficacy, and therapeutic effects of our product candidates;
- our estimates of the number of patients in the United States who suffer from the diseases we are targeting and the number of patients that will enroll in clinical trials;
- the timing or likelihood of regulatory filings and approvals for our product candidates for various diseases;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to commercializing our product candidates, if approved, including which indications will be pursued;
- the development of competitors’ product candidates;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- the impact of the ongoing COVID-19 pandemic, rising interest rates, and geopolitical risks on our business and operations;
- our ability to retain key personnel and to attract and retain additional qualified personnel;
- our plans and ability to obtain, maintain, enforce, or protect intellectual property rights;
- our ability to establish and maintain relationships with, and our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials; and
- the success of our licensing agreements and clinical development by our licensees.

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

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

PART I

Item 1. Business.

Unless otherwise indicated or the context otherwise requires, references included in this Business section to "Apexigen," "Apexigen's," "we," "our," and "us," refer to Legacy Apexigen prior to the consummation of the Business Combination and Apexigen, Inc. following the Business Combination.

Background of the Business Combination

In March 2022, Brookline Capital Acquisition Corp. ("BCAC"), our legal predecessor company and a special purpose acquisition company, and Apexigen America, Inc., which was then known as Apexigen, Inc. ("Legacy Apexigen") entered into a definitive business combination agreement ("Business Combination Agreement"). When the transactions contemplated under the Business Combination Agreement closed on July 29, 2022 (the "Business Combination"), Legacy Apexigen survived as a wholly-owned subsidiary of BCAC, BCAC changed its name to Apexigen, Inc., and Legacy Apexigen changed its name to Apexigen, America, Inc. On July 30, 2022, our common stock and public warrants, formerly those of BCAC's, began trading on the Nasdaq Stock Market under the ticker symbols "APGN" and "APGNW," respectively.

Concurrently with the execution of the Business Combination Agreement, BCAC entered into subscription agreements with certain investors for a private investment in public equity ("PIPE") transaction to close concurrently with the Business Combination. In addition, concurrent with the execution of the Business Combination Agreement, BCAC, Legacy Apexigen and Lincoln Park entered into a committed investment agreement under which we have the right to direct Lincoln Park to purchase up to an aggregate of $50.0 million of our common stock over a 24-month period pursuant to the terms of a purchase agreement, subject to certain limitations set forth therein, including the closing stock price of our common stock not being below $3.00 per share at the time we deliver a purchase notice to Lincoln Park.

Legacy Apexigen was incorporated in Delaware in 2010 to focus on the discovery, development and commercialization of humanized monoclonal antibody therapies. Apexigen is headquartered in San Carlos, California.

Overview

We are a clinical-stage biopharmaceutical company focused on discovering and developing a new generation of antibody therapeutics for oncology, with an emphasis on new immuno-oncology agents designed to harness the patient's immune system to combat and eradicate cancer. We and our licensees are researching and developing several protein therapeutics that were discovered using our APXiMAB antibody platform. We have one clinical-stage candidate, sotigalimab ("sotiga" or "APX005M") that we are developing. We also have several preclinical and research stage antibodies we discovered using our APXiMAB platform that we are not currently advancing as we focus our resources on completing ongoing clinical and manufacturing activities for the sotiga program. Our licensees are advancing five product candidates in clinical development that were enabled by discoveries from our APXiMAB platform.

Our clinical-stage candidate, sotigalimab, is a humanized agonist antibody that targets and activates CD40, a co-stimulatory receptor that is essential for activating both the innate and adaptive arms of the immune system, to stimulate an anti-tumor immune response. Sotigalimab is currently in Phase 2 clinical development for the treatment of solid tumors such as soft tissue sarcomas, esophageal and gastroesophageal junction ("GEJ") cancers and melanoma in combination with chemotherapy, radiation therapy and immunotherapy.

Our APXiMAB platform was used to enable the discovery of multiple protein therapeutic product candidates against a variety of molecular targets, including targets that are difficult to drug with conventional antibody technologies. In addition to the product candidates that we wholly own, several product candidates discovered through the use of the APXiMAB platform are in clinical development by our licensees. The most advanced of these programs is Novartis' Beovu® (brolucizumab-dbll) product, which received FDA approval in 2019 and is marketed in over 70 countries. Two other programs being developed by our licensees are in later-stage development; Simcere's suvemcitug (BD0801) is in Phase 3 clinical development in ovarian cancer and Mabwell's 9MW0211 is in an adaptive, pivotal Phase 2/3 clinical trial in wet age-related macular degeneration ("AMD"). There is no guarantee that any of the product candidates discovered using our APXiMAB antibody platform, whether developed by us or our licensees, will receive regulatory approval.

Our Strategy

We are focused on discovering and developing next-generation antibody therapeutics for the treatment of cancer. Our goal is to leverage the power of the body's immune system to combat and eradicate tumor cells, generating enhanced tumor-specific immunity and leading to significant clinical benefits such as improved survival for patients across a wide range of cancers. The key tenets of our business strategy to achieve this goal include:

- **Advance sotiga to registrational clinical trials with a partner**. We believe sotiga could be an effective treatment in a broad range of oncology indications and therapeutic combinations. We are evaluating sotiga in combination with other immuno-oncology agents, chemotherapy, radiation therapy, and cancer vaccines in multiple clinical trials in patients with solid tumors, including soft tissue sarcomas, esophageal and GEJ cancers and melanoma.

- **Invest in the advancement and expansion of our pipeline.** In addition to sotiga, we plan to advance the remainder of our internal pipeline, which consists of two preclinical programs and multiple research-stage programs after we obtain adequate financial resources. We may supplement our current pipeline by selectively acquiring or exclusively in-licensing rights to develop product candidates from biotechnology and pharmaceutical companies.

- **Leverage our APXiMAB platform to develop additional novel product candidates**. Our APXiMAB platform has enabled discovery of a robust wholly owned pipeline as well as five additional product candidates that our licensees are developing. We believe there is significant opportunity to utilize our APXiMAB platform to discover and develop additional monoclonal antibodies with desirable attributes for oncology indications.

- **Establish strategic out-licenses and collaborations to supplement our development capabilities and generate funding.** We plan to establish additional collaborations and out-licenses, in particular in the near term for the development and commercialization of sotigalimab and one or more of our pre-clinical product candidates. These collaborations may allow us to supplement our development, manufacturing, regulatory and commercialization capabilities to broaden and accelerate clinical development and potential commercialization of our product candidates, provide us with significant funding to advance our pipeline and significantly reduce our share of the costs of the development and manufacturing of sotigalimab and any pre-clinical product candidates with respect to which we out-license development or commercialization rights.

Our Out-Licensed Programs

Our APXiMAB platform was used to enable the discovery of multiple protein therapeutic product candidates against a variety of molecular targets, including targets that are difficult to drug with conventional antibody technologies. In addition to the product candidates that we wholly own, several programs for the development of product candidates discovered through the use of the APXiMAB platform are in clinical development by our licensees. The most advanced of these programs is Novartis' Beovu® (brolucizumab-dbll) product, which received FDA approval in 2019 and is marketed in over 70 countries. Two other programs being developed by our licensees are in late-stage development: Simcere's suvemcitug (BD0801) is in Phase 3 clinical development in ovarian cancer and Mabwell's 9MW0211 is in an adaptive, pivotal Phase 2/3 clinical trial in wet age-related macular degeneration. An additional program, OCS-02, is being developed by Oculis SA and is in Phase 2 development for ocular disease, and a final program, TRK-950, is being developed by Toray Industries and is in Phase 1 development for oncology. There is no guarantee that any of the product candidates discovered using our APXiMAB antibody platform and developed by our third-party licensees will receive regulatory approval.

Background on Immuno-oncology

Immuno-oncology therapeutics harness the power of the immune system to treat cancer. This class of therapeutics has transformed patient care over the last decade. Immunosurveillance and activation of the immune system is mediated by both innate and adaptive immune mechanisms and normally protects patients from tumor growth and metastasis. Antigen-presenting cells ("APCs"), including dendritic cells ("DCs") and monocytes, are also key mediators of innate immunity, recognizing cancer cells and destroying them via phagocytosis or by recruiting and activating adaptive immune cells through direct cell contact and effective presentation of cancer-specific antigens in concert with costimulatory molecules and cytokines. Adaptive immune cells can mediate durable anti-tumor immunity by multiple mechanisms including production of anti-tumor antibodies by B cells and direct cytotoxicity by CD8 T cells.

While the immune system may initially control tumor formation and growth, over time, tumor cells may evolve to evade recognition and elimination by immune cells. These evasion strategies involve modulation of activating and inhibitory immune checkpoint pathways. Currently, many approved therapeutic antibodies target T cells by blocking inhibitory checkpoint molecules, including CTLA-4 and PD-1. While these antibodies have shown efficacy in certain subsets of patients, the majority of patients are refractory to treatment, suggesting that the treatment of cancer requires additional approaches which employ diverse or additional mechanisms of action that facilitated the engagement of both innate and adaptive immune components.

Sotigalimab (APX005M) Program

Harnessing the body's immune system through immunotherapies is an effective means of treating patients with cancer. For example, immune checkpoint inhibitors to PD-1, PD-L1, and CTLA-4 have shown meaningful increases in overall patient survival. Most tumors, however, are either resistant to checkpoint inhibition or become resistant after treatment. Immune suppressive mechanisms of resistance include reductions in tumor-infiltrating lymphocytes and impaired T cell function. Restoring or increasing T cell functionality and infiltration is believed to be crucial to cancer treatment, with the potential to overcome checkpoint inhibition resistance, enhance the effects of chemotherapy, radiotherapy or vaccine therapy, and increase survival.

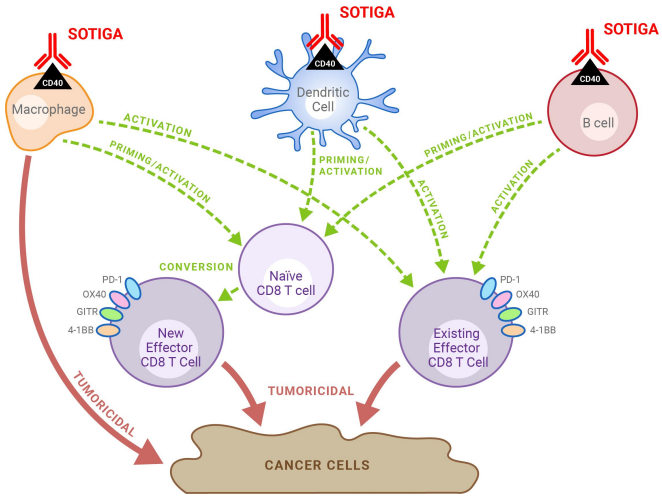
DCs are APCs that provide signaling leading to T cell activation, function and infiltration. CD40, which is predominantly expressed on APCs such as DCs, is a key mediator of this activation. Activation of CD40 initiates and amplifies a multi-cellular immune response, bringing different components of both the innate and adaptive arms of the immune system to work in concert and resulting in increased antigen presentation, maturation of DCs and activation of CD4+ and CD8+ T cells, NK cells and neutrophils to attack tumor cells.

Sotiga is a CD40 agonist antibody that we designed to maximize its agonistic properties through:

- Unique epitope specificity to mimic the binding of CD40 ligand ("CD40L") to the CD40 receptor binding site for increased potency;
- An engineered increase in binding to Fc gamma receptor 2B (FcgRIIB) to increase antibody cross-linking and antitumor potency; and
- An engineered reduction in binding to Fc gamma receptor 3a (FcgRIIIa) to eliminate antibody-dependent cell-mediated cytotoxicity ("ADCC") effects on CD40-expressing APCs.

We believe that sotiga's ability to stimulate both innate and adaptive immunity enhances tumor infiltration of immune and proinflammatory cells such as M1 macrophages and T cells and immune stimulatory cytokines such as interferon-g. Tumors with an inflamed phenotype tend to be more responsive to anti-cancer therapies. We therefore believe sotiga may combine well with and enhance the efficacy of other immuno-oncology agents, targeted therapeutics, chemotherapies, vaccines and radiation therapy to improve outcomes for patients.

Figure 1: Sotiga Targets CD40: A Key Pathway in Stimulating Immune Response in Cancer



We have studied sotiga in over a dozen company-sponsored or investigator- or cooperative group-sponsored clinical trials in numerous tumor settings as both a monotherapy and in combination with chemotherapies, radiation therapies, immuno-oncology therapeutics and cancer vaccines. None of these clinical trials was powered to determine statistical significance over a control arm. We have dosed over 500 patients with sotiga across these studies, generating a significant amount of safety and efficacy data to guide our continued development of sotiga. The data to date demonstrate that sotiga is reasonably well tolerated as a monotherapy and also in combination with other cancer therapeutics. The serious adverse effects ("SAEs") considered at least possibly related to sotiga across all clinical trials reported in more than one subject were cytokine release syndrome (n= 16, ~3%), blood bilirubin increased (n= 3,<0.6%), infusion-related reaction (n= 3,<0.6%), aspartate aminotransferase increased (n=3, <0.6%), alanine aminotransferase increased (n= 2,<0.4%), colitis (n=2, <0.4%), pyrexia (n= 2, <0.4%), thrombocytopenia/platelet count decreased (n=2, <0.4%) and pancreatitis/ acute pancreatitis (n=2, <04%). Following the data cut, a new SAE of hepatic failure (dysfunction) was reported, bringing the number of hepatic failure (dysfunction) cases to two (<0.4%). In several clinical trials, sotiga was dosed in combination in with other therapeutics, including anti-PD-1 antibodies, chemotherapy or radiation, and in several of the SAEs listed above such as colitis, the events were also considered related to the other components of the combination such as an anti-PD-1 antibody. We have observed single-agent anti-tumor activity, including complete responses (“CRs”) in patients with unresectable or metastatic melanoma who had not previously received immuno-oncology therapeutics, and efficacy in combination with antibodies to PD-1 or PD-L1 (together, “PD-(L)1”), chemotherapies and radiation therapies in Phase 2 clinical development in multiple tumor settings. Our current clinical development activities are focused on completing the enrollment and treatment of patients with advanced sarcoma with sotiga in combination with doxorubicin.

Sotiga in Advanced Sarcoma

Background

In 2021, there were approximately 13,000 new cases of soft tissue sarcoma (including heart cancer) in the United States resulting in over 5,300 deaths. The overall prevalence in the United States in 2018 was approximately 158,000 cases. The five-year survival rate for patients with metastatic sarcoma is approximately 15%.

Soft tissue sarcomas are a heterogeneous group of malignancies of mesenchymal origin. More than 50 subtypes are defined, each with distinct clinical and biologic features. Chemotherapy remains the standard approach for most soft tissue sarcoma subtypes when disease is unresectable or metastatic. Doxorubicin and the combination of gemcitabine and docetaxel are front-line chemotherapy regimens used for initial treatment of most soft tissue sarcoma. Across several recent large randomized controlled studies evaluating new agents in sarcoma, response rates in the doxorubicin control were between 5-19%. In a recent Phase 3 study of olaratumab, the doxorubicin control arm was reported to have an overall response rate ("ORR") of 18.3% and a median progression-free survival ("mPFS") of 6.8 months in the soft tissue sarcoma population. Studies of immunotherapy-based approaches for the treatment of sarcoma have shown limited efficacy to date. Newer and more effective treatments are needed in this difficult-to-treat indication.

In August 2021, the FDA granted us Orphan Drug Designation for sotigalimab for the treatment of soft tissue carcinoma.

Phase 2 Clinical Trial of Sotiga in Combination with Doxorubicin

We are collaborating with Columbia University on a multi-center, investigator-sponsored Phase 2 clinical trial (NCT03719430) of sotiga in combination with doxorubicin in patients with advanced soft tissue sarcoma (the APX005M-009 Trial). This trial completed enrollment of the originally planned 32 patients in January 2023. In November 2022, we announced that we had observed a mPFS of 12.45 months (data as of September 27, 2022) in the evaluable patients (n=10) with advanced/unresectable or metastatic de-differentiated liposarcoma (LPS). Based on the mPFS observed in these LPS patients, which is meaningfully higher than the historical mPFS of patients with LPS who are treated with standard-of-care doxorubicin alone, we and our collaborator Columbia University decided to expand the LPS cohort to enroll 10 additional patients with LPS to supplement the data we have observed and potentially inform a registration-enabling study in de-differentiated LPS.

Sotiga in Anti-PD-(L)1 Refractory Melanoma

Background

In 2020, there were an estimated 324,000 new cases of melanoma of skin worldwide resulting in over 57,000 deaths. The five-year survival rate for patients whose melanoma is diagnosed while it is still localized and treated early is greater than 95%. However, melanoma is more likely to spread than other skin cancers in patients with later stage diagnoses. In general, treatments for advanced melanoma can be effective but rarely curative. For patients with distant spread of melanoma at diagnosis, the five-year relative survival rate is approximately 30%.

The current standard-of-care treatment for patients with metastatic or unresectable melanoma includes immuno-oncology agents such as anti-PD-1 drugs (e.g., pembrolizumab and nivolumab), the anti-CTLA-4 antibody, ipilimumab, the anti-LAG-3 antibody, relatlimab, and BRAF/MEK inhibitors for tumors that harbor specific gene mutations. These drugs have shown responses in approximately 15% to 40% of melanoma patients and extended the progression-free survival (“PFS”) and overall survival (“OS”) of patients receiving these therapies. Despite these treatments, the majority of patients have not had durable responses and have relapsed. For those patients whose disease progresses following approved targeted therapy or immunotherapy regimens, treatment options are limited to minimally active agents that include chemotherapy, radiation, surgery and investigational agents. Therefore, there is an unmet need for new effective treatments.

Phase 1b/2 Clinical Trial of Sotiga in Combination with Nivolumab

In 2021, we completed a Phase 1b/2 open-label trial (NCT03123783) in which we studied sotiga in combination with nivolumab, an anti-PD-1 antibody, in subjects with unresectable or metastatic melanoma that had progressive disease (PD) during treatment with anti-PD-(L)1 therapy as one arm of a multi-indication trial (the "APX005M-002 Trial"). Eligible patients with melanoma had to have documented disease progression by two consecutive tumor assessments.

In the Phase 1b portion of the APX005M-002 Trial, we evaluated sotiga at three dose levels administered every three weeks in combination with nivolumab (360mg). No dose-limiting toxicities occurred and 0.3 mg/kg of sotiga administered every three weeks was determined to be the recommended dose for use in the Phase 2 portion (RP2D) of the study.

In the Phase 2 portion of the APX005M-002 Trial, 38 patients with anti-PD-(L)1 refractory metastatic melanoma were enrolled and evaluable for safety and 33 of these patients were evaluable for efficacy. Of the efficacy-evaluable patients, 14 (42%) had elevated levels of lactate dehydrogenase (LDH) at baseline, a poor prognostic indicator of response to PD-(L)1 blockade therapy, seven (21%) had received two or more prior lines of therapy and eight (24%) had previously been treated with an anti-CTLA-4 antibody.

There were five partial responses (“PRs”) in the trial for an overall response rate (“ORR”) of 15.2% and ten patients with stable disease (“SD”) (30.3%). The duration of response (“DoR”) as determined in the trial ranged from 4.1+ to 24.7+ months, and was measured from the first documented PR to the earlier of the date of progression or the last imaging study prior to the end of the trial even if the patient was in an ongoing PR. Four of the responding patients remained in an ongoing PR at the completion of the trial, after which we ceased following and monitoring these patients for progression. The fifth responding patient developed an isolated brain lesion approximately nine months after stopping combination therapy (DoR of approximately 18.7 months), subsequently received radiation therapy for the brain lesion, and did not require any further local or systemic therapy through the end of the trial. The duration of SD was up to 14.0+ months and the majority of patients with SD had a duration of SD lasting longer than 3.5 months. These data suggest that treatment with sotiga in combination with nivolumab resulted in clinical benefits in PD-1 blockade refractory patients by achieving durable objective tumor responses and stable disease.

In the APX005M-002 Trial, we observed that the combination of sotiga and nivolumab could be administered to patients with anti-PD-(L)1 refractory melanoma repeatedly for greater than one year with an acceptable safety profile. The majority of adverse events ("AEs") considered related to sotiga, nivolumab or the combination were transient and grade 1 or 2. The most common AEs consisted of fever, fatigue, chills, headache, nausea, pruritus, vomiting, rash, arthralgias, myalgias, and elevated liver function tests. No SAEs or deaths were considered related to the study drugs and no treatment withdrawals or discontinuations were reported as due to AEs related to sotiga. The incidence of immune-related adverse events was low, and the AEs were similar in nature to those that have been reported with nivolumab alone. There were no reported cases of cytokine release syndrome.

We believe the data observed in the APX005M-002 Trial support the advancement of the development of sotiga as a potential treatment in combination with a PD-(L)1 inhibitor for patients with unresectable or metastatic melanoma that had progressive disease during treatment with anti-PD-(L)1 therapy. Accordingly, in June 2022, we discussed with the FDA in a Type C meeting our plans for a registration-enabling study of sotiga in this combination and setting. We received feedback and support from the FDA for a potential randomized registration-enabling clinical trial of sotigalimab in combination with a PD-1 inhibitor to treat patients with PD-1 blockade refractory melanoma, which potential trial would compare the combination of sotigalimab and a PD-1 inhibitor against an investigator's choice of standard of care therapy and would demonstrate the contribution of sotigalimab and the PD-1 inhibitor as components of the combination regimen. Due to the development potential of sotiga in other oncology settings, the significant cost of conducting a subsequent trial of sotiga in this setting, our current resources and the state of the capital markets, we do not plan to develop sotiga in this setting independently and are seeking to engage a global collaboration partner to advance the development of sotiga in this and other settings.

Sotiga in Esophageal and GEJ Cancer

Background

Esophageal cancer is the sixth leading cause of cancer-related deaths and the eighth most common cancer worldwide. Approximately 19,000 and 604,000 new cases of esophageal cancer were estimated to have occurred in 2020 in the United States and worldwide, respectively, resulting in over 15,000 and 544,000 deaths in the United States and worldwide, respectively. The overall five-year survival rate for patients diagnosed with esophageal cancer in the United States is approximately 20%. Trends for histologic subtypes have been shifting, with the incidence of adenocarcinomas steadily climbing in the past several decades compared to the more common squamous cell carcinoma. Today, adenocarcinomas present the predominant subtype in the United States and European countries compared to squamous cell carcinoma, which is the major histologic type in Asia and other countries.

In October 2020, the FDA granted us Orphan Drug Designation for sotigalimab for the treatment of esophageal and GEJ cancers.

Phase 2 Clinical Trial of Sotiga as a Neoadjuvant Therapy

In December 2021, we completed enrollment of 34 patients in our Phase 2 clinical trial (NCT03165994) to study sotiga in combination with standard-of-care chemoradiation as a neoadjuvant treatment for patients with respectable esophageal or GEJ cancer (the "APX005M-006 Trial"). The primary objective of the APX005M-006 Trial is to assess the efficacy of the combination, as measured by the pathologic complete response ("pCR") rate, and to further characterize the safety and feasibility of the combination in this setting.

In September 2022, we reported results and data from our APX005M-006 Trial that were featured in a poster presentation at the annual European Society for Medical Oncology (ESMO) Congress. The data presented from the APX005M-006 Trial showed that sotiga combined with neoadjuvant chemoradiation for esophageal and GEJ cancers was generally safe and well tolerated. The majority of patients treated in the trial had Grade 1-2 AEs. Six serious AEs considered at least possibly related to sotiga included cytokine release syndrome observed in three patients, nausea and vomiting in one patient, dysphagia in one patient and Guillain-Barre Syndrome in one patient. There were no patient withdrawals due to sotiga and no deaths related to the combination. As of July 2022, of the 29 evaluable patients, 11 (38%) patients had a pCR and 19 (66%) patients had a mPR (major pathological response) with less than 10% of the residual tumor remaining after treatment. By histology, the pCR rate was 33% (8/24) in patients with adenocarcinoma and 60% (3/5) in patients with squamous cell carcinoma. The pCR rate was 41.2% for patients (n= 17) receiving four doses of sotiga versus 33.3% for patients (n= 12) receiving three doses. The R0 resection was achieved in 86% (25/29) of the patients and progressive disease was only 7%. Paired biomarker analysis collected before and one to two weeks following a single run-in dose of sotiga alone demonstrated significantly increased tumor infiltration of activated dendritic cells, monocytes and both CD8 and CD4 T cells compared to baseline. We believe that the observed immune/inflammatory response in the tumor demonstrates the ability of sotiga to change the tumor immune microenvironment from "cold" to "hot", which we believe validates sotiga's mechanism of action.

We believe the data observed in the APX005M-006 Trial support the advancement of the development of sotiga as a potential treatment in combination with other therapeutics in patients with esophageal or GEJ cancer. However, due to the development potential of sotiga in other oncology settings, the significant cost of conducting a subsequent trial of sotiga to explore use as a treatment in patients with esophageal or GEJ cancer, our current resources and the state of the capital markets, we do not plan to develop sotiga in this setting independently and are seeking to engage a global collaboration partner to advance the development of sotiga in this and other settings.

Our APXiMAB Platform

Our APXiMAB platform was used to discover all of our wholly owned product candidates and several programs for the development of product candidates that we have out-licensed. Our proprietary APXiMAB platform is comprised of two primary components:

- Generation of hybridomas from rabbit B cells using fusion cell lines which enable us to reproducibly generate large numbers of rabbit monoclonal antibodies; and
- Humanization of these antibodies using our multi lineage guided (MLG) humanization technology.

Advantages of Rabbit Antibodies

Rabbits offer numerous advantages over other animal species for the generation of therapeutic antibodies. Unlike rodents and humans, which rely primarily on VDJ rearrangement (variable (V), diversity (D) and joining (J) gene segment rearrangements), rabbits use an additional process called gene conversion, to generate a broad and diverse antibody repertoire.

Rabbit antibodies offer:

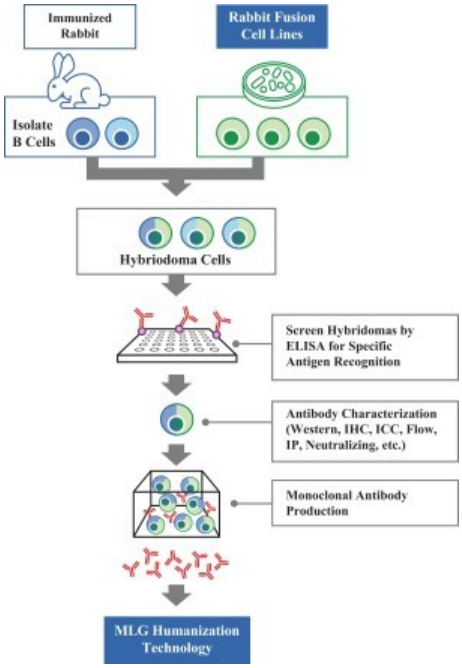
- diverse epitope recognition to enable fit-for-purpose therapeutic antibody generation;
- the ability to recognize epitopes that are not immunogenic in other species, including small-size epitopes; and
- high affinity and specificity.

Our Hybridoma Technology

Despite the multiple advantages of rabbit-derived antibodies, they were generally not used as a source of monoclonal antibodies until Epitomics, our predecessor, developed a fusion cell line capable of generating stable hybridoma clones, which enables us to generate high quality rabbit-derived antibodies from hybridoma cell lines.

Our antibody generation process begins with immunization of rabbits from which B cells are isolated and fused to a rabbit myeloma cell line, generating hybridoma cells capable of stably producing rabbit antibodies. These antibodies are screened for desired properties such as affinity and specificity and evaluated in panels of biochemical and cellular assays.

Figure 2: The APXiMAB Platform Process



Our Proprietary MLG Humanization Technology

To facilitate drug development, we humanize these rabbit monoclonal antibodies using our proprietary MLG humanization technology. Antibodies generated in non-human species and given to people as drugs can induce the formation of antibodies that neutralize the antibody drug or induce an undesirable immune response. These are often referred to as anti-drug antibodies or ADAs. Most therapeutic antibodies are therefore modified to have their sequences resemble human antibody sequences as much as possible in an attempt to avoid the development of ADAs.

In conventional humanization, sequences of antibodies derived from non-human species are altered to be closer to human antibody sequences by replacing the sequences of the antibody scaffold with that of human scaffolds. This creates a novel antibody in which the majority of the sequence comes from human antibody genes and the antigen-binding portions from the originating non-human species.

In our MLG humanization technology, we examine the antibody sequences generated in rabbits to better understand the importance of various residues both in the antigen-binding portions and the antibody scaffold. Residues that are highly conserved are preserved while other residues that are highly variable in the sequences of the rabbit antibodies are replaced with conservative amino acid substitutions found in human antibodies. Because our MLG technology enables humanization of antigen-binding regions, we believe that this process results in humanized antibodies that maintain the desired characteristics of the original rabbit antibody, including high affinity, while reducing immunogenicity.

Our Antibody Engineering Expertise

We deploy our knowledge of immunology and experience with therapeutic antibodies to engineer desirable features into our product candidates. For example, we incorporated the S267E mutation into the Fc portion of sotiga with the goal of achieving better potency and safety. This mutation, which had previously been described in scientific literature, changes the binding affinity to FcγRIIb and FcγRIIIa receptors to increase cross-linking and the potency of sotiga and reduce immune activation in circulation, where less FcR crosslinking occurs. Elimination of binding to FcγRIIIa minimizes ADCC and consequently prevents the depletion of CD40-expressing immune cells. Binding of sotiga to the CD40 ligand binding domain mimics that of the natural CD40 ligand and enhancing sotiga's activation of CD40. We have employed other strategies to design favorable properties into our product candidates.

Our Out-License Relationships

Our APXiMAB platform has enabled the discovery of multiple protein therapeutic product candidates with potential utility in multiple therapeutic areas. We have licenses with several biopharmaceutical companies that are developing product candidates that were discovered using our APXiMAB platform, which has been important to prosecuting the full value of our platform. We believe the licenses for the programs for the development of product candidates we have helped generate demonstrate the productivity and utility of our platform and position us to receive meaningful royalty payments if those product candidates are approved and successfully commercialized. Described below are the out-license relationships and the related agreements under which we may receive milestone or royalty payments. The aggregate payments received from these relationships as of December 31, 2022 include milestone payments of approximately $3.6 million, upfront or execution payments of approximately $1.9 million, and other service-related payments of approximately $0.3 million. Apexigen has also recorded $5.7 million in deferred revenue relating to certain royalty payments made under the ESBATech Agreement as of December 31, 2022.

Beovu and Novartis Antibody Candidate Discovery and Development Agreement

Our predecessor, Epitomics, entered into an antibody candidate discovery and development agreement with ESBATech AG in March 2007 (the "ESBATech Agreement"). In September 2009, Alcon Research, Ltd. ("ARL") acquired ESBATech and in April 2011 ARL's parent, Alcon, Inc. merged with Novartis AG ("Novartis"). Epitomics assigned the ESBATech Agreement to us in connection with our spin-out from Epitomics.

Under the ESBATech Agreement, Epitomics provided to ESBATech antibodies discovered using the APXiMAB platform that target certain molecules. ESBATech used those antibodies to develop drug product candidates to two different drug targets. Under the ESBATech Agreement, we granted ESBATech a non-exclusive, irrevocable, worldwide, sublicensable, royalty-bearing and perpetual license to our rights in certain intellectual property to develop and commercialize those drug product candidates. Other than financial interests, we do not have any ownership or right in those drug product candidates or any intellectual property covering or enabling the manufacture, use or sale of those drug product candidates.

Novartis, the successor in interest to ESBATech, has successfully developed and begun commercializing one of those drug product candidates, brolucizumab-dbll, a single-chain antibody fragment (scFv) targeting all of the isoforms of VEGF-A, which Novartis markets under the brand name Beovu®. Beovu is approved for use in over 70 countries and indicated for the treatment of neovascular (wet) AMD and has received European Commission approval for the use of Beovu for the treatment of visual impairment due to diabetic macular edema. Novartis is also developing Beovu for additional uses in several Phase 3 clinical trials.

In or around January 2019, Novartis licensed to Oculis SA another of the drug product candidates covered by the ESBATech Agreement, which was named LME636. Oculis renamed the drug candidate OCS-02. OCS-02 is a topical single-chain anti-TNF alpha antibody fragment. Oculis is in Phase 2 development of OCS-02 for the treatment of dry eye and uveitis.

Novartis and its predecessors have paid all of the upfront fee and milestone payments due under the ESBATech Agreement. The term of the ESBATech Agreement expired in March 2010; however, Novartis' royalty payment obligations under the agreement survive indefinitely. Novartis is obligated to pay Apexigen a very low single-digit royalty on worldwide net sales of Beovu and OCS-02 for therapeutic uses by Novartis, its affiliates or licensees in perpetuity. In October 2019, Novartis' Beovu was approved for commercial sale. However, Novartis has disputed its obligation to pay royalties to Apexigen under the ESBATech Agreement and continues to pay such royalties under protest. As a result, Apexigen has determined that any sales-based royalty revenue Apexigen has earned under the ESBATech Agreement is currently fully constrained and Apexigen has recorded the royalty proceeds as deferred revenue in its balance sheets in an aggregate amount of $5.7 million as of December 31, 2022.

Simcere License and Collaboration Agreement

In December 2008, Epitomics and Jiangsu Simcere Pharmaceutical R&D Co., Ltd. (Simcere) entered into a license and collaboration agreement (the "Simcere Agreement") for the development and commercialization of suvemcitug (BD0801) for oncology in the People's Republic of China ("China"). Suvemcitug is, a humanized anti-VEGF rabbit monoclonal antibody molecule. In connection with our spin-out from Epitomics, Epitomics assigned the Simcere Agreement to us. Simcere is responsible for conducting the development and commercialization of suvemcitug in China at its cost. We have reserved the right to develop and commercialize suvemcitug outside of China at our discretion. If we develop and commercialize suvemcitug outside of China, we will share with Simcere costs incurred and revenue earned outside of China. Under the Simcere Agreement, Simcere has an exclusive, royalty-bearing license (without the right to sublicense) to our rights in certain intellectual property that we licensed from Epitomics to develop and commercialize suvemcitug in the field of oncology therapeutics in China. Simcere granted us a non-exclusive, royalty-free, worldwide license (without the right to sublicense) to improvements derived from suvemcitug using the intellectual property we licensed to Simcere for any purpose outside of China and for purposes outside of oncology therapeutics in China. Intellectual property created in our collaboration program with Simcere is jointly owned by us and Simcere. Simcere is obligated to pay us milestone payments for achievement of certain clinical development milestones and low to high single-digit percentage royalties on net sales of suvemcitug in China until 15 years after the first commercial sale of suvemcitug. If we choose to commercialize suvemcitug outside of China, we share with Simcere a mid-double-digit percentage of costs and revenue arising from the development and commercialization of suvemcitug outside of China. Unless earlier terminated, the Simcere Agreement continues until 15 years after the first commercial sale of suvemcitug. Either party may terminate the Simcere Agreement for the other party's uncured material breach. Simcere may terminate the Simcere Agreement upon a decision by an appellate court in China that suvemcitug infringes a third party patent and such dispute cannot be resolved by settlement, licensing or other alternatives. Simcere is currently developing suvemcitug in Phase 3 clinical development for use in combination with chemotherapy to treat patients with recurrent, platinum-resistant ovarian cancer.

T-Mab/Mabwell Agreement

In May 2008, Jiangsu T-Mab Biotechnology Ltd., Co. ("T-Mab") entered into a license, co-development and contract manufacture agreement (the "T-Mab Agreement") with Epitomics for the development and commercialization of therapeutic candidates in two therapeutic programs, each directed to a specified target for specified fields, including VEGF for the treatment of ocular diseases, in China. Epitomics assigned the T-Mab Agreement to us in connection with our spin-out from Epitomics. Mabwell (Shanghai) Bioscience Co., Ltd. ("Mabwell") acquired T-Mab in 2015. Mabwell is responsible for conducting the development and commercialization of the therapeutic candidates in China. We may, at our discretion, develop and commercialize such therapeutic candidates outside of China, however, we must pay Mabwell a royalty on sales of such therapeutic candidates made outside of China if we do so. Under the agreement, we granted Mabwell an exclusive, royalty-bearing, perpetual license (without the right to sublicense) to our rights in certain intellectual property that we licensed from Epitomics to develop and commercialize such therapeutic candidates. Mabwell is obligated to pay us a mid-single-digit percentage royalty on net sales of such therapeutic candidates in China. If we choose to commercialize such therapeutic candidates outside of China, we would be obligated to pay Mabwell a mid-single-digit percentage royalty on net sales of such therapeutic candidates outside of China that we sell directly to end users and a mid-single-digit percentage of revenue we receive as sublicense fees, milestone payments and royalties related to the sale of such therapeutic candidate. Each party's obligations to pay royalties to the other party continue until 15 years after the first commercial sale of licensed product in each party's respective territory. The term of the T-Mab Agreement expired in May 2013; however, Mabwell's royalty payment obligations under the agreement survive expiration. The royalty term for 9MW0211, an anti-VEGF antibody licensed under the T-Mab Agreement, will begin on the first commercial sale in China and end a low two-digit number of years after such first commercial sale. Mabwell is currently in Phase 3 development of 9MW0211.

Toray Sublicense Agreement

Under an agreement between Epitomics and Toray Industries, Inc. ("Toray"), Epitomics provided Toray with antibodies created using the APXiMAB platform that target certain molecules to use in the development of its drug product candidates. In May 2012, we entered into a non-exclusive sublicense agreement with Toray (the "Toray Agreement") under which we granted Toray a non-exclusive, worldwide sublicense, with the right to grant further sublicenses, under the intellectual property that we licensed from Epitomics to develop and commercialize drug product candidates that Toray develops using those antibodies in the field of pharmaceutical products for human or veterinary use. Under the Toray Agreement, Toray paid us an upfront fee, and agreed to pay us certain development- and regulatory-related milestone payments and a low single-digit percentage royalty on net sales of licensed products by Toray or its affiliates. Toray is also obligated to pay us a mid-teens percentage of certain payments Toray receives from sublicensees under the Toray Agreement, which payments may limit Toray's obligations to pay the milestone payments described above. Subject to certain termination rights, including Toray's right to terminate the agreement for convenience upon 60 days' prior written notice, the agreement continues on a product-by-product and country-by-country basis until 10 years after the first commercial sale of such product in such country. Upon expiration or early termination of the agreement, Toray's sublicense and any further sublicenses granted by Toray will automatically terminate. Toray is currently in Phase 1b development of TRK-950, an antibody licensed under the Toray Agreement.

Competition

The biotechnology industry is highly competitive and subject to rapid and significant technological change. Moreover, the oncology field is characterized by strong and increasing competition, and a strong emphasis on intellectual property. Sotiga and products we may develop in the future for the treatment of cancer and any other diseases are likely to face competition from other drugs and therapies, including those of which we may not currently be aware. In addition, our products may need to compete with off-label drugs used by physicians to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our products.

Major multinational pharmaceutical and biotechnology companies, emerging and start-up companies, universities and other research institutions could focus their future efforts on developing competing therapies and treatments for any of the targets or indications we are currently targeting or may target in the future. For example, each of Hoffman-La Roche AG, Janssen Biotech, Inc., a subsidiary of Johnson & Johnson (in collaboration with Alligator Bioscience AB), Celldex Therapeutics, Inc., Seagan Inc., Eucure Biopharma, a subsidiary of Biocytogen, Lygen Pharma and AbbVie Inc. are developing CD40-based antibody product candidates for solid tumor oncology indications, typically in combination therapies, and other companies and institutions have other CD40-based product candidates in development.

Many of these current and potential competitors have significantly greater financial, manufacturing, commercial, drug development and technical expertise and human resources than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research, development and marketing capabilities than we do and may also have products that have been approved or are in late later stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These smaller and large companies compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for planned clinical trials, as well as in acquiring technologies that may be complementary to, or necessary for, our programs.

Manufacturing

We must manufacture drug substance and drug product for clinical trial use in compliance with good manufacturing practices (“GMP”) regulations. The GMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, quality controls and stability, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned products. The manufacturing facilities for our product candidates must meet GMP requirements and FDA or comparable foreign regulatory authority’s satisfaction before any product is approved and sold commercially. Our third-party manufacturers are also subject to periodic facility inspections by the FDA and other foreign authorities, including procedures and operations used in the testing and manufacture of our product candidates to assess our compliance with applicable regulations.

We do not currently have the infrastructure or internal capability to manufacture our product candidates for use in clinical development or commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates in compliance with GMP requirements. For sotiga and our preclinical candidate, APX601, we rely on a single third-party manufacturer, WuXi Biologics (Hong Kong) Limited (“WuXi”), and we currently have no alternative manufacturer in place for drug substance or drug product for both sotiga and APX601. We have a non-exclusive clinical supply agreement with WuXi in which WuXi manufactures sotiga and APX601 on a fee-for-service basis in addition to providing certain process development services. For the APX601 product candidate, we have successfully completed a drug substance and drug product runs at WuXi.

We originally manufactured sotiga at another third-party manufacturer. The clinical supply we are currently using was manufactured by that other third-party manufacturer. We expect the quantity and stability of our current supply of sotiga from that prior manufacturer will be sufficient to supply our currently ongoing clinical trials through mid-2023. We have developed with Wuxi a new cell line and manufacturing process and analytical methods for sotiga to meet our clinical supply needs by mid-2023.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We have personnel with significant technical, manufacturing, analytical, quality, regulatory, including GMP, and project management experience to oversee our third-party manufacturers and to manage manufacturing and quality data and information for regulatory compliance purposes.

Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. Contract manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. Any of these actions or events could have a material impact on the availability of our products.

Commercialization Plan

We do not currently have any approved drugs and we do not expect to have any approved drugs in the near term. As a result, we have no sales, marketing or commercial product distribution capabilities and have no experience as a company in marketing drugs. When and if any of our product candidates are approved for commercialization, we intend to develop a commercialization infrastructure for those products in various key markets. We may also rely on partnerships to provide commercialization infrastructure, including sales and marketing and commercial distribution.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology, programs, and know-how related to our business, to operate without infringing, misappropriating, or otherwise violating valid and enforceable intellectual property rights of others, to prevent others from infringing, misappropriating, or otherwise violating our intellectual property rights, in particular, our patent rights, and to preserve the confidentiality of our trade secrets. Our strategy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, and product candidates that are important to the development and implementation of our business. Our patent portfolio is intended to cover our product candidates and related components, their methods of use and processes for their manufacture and any other inventions that are commercially important to our business.

We also rely on trademarks as well as trade secret protection of our confidential information and know-how relating to our proprietary technology, platforms, and product candidates to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We believe that we have substantial know-how and trade secrets relating to our technology and product candidates and we seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. However, trade secrets can be difficult to protect.

Sotigalimab

Our patent portfolio for our sotigalimab program includes U.S. and foreign patents and patent applications, all of which are wholly owned by us. The patent portfolio includes claims to compositions of matter, methods of use, companion diagnostics, biomarkers, combination therapies and formulations relating to sotigalimab. Our issued U.S. patents and issued or allowed foreign patents, including one or more issued or allowed patents in each of Australia, Belgium, Brazil, Canada, China, Denmark, France, Germany, Hong Kong, India, Ireland, Italy, Japan, Luxembourg, Macau, Monaco, Netherlands, Norway, Republic of Korea, Mexico, New Zealand, Russian Federation, Singapore, Spain, South Africa, Sweden, Switzerland and United Kingdom expire between 2032 and 2033, without giving effect to any patent term adjustments or patent term extensions that may be available. Patents that may issue from the pending U.S. and foreign applications would expire, if issued, between 2032 and 2042, without giving effect to any patent term adjustments or patent term extensions that may be available.

Platform Technology

We have an exclusive, worldwide license, with the right to sublicense, under certain rights controlled by Epitomics, now a wholly owned subsidiary of Abcam, to develop and commercialize rabbit monoclonal antibodies generated using Epitomics' technology and fragments thereof, each in the field of pharmaceutical products for human or veterinary use. We entered into this license with Epitomics in 2010 in connection with our spin-out from Epitomics. The intellectual property licensed to us by Epitomics includes patents that generally relate to our APXiMAB platform and that cover antibody generation and a process for humanizing antibodies, as well as related know-how and materials. We have the sole right to enforce the patents licensed by Epitomics for infringement arising in our field of use and a step-in right to control the filing, prosecution and maintenance of any patent or patent application licensed to us by Epitomics that Epitomics determines not to file or decides to abandon. If we elect to file or prosecute any such patent or patent application, Epitomics would assign the relevant patent or patent application to us. Those patents begin to expire in 2023. We do not believe the expiration of these patents will have a material impact on our business. We are obligated to pay Epitomics 10% of certain amounts that we receive from third parties if we grant a sublicense to the Epitomics technology, with such amounts capped at $1 million per target. By its terms, the agreement expired in 2020 and the license granted by Epitomics to us became irrevocable. Our obligation to pay Epitomics a share of amounts we receive in consideration of a sublicense survives this expiration only with respect to sublicenses granted prior to expiration of the agreement. The ESBATech Agreement, Simcere Agreement, T-Mab Agreement and Toray Agreement (the "Out-License Agreements") were each entered into prior to the expiration of our license agreement with Epitomics. Therefore, certain payments we receive under the Out-License Agreements with respect to sublicenses of the Epitomics technology, including certain payments made with respect to Beovu, OCS-02, suvemcitug, 9MW0211 and TRK-950 under the Out-License Agreements, will be subject to the payment obligations we have under our license agreement with Epitomics. Abcam plc ("Abcam") acquired Epitomics in 2012.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products such as those we are developing. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Drug Development

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

Biologic and non-biologic drug product candidates must be approved by the FDA through either a Biologics License Application ("BLA") or New Drug Application ("NDA") process, respectively, before they may be legally marketed in the United States. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with Good Laboratory Practice ("GLP")
- submission to the FDA of an Investigational New Drug Application ("IND"), which must become effective before human clinical trials may begin;
- approval by an Institutional Review Board ("IRB"), or ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, Good Clinical Practice ("GCP") requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;

- submission to the FDA of an NDA or BLA;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to accept the filing for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug or biologic will be produced to assess compliance with GMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug or biologic's identity, strength, quality and purity;
- potential FDA audit of the preclinical study and/or clinical trial sites that generated the data in support of the NDA or BLA;
- FDA review and approval of the NDA or BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug or biologic in the United States; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy ("REMS"), and the potential requirement to conduct post-approval studies.

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

Preclinical Studies and IND

The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational product to humans, and must become effective before human clinical trials may begin.

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

Clinical Trials

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

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or BLA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with GCP requirements and the FDA is able to validate the data through an onsite inspection if deemed necessary.

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

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, pharmacokinetics, toxicity, tolerability, and safety of the drug in humans, and side effects associated with increasing doses for determining a safe clinical dosage range in humans.

- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

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

Post-approval 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 as a condition of approval of an NDA or BLA.

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

Phase 1, Phase 2, and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check-points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug or biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality, and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that an investigational product candidate does not undergo unacceptable deterioration over its shelf life.

Further, as a result of the COVID-19 pandemic, the extent and length of which are uncertain, we may be required to develop and implement additional clinical trial policies and procedures designed to help protect trial participants from COVID-19 in accordance with new or updated FDA guidance and other regulatory requirements. For example, the FDA has issued guidance on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical trial report contingency measures implemented to manage the trial and any disruption of the trial as a result of COVID-19 and the impact of implemented contingency measures on the safety and efficacy results reported for the trial. The FDA has also published other COVID-19-related industry guidance regarding GMPs, remote interactive evaluations of drug manufacturing and bioresearch monitoring facilities, and drug product manufacturing and supply chain inspections. 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. The extent to which the COVID-19 pandemic impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

NDA/BLA Review Process

Following completion of the clinical trials, data is analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA or BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. In short, the NDA or BLA is a request for approval to market the drug or biologic for one or more specified indications and must contain proof of safety and efficacy for a drug or safety, purity, and potency for a biologic. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA. FDA approval of an NDA or BLA must be obtained before a drug or biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act, as amended ("PDUFA"), each NDA or BLA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's FY 2023 fee schedule, effective through September 30, 2023, the user fee for an application requiring clinical data, such as an NDA or BLA, is approximately $3.2 million. PDUFA also imposes an annual program fee for each marketed human drug or biologic (approximately $393,933 in FY 2023) and an annual establishment fee on facilities used to manufacture prescription drugs and biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted NDAs and BLAs before it accepts them for filing, and may request additional information rather than accepting the NDA or BLA for filing. The FDA must make a decision on accepting an NDA or BLA for filing within 60 days of receipt. If the FDA determines there is significance to any missing or incomplete information in the context of the proposed product candidate, the proposed indication(s), and the amount of time needed to address any given deficiency, it can issue a refusal-to-file letter. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months, from the filing date, in which to complete its initial review of a new molecular-entity NDA or original BLA and respond to the applicant, and six months from the filing date of a new molecular-entity NDA or original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs or BLAs, and the review process is often extended by FDA requests for additional information or clarification.

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

The FDA may delay or refuse approval of an NDA or BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product. FDA approval of any NDA or BLA submitted by us will be at a time the FDA chooses. Also, if regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require Phase 4 post-marketing studies to monitor the effect of approved products and may limit further marketing of the product based on the results of these post-marketing studies. 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 ongoing development programs as well as regulations that apply to approved products.

Orphan Drugs

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

Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care or in instances of drug supply issues. However, competitors may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication.

Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if a product candidate is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of our products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

In *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with the FDA's longstanding position that the orphan drug exclusivity only applies to the approved use or indication within an eligible disease. 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.

Expedited Development and Review Programs

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

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

A Fast Track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA or 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 BLA or NDA, the FDA agrees to accept sections of the BLA or NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA or NDA.

A product may also be eligible for accelerated approval, if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM), which is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug or biologic shown to be effective can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions as it deems necessary to assure safe use of the product.

Additionally, a drug or biologic may be eligible for designation as a Breakthrough Therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of Breakthrough Therapy designation include the same benefits as Fast Track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Fast Track designation, priority review, accelerated approval and Breakthrough Therapy designation do not change the standards for approval, but may expedite the development or approval process. In December 2022, the Consolidated Appropriations Act, 2023, including the Food and Drug Omnibus Reform Act (FDORA), was signed into law. FDORA made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements.

Abbreviated Licensure Pathway of Biological Products as Biosimilar or Interchangeable

The ACA, signed into law in 2010, includes the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products shown to be highly similar to an FDA-licensed reference biological product. The BPCIA attempts to minimize duplicative testing, and thereby lower development costs and increase patient access to affordable treatments. An application for licensure of a biosimilar product must include information demonstrating biosimilarity based upon the following, unless the FDA determines otherwise:

- analytical studies demonstrating that the proposed biosimilar product is highly similar to the approved product notwithstanding minor differences in clinically inactive components;
- animal studies (including the assessment of toxicity); and
- a clinical trial or trials (including the assessment of immunogenicity and pharmacokinetic or pharmacodynamic) sufficient to demonstrate safety, purity and potency in one or more conditions for which the reference product is licensed and intended to be used.

In addition, an application must include information demonstrating that:

- the proposed biosimilar product and reference product utilize the same mechanism of action for the condition(s) of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism(s) of action are known for the reference product;
- the condition or conditions of use prescribed, recommended, or suggested in the labeling for the proposed biosimilar product have been previously approved for the reference product;

- the route of administration, the dosage form and the strength of the proposed biosimilar product are the same as those for the reference product; and

- the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

Biosimilarity means that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and that there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product. In addition, the law provides for a designation of "interchangeability" between the reference and biosimilar products, whereby the biosimilar may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product. The higher standard of interchangeability must be demonstrated by information sufficient to show that:

- the proposed product is biosimilar to the reference product;

- the proposed product is expected to produce the same clinical result as the reference product in any given patient; and

- for a product that is administered more than once to an individual, the risk to the patient in terms of safety or diminished efficacy of alternating or switching between the biosimilar and the reference product is no greater than the risk of using the reference product without such alternation or switch.

FDA approval is required before a biosimilar may be marketed in the United States. However, complexities associated with the large and intricate structures of biological products and the process by which such products are manufactured pose significant hurdles to the FDA's implementation of the law that are still being worked out by the FDA. For example, the FDA has discretion over the kind and amount of scientific evidence—laboratory, preclinical, and/or clinical—required to demonstrate biosimilarity to a licensed biological product.

The FDA intends to consider the totality of the evidence provided by a sponsor to support a demonstration of biosimilarity, and recommends that sponsors use a stepwise approach in the development of their biosimilar products. Biosimilar product applications thus may not be required to duplicate the entirety of preclinical and clinical testing used to establish the underlying safety and effectiveness of the reference product. However, the FDA may refuse to approve a biosimilar application if there is insufficient information to show that the active ingredients are the same or to demonstrate that any impurities or differences in active ingredients do not affect the safety, purity, or potency of the biosimilar product. In addition, as with BLAs, biosimilar product applications will not be approved unless the product is manufactured in facilities designed to assure and preserve the biological product's safety, purity and potency.

The submission of a biosimilar application does not guarantee that the FDA will accept the application for filing and review, as the FDA may refuse to accept applications that it finds are insufficiently complete. The FDA will treat a biosimilar application or supplement as incomplete if, among other reasons, any applicable user fees assessed under the Biosimilar User Fee Act of 2012 have not been paid. In addition, the FDA may accept an application for filing but deny approval on the basis that the sponsor has not demonstrated biosimilarity, in which case the sponsor may choose to conduct further analytical, preclinical, or clinical trials and submit a BLA for licensure as a new biological product.

The timing of final FDA approval of a biosimilar for commercial distribution depends on a variety of factors, including whether the manufacturer of the branded product is entitled to one or more statutory exclusivity periods, during which time the FDA is prohibited from approving any products that are biosimilar to the branded product. The FDA cannot approve a biosimilar application for 12 years from the date of first licensure of the reference product. Additionally, a biosimilar product sponsor may not submit an application for four years from the date of first licensure of the reference product. A reference product may also be entitled to exclusivity under other statutory provisions. For example, a reference product designated for a rare disease or condition (an orphan drug) may be entitled to seven years of exclusivity, in which case no product that is biosimilar to the reference product may be approved until either the end of the 12-year period provided under the biosimilarity statute or the end of the seven-year orphan drug exclusivity period, whichever occurs later. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block biosimilarity applications from being approved on or after the patent expiration date. In addition, the FDA may under certain circumstances extend the exclusivity period for the reference product by an additional six months if the FDA requests, and the manufacturer undertakes, studies on the effect of its product in children, a so-called pediatric extension.

The first biological product determined to be interchangeable with a branded product for any condition of use is also entitled to a period of exclusivity, during which time the FDA may not determine that another product is interchangeable with the reference product for any condition of use. This exclusivity period extends until the earlier of: one year after the first commercial marketing of the first interchangeable product; 18 months after resolution of a patent infringement against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; 42 months after approval of the first interchangeable product, if a patent infringement suit against the applicant that submitted the application for the first interchangeable product is still ongoing; or 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued.

Post-Approval Requirements

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

Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and the implementation of other risk management measures. The FDA may also place other conditions on approvals including the requirement for REMS, to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription, or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications;
- applications, or suspension or revocation of product license approvals;

- 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;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

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

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

Other U.S. Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the CMS, other divisions of the HHS, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments.

For example, in the United States, financial arrangements with healthcare providers and other business arrangements, including, but not limited to, sales, marketing and scientific and educational programs, also must comply with state and federal healthcare fraud and abuse laws. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, and transparency and reporting laws and regulations related to drug pricing and payments and other transfers of value made to physicians and other healthcare providers. Violation of any of such laws or any other governmental regulations that apply, may result in penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and imprisonment. In particular, the federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. HIPAA also created additional federal civil and criminal penalties for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The ACA, through the Physician Payments Sunshine Act, imposes new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Drug manufacturers are required to submit annual reports to the government and these reports are posted on a website maintained by CMS. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices, and/or require the tracking and reporting of gifts, compensation, and other remuneration to physicians.

We may also be subject to data privacy and security requirements that may impact the way in which we conduct research and operate our business. HIPAA, as amended by HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, as well as individuals and entities that provide services on behalf of a covered entity that involve individually identifiable health information, known as business associates. In addition, we may be directly subject to certain state laws concerning privacy and data security. For example, the California Consumer Privacy Act (CCPA) took effect in January 2020 and became enforceable in July 2020. The CCPA created new individual privacy rights for California consumers (as the word is broadly defined in the law) and placed increased privacy and security obligations on many organizations that handle personal information of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers a new right to opt-out of certain sales or transfers of personal information, and provides consumers with a new cause of action for certain data breaches. Additionally, California voters voted to approve the California Privacy Rights Act (CPRA) in November 2020, which modifies the CCPA significantly, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. The CCPA and CPRA may impact our business activities and increase our compliance costs and potential liability. Many similar privacy laws have been proposed at the federal level and in other states. Failure to comply with data protection laws and regulations could result in government investigations and/or enforcement actions (which could include civil, criminal, and administrative penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business.

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 ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion, and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of biologic and pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. 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: changes to our manufacturing arrangements; additions or modifications to product labeling; the recall or discontinuation of our products; or additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

U.S. Patent-Term Extension and Marketing Exclusivity

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

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

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

European Union Drug Development

In Europe, our future drugs may also be subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if a marketing authorization ("MA") from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority (NCA), and one or more 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, replacing the current Directive, was adopted, and entered into application on January 31, 2022. The new Regulation seeks to simplify and streamline the approval of clinical trials in the European Union. For example, the sponsor shall submit a single application for approval of a clinical trial via the EU Portal. As part of the application process, the sponsor shall propose a reporting Member State, who will coordinate the validation and evaluation of the application. The reporting Member State shall consult and coordinate with the other concerned Member States. 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 concerned Member States. However, a concerned Member State 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 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 Union Drug Review and Approval

In the EEA, which is comprised of the 27 Member States of the European Union plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a MA. There are two types of MAs.

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

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

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

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 European Union from referencing the innovator's data to assess a generic application for eight years, after which generic MA can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the MA 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.

European Union General Data Protection Regulation

In addition to EU regulations related to the approval and commercialization of our products, we may be subject to the EU's GDPR. The GDPR went into effect on May 25, 2018. The GDPR introduced new data protection requirements in the European Union, as well as potential fines for noncompliant companies of up to the greater of €20 million or 4% of annual global revenue. The regulation imposes numerous new requirements for the collection, use and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e.g., the right to access, correct and delete their data). In addition, the GDPR includes restrictions on cross-border data transfer. The GDPR will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules. Further, the United Kingdom's vote in favor of exiting the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear whether the United Kingdom will enact data protection legislation equivalent to the GDPR and how data transfers to and from the United Kingdom will be regulated.

Rest of the World Regulation

For other countries outside of the European Union and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country. Additionally, the 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.

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.

Coverage and Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance, and managed healthcare organizations. In the United States, no uniform policy of coverage and reimbursement for drug or biological products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The United States government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. For example, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs.

The Medicaid Drug Rebate Program 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 Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of Average Manufacturing Price (AMP), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. CMS has proposed to expand Medicaid rebate liability to the territories of the United States as well.

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 Part A and Part B, Part D coverage is not standardized. 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. However, 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 products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will 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 noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. An increasing emphasis on cost containment measures in the United States has increased and we expect 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 are 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 most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

U.S. Healthcare Reform

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of drug candidates, restrict, or regulate post-approval activities and affect a biopharmaceutical company's ability to profitably sell any approved drugs.

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 third-party payors, it is not clear what effect, if any, the research will have on the sales of our drug candidates, if any such drug or the condition that they are 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 after approval 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.

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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. For example, in June 2021, the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and healthcare measures promulgated by the Biden administration will impact the ACA, our business, financial condition and results of operations. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, started in April 2013, and, due to subsequent legislative amendments, will stay 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 will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. On January 2, 2013, the then-U.S. President signed into law the American Taxpayer Relief Act of 2012, which, among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers, and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, 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 pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. 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. 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. 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.

Additionally, on May 30, 2018, the Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain IND 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 pharmaceutical manufacturer to make its product candidates available to eligible patients as a result of the Right to Try Act.

We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework could reduce our ability to generate revenue in the future or increase our costs, either of which could have a material and adverse effect on our business, financial condition and results of operations. It is also possible that additional governmental action will be taken to address the COVID-19 pandemic. The continuing efforts of the government, insurance companies, managed care organizations, and other payers of healthcare services and medical products to contain or reduce costs of healthcare and/or impose price controls may adversely affect the demand for our product candidates, if approved, and our ability to achieve or maintain profitability.

Employees and Human Capital Resources

As of December 31, 2022, we had 20 full-time employees, 14 of whom were engaged in research and development activities. Six of our employees hold Ph.D. or M.D. degrees. None of our employees are represented by a labor union or covered under a collective bargaining agreement.

Our human capital resources objectives include, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees into our collaborative culture. Our compensation program is designed to retain, motivate and attract highly qualified executives and talented employees and consultants. We are committed to fostering a culture that supports diversity and an environment of mutual respect, equity and collaboration that helps drive our business and our mission to leverage the power of the body's immune system to combat and eradicate tumor cells, generating enhanced tumor-specific immunity and leading to clinical benefits such as an improved survival for patients across a wide range of cancers.

Corporate and Available Information

Our corporate headquarters are located in San Carlos, California, where we lease approximately 6,400 square feet of office, research and development and laboratory space pursuant to a lease agreement that will expire on March 31, 2023. We expect to enter into a six-month lease for office space that will begin in March 2023. We believe that these facilities will be adequate for our near-term needs. If required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms.

Our corporate website address is www.apexigen.com. Information contained on our website is not a part of or incorporated by reference into this Annual Report or any other document we file with the SEC, and the inclusion of our website address in this Annual Report is an inactive textual reference only.

Item 1A. Risk Factors.

An investment in our common stock involves a high degree of risk. You should consider carefully the risks described below, together with all of the other information contained in this Annual Report on Form 10-K, including our financial statements and the related notes thereto and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in our other public filings, in evaluating our business. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks not known to us or that we believe are immaterial may also adversely affect our business, operating results and financial condition and the value of an investment in our securities.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties that you should consider before investing in our company, as more fully described below. The principal factors and uncertainties that make investing in our company risky include, among others:

- We have incurred net losses since inception and expect to continue to incur significant net losses for the foreseeable future. In addition, we may be unable to continue as a going concern.
- We will require substantial additional capital to finance 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 research and drug development programs or future commercialization efforts.
- We are in the early stages of clinical drug development and have a limited operating history and no products approved for commercial sale.
- We are dependent on the success of our product candidates, including our lead product candidate, sotigalimab, which is currently in multiple clinical trials.
- The clinical trials of our current and any future product candidates may not demonstrate safety and efficacy to the satisfaction of regulatory authorities or otherwise be timely conducted or produce positive results.
- If our competitors develop and market products that are more effective, safer, or less expensive than our product candidates, we will be negatively impacted.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.
- The regulatory approval processes of the Food and Drug Administration, European Medicines Agency, and comparable foreign regulatory authorities are lengthy, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.
- If we are unable to obtain, maintain, enforce, or protect our intellectual property rights in any products we develop or in our technology, if the scope of the intellectual property protection obtained is not sufficiently broad, or if we infringe the intellectual property rights of others, third parties could develop and commercialize products and technology similar or identical to ours, we could be prevented from commercializing our products and we may not be able to compete effectively in our markets.

Risks Related to Our Business, Financial Condition, and Need for Additional Capital

We have incurred net losses since inception and expect to continue to incur significant net losses for the foreseeable future. In addition, we may be unable to continue as a going concern.

We have incurred net losses since inception, have not generated any significant revenue to date, and financed our operations prior to the Business Combination primarily through the issuance of convertible preferred stock, proceeds from collaborative research and development and out-license agreements, and borrowings under a debt arrangement. Our net loss was $32.1 million and $28.9 million for the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, we had an accumulated deficit of $176.8 million. To date, we have devoted substantially all of our resources and efforts to research and development. Our clinical-stage pipeline currently consists of multiple product candidates, including our lead product candidate, sotigalimab, and our other internal programs are in preclinical or research development. As a result, we expect that it will be several years, if ever, before we generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to develop and market additional potential products. In addition, for certain of our licensees from whom we are entitled to receive royalty payments if they successfully develop and commercialize any products covered by licenses we have with them, there is no guarantee that their product development and commercialization will lead to any such payments even if any such product candidates receive regulatory approval for commercial sale, including Beovu (brolucizumab-dbll), which is commercialized by Novartis, for which we have received sales-based royalties that are currently fully constrained and recorded as deferred revenue on our consolidated balance sheet, as discussed below.

In connection with the Business Combination, we raised approximately $19.0 million of gross proceeds. We incurred approximately $9.2 million in transaction costs relating to the Business Combination, consisting of banking, legal, and other professional fees. The total net cash proceeds to us were approximately $8.9 million after we paid off the Extension and Working Capital Notes that totaled $0.9 million.

Our consolidated financial statements for the years ended December 31, 2022 and 2021, included elsewhere in this Annual Report on Form 10-K have been prepared assuming we will continue as a going concern. As a development stage company, we expect to incur significant and increasing losses until regulatory approval is granted for sotigalimab, our lead product candidate. Regulatory approval is not guaranteed and may never be obtained. Based on our research and development activities and plans, there is uncertainty regarding our ability to maintain liquidity sufficient to operate the business effectively, which raises substantial doubt about our ability to continue as a going concern. If we do not receive proceeds under our equity line or other potential financing or business development transactions, we anticipate that our current cash position would only be sufficient to fund our operations into the third quarter of 2023 based on current operations.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter-to-quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. 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 expected future losses will continue to have an adverse effect on our working capital and our ability to achieve and maintain profitability.

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

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive, and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for sotigalimab and our other product candidates. In order to support the advancement of the sotigalimab clinical development program, we are actively seeking a global development and commercialization collaboration partner for sotigalimab. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing, and distribution. We also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on acceptable terms, or to enter into a collaboration to support the advancement of the sotigalimab development program, we may be forced to delay, reduce, and/or eliminate one or more of our research and drug development programs or future commercialization efforts. 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 continue to use our cash on hand to fund our development of sotigalimab, and for working capital and other general corporate purposes. This may include additional research, hiring additional personnel, capital expenditures, and the costs of operating as a public company. Advancing the development of our current and any future product candidates will require a significant amount of capital. Our current cash and cash equivalents are not sufficient to fund all of the actions that are necessary to complete the development of sotigalimab or any of our other product candidates. We will be required to obtain further funding through public or private equity offerings, sale of shares of our common stock through utilization of our equity line with Lincoln Park, debt financings, partnership, collaborations, and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. In addition, there are certain conditions and limitations on our ability to utilize our $50,000,000 equity line with Lincoln Park. We are required to satisfy various conditions in order to be able to initiate additional purchases by Lincoln Park under the equity line. Once such conditions are satisfied, the Lincoln Park equity line purchases are subject to volume limitations tied to periodic market prices, ownership limitations limiting Lincoln Park from owning more than 4.99% of our common stock, a minimum closing price of $3.00 per share of common stock at which we can deliver a Regular Purchase notice to Lincoln Park to purchase shares of common stock, and other limitations as specified in the Lincoln Park Purchase Agreement. If any of these conditions are not satisfied or limitations are in effect, we may not be able to fully utilize the Lincoln Park equity line, which would have an adverse impact on our ability to satisfy our capital needs and could materially adversely impact our business. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

We are in the early stages of clinical drug development and have a limited operating history and no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are an early clinical-stage biopharmaceutical company with a limited operating history. Apexigen was incorporated and commenced operations in 2010 following a spin-out transaction from its parent company. We have no products approved for commercial sale and have not generated any revenue from commercial product sales. Our operations to date have been limited to performing research and development activities in support of our product development and licensing efforts, hiring personnel, raising capital to support and expand such activities, providing general and administrative support for these operations, developing potential product candidates, conducting preclinical studies and clinical trials, including clinical trials of sotigalimab, our lead product candidate, and our other wholly owned product candidates, and entering into, and performing our obligations under, licensing arrangements that have resulted in additional product candidates in clinical development or commercialization by our licensees. Other than sotigalimab, all of our wholly owned programs are in preclinical or research development. We have not yet demonstrated our ability to successfully complete any large-scale pivotal clinical trials, obtain marketing approvals, manufacture a drug on a commercial scale or arrange for a third party to do so on our behalf, or conduct sales and marketing activities. In addition, only one of our licensees has obtained marketing approvals for product candidates we have out-licensed. As a result, it may be more difficult for you to accurately predict our future success or viability than it could be if we had a longer operating history.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields. We also would need to transition from a company with a research and development focus to a company capable of supporting commercial activities after approval of any of our product candidates. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives.

Our business depends entirely on the successful development and commercialization of our product candidates. We currently generate no revenue from commercial sales of any products. We have no products approved for commercial sale and we do not anticipate generating any revenue from product sales unless and until sometime after we have successfully completed clinical development and received marketing approval for the commercial sale of a product candidate, if ever. In addition, we may not receive significant amounts of royalty revenue, if any, from our licensees for their product candidates if and when such candidates receive regulatory approval for commercial sale and are commercialized, including Beovu, which is commercialized by Novartis, for which we have received sales-based royalties that are currently fully constrained and recorded as deferred revenue on our consolidated balance sheet as discussed below. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives, including:

- raising substantial additional capital to finance our operations;
- negotiating favorable terms in any partnership, collaboration, licensing, or other arrangements that may be necessary to develop, manufacture, or commercialize our product candidates;

- successful and timely completion of preclinical and clinical development of current and any future product candidates;
- timely receipt of marketing approvals from applicable regulatory authorities for current and any future product candidates for which we successfully complete clinical development;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- developing an efficient and scalable manufacturing process for current and any future product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties to obtain finished products that are appropriately packaged for sale;
- successful launch of commercial sales following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more partners or collaborators;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance of current and any future product candidates as viable treatment options by patients, the medical community, and third-party payors;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring, and developing new product candidates;
- obtaining and maintaining patent protection, regulatory exclusivity, and other intellectual property-related protection, both in the United States and internationally;
- enforcing and defending our rights in our intellectual property portfolio, including our licensed intellectual property; and
- attracting, hiring, and retaining qualified personnel.

We may never achieve 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 sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business, or continue our operations.

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

We depend on the success of our product candidates, including our lead product candidate, sotigalimab, which is currently in multiple clinical trials. If we are unable to obtain approval for and commercialize our product candidates for one or more indications in a timely manner, our business will be materially harmed.

Our success depends on our or our partners' or licensees' ability to timely complete clinical trials and obtain marketing approval for, and then successfully commercialize, our product candidates, including our lead product candidate, sotigalimab, for one or more indications. Our product candidates are in the early stages of development and we are investing the majority of our efforts and financial resources in the research and development of sotigalimab for multiple indications, both directly through our own efforts and indirectly through clinical collaboration arrangements, including investigator- and cooperative group-sponsored trials ("ISTs"). Our product candidates will require additional clinical development, preclinical and manufacturing activities, marketing approval from government regulators, substantial investment, and significant marketing efforts before we generate any revenue from product sales. We are not permitted to market or promote any product candidates, in a jurisdiction before receiving marketing approval from the relevant regulatory authority, including, for example, the Food and Drug Administration ("FDA") for marketing in the United States and the European Medicines Agency ("EMA") for marketing in the European Union, and we may never receive such marketing approvals.

- The success of our product candidates will depend on numerous factors, including the following:
- raising additional funds, or entering into collaborations, necessary to complete the clinical development of and to commercialize of our product candidates;

- successful and timely completion of our ongoing clinical trials;
- initiation and successful patient enrollment and completion of additional clinical trials on a timely basis;
- efficacy, safety and tolerability profiles that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers;
- the maintenance of existing or the establishment of new scaled production arrangements with third-party manufacturers to obtain finished products that are appropriately packaged for sale;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio, including our licensed intellectual property;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community, and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, including trial design, implementation, and timely provision of data in our collaboration based clinical trials and ISTs; potential threats to our intellectual property rights; and the manufacturing, marketing, distribution, and sales efforts of any future collaborator. If we are unable to achieve one or more of the objectives set forth above, our business will be materially harmed.

Our clinical trials may reveal serious adverse events, toxicities, or other side effects of our current and any future product candidates that result in a safety profile that could inhibit regulatory approval or market acceptance of our product candidates.

In order to obtain marketing approval for our current or any future product candidates, we must demonstrate the safety and efficacy of the product candidate for the relevant clinical indication or indications through preclinical studies and clinical trials as well as additional supporting data. If our product candidates are associated with undesirable side effects in preclinical studies or clinical trials, or have unexpected characteristics, we may need to interrupt, delay, or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective.

Although we have conducted various preclinical studies and have data from various early-stage clinical trials, we do not know the predictive value of these studies and trials for our future clinical trials, and we cannot guarantee that any positive results in preclinical studies or previous clinical trials will successfully translate to patients in our future clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical testing or previous clinical trials, and many product candidates fail in clinical trials despite promising preclinical or early-stage clinical results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

While we believe that sotigalimab has been reasonably well tolerated in our clinical trials, subjects have experienced adverse events that have been considered treatment-related. Some of the more common adverse events included fever, chills, fatigue, asthenia, nausea, vomiting, pruritus, abnormal liver function/gamma gamma-glutamyl transferase/alkaline phosphatase tests, decreased appetite, rash, headache, diarrhea, infusion-related reactions, and cytokine release syndrome ("CRS"). The majority of these events were mild/moderate in severity, responded to symptomatic treatment and/or were transient and resolved with time.

Serious, including sometimes fatal, adverse events ("SAEs") have been reported in clinical studies with sotigalimab. The majority of these SAEs were considered unrelated to sotigalimab by the investigators. Some SAEs were considered at least possibly related to sotigalimab as well as possibly to other therapies it was combined with.

These possibly related events have included infusion-related reactions, CRS, elevated liver enzymes, bilirubin, fever, and colitis. Less frequent related SAEs reported in one patient each have included kidney injury, hepatic failure, bleeding, immune-mediated encephalitis, myositis, optic neuritis. Many of these SAEs were also considered possibly related to the chemotherapy, radiation or anti-PD(L)1 agent that were used in combination or were assessed as not related to sotigalimab after a safety review by the trial sponsor.

Subjects experienced numerous other SAEs that have been determined to be caused by their health condition or the side effects from other components of the treatment regimens, and not or unlikely related to sotigalimab. Given the high mortality rates of the cancers for which we are initially pursuing development, in particular melanoma, esophageal and gastroesophageal junction ("GEJ") cancers, sarcoma, and ovarian cancer, and the pretreated nature of many patients in our completed, ongoing and planned clinical trials of sotigalimab, a number of these subjects have died as a result of their cancer or from direct side effects of surgery and other treatment regimens for their cancer. For example, in our clinical trial for esophageal and GEJ cancers, sotigalimab is combined with standard of care neoadjuvant chemotherapy, radiation and surgery. These standard of care treatments alone are associated with significant toxicities including fatal outcomes, and in this study, complications of surgery have resulted in the death of a patient.

We expect that subjects in our ongoing and planned clinical trials for our product candidates may in the future suffer adverse effects ("AEs"), SAEs or other side effects, including those not observed in our preclinical studies or previous clinical trials. Results of these trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could result in the delay, suspension, or termination of clinical trials by us or the FDA, EMA or comparable foreign regulatory authority for a number of reasons. Additionally, a number of the subjects in these clinical trials are expected to die during a trial due to the cancers they suffer and any of the treatment regimens they may have previously experienced, which could impact the development of our product candidates. If we elect or are required to delay, suspend, or terminate any clinical trial, the commercial prospects of our product candidates will be harmed and our ability to generate product revenue from this product candidate will be delayed or eliminated. SAEs observed in clinical trials could hinder or prevent market acceptance of our drug candidates. Any of these occurrences may harm our business, prospects, financial condition, and results of operations significantly.

Even in circumstances in which we do not believe that an AE is related to our product candidates, the investigation into the circumstances of such AE may be time-consuming or inconclusive. In particular, patients may face serious medical issues associated with the underlying cancer indications that our product candidates target, as well as AEs from toxicities and other complications related to other study drugs administered alongside or in combination with our product candidates in clinical trials. For example, some of our clinical trials involve combination therapies of our product candidate with other cancer therapies, such as standard-of-care chemotherapy, chemoradiation or anti-PD-(L)1 agents. In these trials, it is difficult to ascertain whether treatment-related AEs are attributable to our product candidates or to the other agents, and the combination of therapies may have a complicating multiplier effect on such AEs that cannot be determined. As a result, while not directly associated with our product candidates, there are attendant risks with the space in which our product candidates operate, and any related investigations may interrupt our development and commercialization efforts, delay our regulatory approval process or impact and limit the type of regulatory approvals our product candidates receive or maintain.

If further SAEs 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 discontinue treatment or withdraw from our trials or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, the EMA, other applicable regulatory authorities or an Institutional Review Board ("IRB")/Ethics Committee may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude a drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition, and prospects.

Further, if any of our product candidates obtains marketing approval, toxicities associated with our product candidates may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional warnings being added to the labeling, significant restrictions on the use of the product, or the withdrawal of 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 testing.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.

We may not initiate, continue or complete clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, EMA, or comparable foreign regulatory authorities.

Patient enrollment is a significant factor in the timing of clinical trials, and our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. Patient enrollment may also 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;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- clinicians' and patients' awareness of, and perceptions as to the potential advantages and risks of, our product candidates in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- the ability to monitor patients adequately during and after treatment;
- competing ongoing clinical trials for the same indications as our product candidates;
- proximity and availability of clinical trial sites for prospective patients;
- whether we become subject to a partial or full clinical hold on any of our clinical trials; and
- continued enrollment of prospective patients by clinical trial sites, including delays due to pandemics, wars etc. that can impact patient willingness to participate and travel for investigative therapy and reductions in clinical trial site staff and services.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more of our clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates.

The clinical trials of our current and any future product candidates may not demonstrate safety and efficacy to the satisfaction of regulatory authorities or otherwise be timely conducted or produce positive results.

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

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

- obtaining regulatory approval to commence a trial;
- delays in reaching, or the inability to reach, agreement on acceptable terms with prospective contract research organizations (“CROs”), clinical trial sites, laboratory service providers, companion diagnostic development partners, contract manufacturing organizations, or CMOs, and other service providers we may engage to support the conduct of our clinical trials;
- obtaining IRB approval at each clinical trial site;
- recruiting a sufficient number of suitable patients to participate in a trial;
- patients failing to comply with trial protocol or dropping out of a trial, rendering them not evaluable for study endpoints;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- the availability of any applicable combination therapies;
- developments in the safety and efficacy of any applicable combination therapies;
- the need to add new clinical trial sites; or
- delays in the testing, validation and manufacturing of product candidates and the delivery of these product candidates to clinical trial sites.
- We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent receipt of marketing approval or our ability to commercialize our product candidates, including:
- receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain drug development programs;
- regulators or IRBs may not authorize us, our collaborators, or our investigators to commence a clinical trial or to conduct a clinical trial at a prospective site;
- the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated, or participants dropping out of these clinical trials at a higher rate than anticipated;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects, safety or efficacy concerns, or any particular combination therapy or other unexpected characteristics or risks;

- the cost of clinical trials of our product candidates being greater than anticipated;

- for clinical trials testing combination treatment of our product candidates with third-party drug products, delays in procuring such third-party drug products and the delivery of such third-party drug products to clinical trial sites, or the inability to procure such third-party drug products at all; and

- regulators revising the requirements for approving our product candidates, including as a result of newly approved agents changing the standard of care of an indication.

Any unforeseen events may cause us to be required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, or to be unable to successfully complete clinical trials of our product candidates or other testing. Clinical trial or test results may also not be positive or may be only modestly positive or may have safety concerns. For example, in the APX005M-002 Trial, we enrolled 95 patients with non-small cell lung cancer ("NSCLC") who were either immunotherapy naïve or who had progressed while on anti-PD(L)1 therapy and treated those patients with sotigalimab in combination with nivolumab. Although we observed a modest number of objective responses in immunotherapy naïve patients and stable disease in patients who had previously progressed on or were refractory to prior anti-PD-(L)1 therapy, the data did not support advancing the development of sotigalimab in these lines of therapy in patients with NSCLC. Any of the foregoing events may cause us to incur unplanned costs, be delayed in obtaining marketing approval, if ever, receive more limited or restrictive marketing approval, be subject to additional post-marketing testing requirements, or have the drug removed from the market after obtaining marketing approval.

The outcome of preclinical testing and early clinical trials that we obtain and that we publish may not predict the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA, or comparable foreign regulatory authorities.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable drugs. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any future collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Success in preclinical studies and early-stage clinical trials does not mean that future larger registration clinical trials will be successful. This is because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA, and other regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. In particular, no compound with the mechanism of action of sotigalimab has been commercialized, and the outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later-stage clinical trials. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety results sufficient to obtain marketing approval to market our product candidates.

Summary or preliminary data from our clinical trials that we announce or publish may change as new or revised patient data becomes available, and is subject to source verification procedures that could result in material changes in the final data.

As more patient data becomes available, we may publicly disclose new or revised preliminary data from our clinical trials. These preliminary updates are based on analyses of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to evaluate all data fully and carefully. As a result, the summary or preliminary 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. Summary or preliminary data also remain subject to source verification procedures that may result in the final data being materially different from the summary or preliminary data we previously published. As a result, summary or preliminary 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. Preliminary data from clinical trials that we conduct may not be indicative of the final results of the trials and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between preliminary data and final data could significantly harm our business and prospects. Further, additional disclosure of preliminary data by us or by our competitors in the future could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. Interested parties 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, our product candidates may be harmed, which could harm our business, financial condition, results of operations, and prospects.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols, use in combination with other therapies, and the rate of discontinuations by clinical trial participants. In addition, we may use patient-reported outcome assessments in some of our clinical trials, which involve patients' subjective assessments of efficacy of the treatments they receive in the trial. Such assessments can vary widely from day to day 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.

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

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors, and others in the medical community. For example, current standard-of-care cancer treatments, such as existing chemotherapy and radiation therapy, are well established in the medical community, and doctors may continue to rely on these treatments. The degree of market acceptance of any of our approved product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the approval of other new therapies for the same indications;
- the clinical indications for which the product candidate is approved;
- restrictions on the use of our products, if approved, such as boxed warnings, contraindications in labeling, or restrictions on use of our products together with other medications, or a risk evaluation and mitigation strategy ("REMS"), if any, which may not be required of alternative treatments and competitor products;

- the potential and perceived advantages of product candidates over alternative treatments or in combination therapies;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the effectiveness of sales and marketing efforts;
- the willingness of the target population to try new therapies and of physicians to prescribe these therapies; and
- unfavorable publicity relating to the product candidate.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors, and patients, we may generate less revenue from that product candidate than anticipated, which could harm our financial results.

The sizes of the patient populations suffering from some of the diseases we are targeting may be based on estimates that are inaccurate, may be small, or may be smaller than estimated.

We rely on estimates to project the incidence and prevalence of diseases we are targeting and the subset of patients with these diseases who have the potential to benefit from treatment with sotigalimab and our other product candidates. We derive these estimates from a variety of sources, including United States and global cancer databases, scientific literature, surveys of clinics, physician interviews, patient foundations, and market research, and they may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for sotigalimab and any other future product candidates may be more limited than we originally estimated or may not be amenable to treatment with sotigalimab and any other product candidates, if and when approved. For example, in March 2022, the FDA approved nivolumab and relatlimab-rmbw (Opdualag™) for use in patients with unresectable or metastatic melanoma, which may limit the number of patients with unresectable or metastatic melanoma that have progressive disease during treatment with anti-PD-(L)1 therapy, which would be the target population for a potential registration-enabling study of sotigalimab in combination with a PD-(L)1 inhibitor that we are considering. Even if we obtain significant market share for sotigalimab and any other product candidates, small potential target populations for certain indications means we may never achieve profitability without obtaining market approval for additional indications.

Many of our additional internal programs, including APX601, are at earlier stages of development than sotigalimab and may fail in development or suffer delays, including if we are unable to raise adequate additional funding, that adversely affect their commercial viability.

Other than sotigalimab, all of our internal programs are in preclinical development or at the research stage and may fail in development or suffer delays that adversely affect their commercial viability. These programs may fail to yield product candidates. 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 testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later-stage clinical trials of the product candidate. The success of any product candidates we may develop will depend on many factors, including the following:

- generating sufficient data to support the initiation or continuation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- the successful enrollment of patients in, and the completion of, clinical trials;

- the timely manufacture of sufficient quantities of the product candidate, and any combination therapy, for use in clinical trials; and
- acceptable adverse profile in the clinical trials.

We will need additional funding to continue to advance the development of our other internal programs, including APX601. If we are unable to secure adequate funding to continue such development, we expect that we will be required to delay or stop the development of such programs.

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 develop, obtain regulatory approval of, commercialize, or generate significant revenue from any product candidate.

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

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

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

Increasingly, third-party payors require that drug companies provide them with predetermined discounts from list prices and challenge the prices charged for medical products. Further, such payors increasingly challenge the price, examine the medical necessity and review the cost effectiveness of medical drug products. There may be especially significant delays in obtaining coverage and reimbursement for newly approved 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.

Third-party payors may limit coverage to specific drug products on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive studies to demonstrate the medical necessity and cost-effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

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

Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

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

If our competitors develop and market products that are more effective, safer, or less expensive than our product candidates, our commercial opportunities will be negatively impacted.

The biotechnology industry is highly competitive and subject to rapid and significant technological change. Moreover, the oncology field is characterized by strong and increasing competition, with a strong emphasis on intellectual property. Products we may develop in the future for the treatment of cancer and any other diseases are likely to face competition from other drugs and therapies, including those of which we may not currently be aware. In addition, our products may need to compete with off-label drugs used by physicians to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our products.

Major multinational pharmaceutical and biotechnology companies, emerging and start-up companies, universities, and other research institutions, could focus their future efforts on developing competing therapies and treatments for any of the indications we are currently targeting or may target in the future. For example, each of Hoffmann-La Roche AG, Alligator Bioscience AB, Celldex Therapeutics, Inc., Seagen Inc., Lyvgen Biopharma, Eucure Biopharma, a subsidiary of Biocytogen, and AbbVie Inc. are developing CD40-based antibody product candidates for solid tumor oncology indications that are in clinical trials, typically in combination therapies, and other companies and institutions have other CD40-based product candidates in development.

Many of these current and potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources, and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients, and manufacturing biotechnology products. These companies also have significantly greater research, development, 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. As a result of any of these factors, our competitors may succeed in obtaining approval from the FDA, EMA, or foreign regulatory authorities or discovering, developing, and commercializing products in our field before or more successfully than we do.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for planned clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biotechnology industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

We have limited resources and are currently focusing our efforts on developing sotigalimab. As a result, we may fail to capitalize on other product candidates or indications that may ultimately have proven to be more profitable.

We are currently focusing our efforts on completing clinical trials of sotigalimab for a variety of indications, including sarcoma, esophageal and GEJ cancers and melanoma. As a result, we may forego or delay pursuit of opportunities for other indications or with other product candidates that may have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable product candidates or profitable market opportunities. Our spending on current and future research and development activities for specific indications may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target markets for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We are developing some our product candidates for use in combination with standard-of-care as well as emerging or experimental cancer therapies, which exposes us to several risks beyond our control.

We are developing some of our product candidates, including sotigalimab, for use in combination with current standard of care or other emerging or experimental cancer therapies. This exposes us to supply risk to the extent there is not an adequate supply of these therapies for use in combination with our product candidates, either in clinical trials or after any approval, as well as pricing risk if these combination therapies are expensive and the addition of our product candidates would be too costly to support reimbursement or payor coverage. In particular, providers of some of these emerging or experimental therapies have been contributing their therapies to use in combination trials at generally no or limited cost to us. If this were to change, our trial costs could increase substantially. Also, although combinations with an experimental agent that has not been approved may prove to be clinically beneficial, the experimental agent will still need to meet regulatory approval requirements for the combined therapy to become commercially available. In addition, if the standard of care were to evolve or change, the clinical utility of our product candidates could be diminished or eliminated. If any of these were to occur, our business could be materially harmed.

We may use companion diagnostics in the future in our development programs, and if such companion diagnostics for our product candidates are not successfully, and in a timely manner, validated, developed, or approved, we may not achieve marketing approval or realize the full commercial potential of our product candidates.

We may use companion diagnostics in our future product candidate development programs. If such companion diagnostics are developed in conjunction with clinical programs, the FDA, EMA, or comparable regulatory authority may require regulatory approval of a companion diagnostic as a condition to approval of the product candidate. For example, if we use a diagnostic to test which patients are most likely to benefit from our product candidate for the treatment of a particular indication as a criterion for enrollment, then we will likely be required to obtain FDA approval or clearance of the companion diagnostic, concurrent with approval of our product candidate. We may also be required to demonstrate to the FDA the predictive utility of a companion diagnostic, i.e., that the diagnostic selects for patients in whom the therapy will be effective or more effective compared to patients not selected for by the diagnostic. We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely in large part on third parties to perform these functions. We do not currently have any agreement in place with any third party to develop or commercialize companion diagnostics for any of our product candidates. Companion diagnostics are subject to regulation by the FDA, the EMA, and other foreign regulatory authorities as medical devices and require separate regulatory approval or clearance prior to commercialization.

- If we or our partners, or any third party, are unable to successfully develop companion diagnostics in the future in our product candidates, or experience delays in doing so:
- the development of our product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our planned clinical trials;
- our product candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and
- we may not realize the full commercial potential of any product candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients targeted by our product candidates.

In addition, any future product candidates developed in conjunction with companion diagnostics may be perceived negatively compared to alternative treatments that do not require the use of companion diagnostics, either due to the additional cost of the companion diagnostic, the requirement of samples for testing, or the need to complete additional procedures to identify genetic markers prior to administering our product candidates. If any of these events were to occur, it would significantly harm our business, results of operations and prospects.

Our business entails a significant risk of product liability, and if we do not obtain sufficient insurance coverage, the costs of product liability could have an adverse effect on our business and financial condition.

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

Risks Related to Regulatory Approval and Other Legal Compliance Matters for Our Product Candidates

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

The time required to obtain approval by the FDA, EMA, and 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. For example, 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 early clinical setting, among other goals. How the FDA plans to implement these goals and their impact on specific clinical programs and the industry are unclear. We have not submitted for, or obtained regulatory approval for, any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval in an initial or subsequent indication for many reasons, including the following:

- the FDA, EMA, or comparable foreign regulatory authorities may disagree with the design, implementation, or results of our clinical trials;
- the FDA, EMA, or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective, or have undesirable or unintended side effects, toxicities, or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety and efficacy in the full population for which we seek approval, including for example due to biologic and genetic differences that might occur in subjects in certain populations such as defined by race or other factors;
- we may be unable to demonstrate to the FDA, EMA, or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio when compared to the standard of care is acceptable;
- the FDA, EMA, or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application ("BLA"), New Drug Application ("NDA"), or other submission or to obtain regulatory approval in the United States or elsewhere;

- we may be unable to demonstrate to the FDA, EMA, or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for a proposed indication is acceptable;

- the FDA, EMA, or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA, EMA, or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control. For example, a U.S. federal government shutdown or budget sequestration, such as ones that occurred during 2018 and 2019, or other FDA priorities, such as responding to COVID-19, may result in significant reductions to, or demands on, the FDA's budget, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates.

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

Our product candidates may cause undesirable side effects or have other properties that could prevent their regulatory approval or result in significant negative consequences.

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA, or other comparable foreign regulatory authorities. Drug-related side effects could affect patient recruitment, the ability of enrolled patients to complete the trial, and/or result in potential product liability claims. Regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical trial participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates, and decreased demand for our product candidates, if approved for commercial sale.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product and cause us to recall our products;

- regulatory authorities may require additional warnings on the label or impose a more restrictive, narrower indication for use of the agent;

- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;

- we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements, such as boxed warning on the packaging, to assure safe use;

- we could be sued and held liable for harm caused to patients; and

- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, financial condition, results of operations, and growth prospects.

For any current and future clinical trials for our product candidates outside the United States, the FDA, EMA, and applicable foreign regulatory authorities may not accept data from such trials.

We conduct clinical trials outside the United States, including in Europe, and we may choose to conduct future clinical trials outside the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA, EMA, or applicable foreign regulatory authority may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless the data are applicable to the United States population and United States medical practice, and the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice ("GCP") regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have comparable approval requirements, including appropriate examination of the product in the country-specific population. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA, or any applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, EMA, or any applicable foreign regulatory authority does not accept such data, it may result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will succeed 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 obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA, EMA, or comparable foreign regulatory authority grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing, and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Obtaining foreign regulatory approvals and 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 partner we work with fails to comply with the regulatory requirements in international markets or fails to receive applicable marketing approvals, our target market will be reduced, and our ability to realize the full market potential of our product candidates will be harmed.

Even if we apply for and obtain accelerated approval or Breakthrough Therapy, Fast Track or other designation intended to expedite, facilitate or reduce the cost of pursuing development or regulatory review or approval with the FDA or other regulatory authorities for any of our product candidates, there is no guarantee that such designation would lead to faster development, regulatory review, or approval, nor would it increase the likelihood that any such product candidate will receive marketing approval.

If a product candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for such condition or a substantial improvement over available therapy for such condition, a product candidate sponsor may apply for FDA Fast Track or Breakthrough Therapy designation, and there may be other priority designations available under various regulatory bodies. In the future, we may apply for such priority designation depending on the results of our clinical trials. Even though we may apply for and receive a Fast Track, Breakthrough Therapy or other priority designations, such priority designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with the priority designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track or Breakthrough Therapy designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track or Breakthrough Therapy designation alone does not guarantee qualification for the FDA's priority review procedures. Further, even if any of our products obtain Fast Track or Breakthrough Therapy designation, this may not lead to earlier regulatory approval or commercialization of our products due to the extensive and time-consuming steps necessary to obtain FDA approval and commercialize a product candidate. In December 2022, the Consolidated Appropriations Act, 2023, including the Food and Drug Omnibus Reform Act (FDORA), was signed into law. FDORA made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to extensive regulatory scrutiny.

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

Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA, EMA, and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to Good Manufacturing Practice ("GMP") regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with GMP and adherence to commitments made in any BLA, NDA, or Marketing Authorization Application ("MAA"). Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we receive for our product candidates will be subject to limitations on the approved indicated uses for which the product may be marketed and promoted or to the conditions of approval (including potentially the requirement to implement a REMS), or contain requirements for potentially costly post-marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA, EMA, and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed, and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval. The holder of an approved BLA, NDA, or MAA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing, or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters that would result in adverse publicity;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approvals;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities;
- seize or detain products; or
- require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, this would significantly harm our business, financial condition, results of operations, and growth prospects.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act ("ACA") was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our products after obtaining any regulatory approval;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement and new payment methodologies. For example, 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 prescription drug provisions of the Inflation Reduction Act and other healthcare reforms that may be implemented in the future could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

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

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to:

- comply with the laws of the FDA, EMA and other comparable foreign regulatory authorities;
- provide true, complete and accurate information to the FDA, EMA and other comparable foreign regulatory authorities;
- comply with manufacturing standards we have established;

- comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or

- report financial information or data accurately or to disclose unauthorized activities to us.

If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We plan to adopt a code of business conduct and ethics in connection with this offering, but it is not always possible to identify and deter misconduct by employees and third 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 be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations, and financial conditions could be adversely affected.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be subject to various federal and state fraud and abuse laws. The laws that may impact our operations include the following:

- The federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, or recommendation of any good, facility, item, or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

- Federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, impose criminal and civil penalties, including through civil actions, against individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other third-party payors that are false or fraudulent, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation.

- The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”) and their respective implementing regulations, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of individually identifiable health information without appropriate authorization.

- The federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations, require manufacturers of drugs, 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 HHS under the Open Payments Program, information related to payments or other transfers of value made to covered recipients, as defined by law, including physicians, certain non-physician providers, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

- Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

Analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection, and unfair competition laws may apply to pharmaceutical business practices, including research, distribution, sales, and marketing arrangements, as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers.

- State laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources.

- State laws also require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations, and other remuneration, and items of value provided to healthcare professionals and entities.

- State and foreign laws also govern 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.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. Further, achieving and sustaining compliance with applicable federal and state privacy, security, and fraud laws may prove costly.

If we or any clinical collaborators, CROs, contract manufacturers, or other contractors and suppliers that we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We and any clinical collaborators, CROs, contract manufacturers, or other contractors and suppliers that 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.

Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. 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, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development, and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. 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 carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our business activities may be subject to the FCPA and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the Foreign Corrupt Practices Act ("FCPA") and similar anti-bribery or anti-corruption laws, regulations, or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits 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, the researchers with whom we conduct clinical trials, and the healthcare providers who prescribe pharmaceuticals, are employed by their government, and the purchasers of pharmaceuticals are government entities. As a result, our dealings with these researchers, prescribers, and purchasers are subject to regulation under the FCPA. Recently the Securities and Exchange Commission ("SEC") and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, contractors or collaborators, 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, 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 expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results and financial condition.

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

We receive, generate, and store significant and increasing volumes of sensitive information, such as employee, personal, patient and collaborator data. In addition, we actively seek access to medical information, including patient data, through research and development partnerships and collaborations or otherwise. We have legal and contractual obligations regarding the protection of confidentiality and appropriate use of personal data. We and our partners may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). These data protection laws and regulations continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our partners, including during our clinical trials. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH, which establish privacy and security standards that limit the use and disclosure of individually identifiable health information and require the implementation of administrative, physical, and technological safeguards to protect the privacy of individually identifiable health information and ensure the confidentiality, integrity, and availability of electronic protected health information. Determining whether individually identifiable health information has been handled in compliance with applicable privacy standards and our contractual obligations can require complex factual and statistical analyses and may be subject to changing interpretation. Depending on the facts and circumstances, we could be subject to civil and criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. We cannot be sure how these regulations will be interpreted, enforced, or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems. Failure to comply with any of these laws could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by customers and other affected individuals, damage to our reputation, and loss of goodwill (both in relation to existing and prospective customers), any of which could have a material adverse effect on our business, financial condition, results of operations, or prospects.

Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or other malicious third parties or viruses or breached due to employee error, malfeasance, or other malicious or inadvertent disruptions. Any such attack, breach, or other security breach or incident, or any interruption, could compromise our networks and the information processed there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost, stolen or otherwise processed without authorization. Any such access, loss, other unauthorized processing, or any other security breach or incident, could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, such as HIPAA and HITECH, and regulatory penalties. Notice of certain security breaches must be made to affected individuals, the Secretary of the HHS, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete. The HHS has the discretion to impose penalties without attempting to resolve violations through informal means. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. Although we have implemented security measures designed to prevent unauthorized access to patient data, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from security breaches or incidents, loss, or other unauthorized processing. Unauthorized access, loss, dissemination or other processing could also damage our reputation or disrupt our operations, including our ability to conduct our analyses, deliver test results, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business.

We may collect, process, use or transfer personal information from individuals located in the European Economic Area ("EEA"), Switzerland, and the United Kingdom (collectively, "Europe") Union in connection with our business, including in connection with conducting clinical trials in Europe. Additionally, if any of our product candidates are approved, we may seek to commercialize those products in Europe. The collection, use, and other processing of personal health data in Europe are governed by laws, regulations, and directives, including the General Data Protection Regulation (EU) 2016/679 ("GDPR"). This legislation imposes requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside of the EEA, including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping. This legislation imposes significant responsibilities and liabilities in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance. In particular, with respect to cross-border transfers of personal data, judicial and regulatory developments in Europe have created uncertainty. In a decision issued by the Court of Justice of the European Union ("CJEU") on July 16, 2020, the CJEU invalidated one mechanism for cross-border personal data transfer, the EU-U.S. Privacy Shield, and imposed additional obligations on companies, including us, relying on standard contractual clauses issued by the European Commission ("SCCs") for cross-border personal data transfers. The European Commission released new SCCs designed to address the CJEU concerns on June 4, 2021, which are required to be implemented. Additionally, the United Kingdom's Information Commissioner's Office issued new standard contractual clauses (the "UK SCCs") to support personal data transfers out of the United Kingdom on February 2, 2022, which also are required to be implemented. We have undertaken certain efforts to conform transfers of personal data from Europe to the United States to our understanding of current regulatory obligations and guidance of data protection authorities, but the CJEU's decision, the revised SCCs and UK SCCs, regulatory guidance and opinions, and other developments relating to cross-border data transfer may require us to implement additional contractual and technical safeguards for any personal data transferred out of Europe or other regions which may increase compliance costs, lead to increased regulatory scrutiny or liability, may require additional contractual negotiations, and may adversely impact our business, financial condition and operating results. Any actual or alleged failure to comply with the requirements of the GDPR or other laws, regulations, and directives of jurisdictions and regulators within Europe may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, U.S. states are adopting new laws or amending existing laws and regulations, requiring attention to frequently changing regulatory requirements applicable to data related to individuals. For example, California has enacted the California Consumer Privacy Act ("CCPA"). The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined and which can include any of our current or future employees who may be California residents or any other California residents whose data we collect or process) and provide such residents new ways to opt out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. As we expand our operations and trials (both preclinical or clinical), the CCPA may increase our compliance costs and potential liability. Additionally, a new privacy law, the California Privacy Rights Act ("CPRA"), was approved by California voters in November 2020. The CPRA created obligations relating to consumer data beginning on January 1, 2022, with enforcement anticipated to commence July 1, 2023. The CPRA modifies the CCPA significantly, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. Additionally, other U.S. states and the U.S. federal government continue to propose, and in the case of certain states adopt, privacy-focused legislation, such as laws enacted in Colorado, Virginia, Utah and Connecticut. Aspects of these state laws remain unclear, resulting in further uncertainty and potentially requiring us to modify our data practices and policies and to incur substantial additional costs and expenses in an effort to comply.

Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we or third parties fail to adequately safeguard confidential personal, employee, or patient data, or if such information or data are wrongfully used by us or third parties or disclosed to unauthorized persons or entities, our reputation could suffer and we could be subject to claims for damages or other liabilities, regulatory investigations and enforcement action, litigation, the imposition of fines or other penalties, and significant costs for remediation. Any of these risks could have a material adverse effect on our business, financial condition, results of operations, or prospects.

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

Our success is highly dependent on the services of our Chief Executive Officer, Dr. Xiaodong Yang, and our other senior management, and our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must recruit, retain, manage, and motivate qualified clinical, scientific, technical, and management personnel, and we face significant competition for experienced personnel, especially in the biotechnology industry in the San Francisco Bay Area of California. We are highly dependent on the principal members of our management and scientific and medical staff, particularly our Chief Executive Officer, Dr. Xiaodong Yang. 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, including Dr. Yang, could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. In addition to competition for personnel, the San Francisco Bay Area in particular is characterized by a high cost of living. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide 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.

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, Apexigen had 20 full-time employees. In order to successfully implement our development and commercialization plans and strategies, and as we continue to transition into operating as a public company after the Business Combination, we expect to need additional managerial, operational, sales, marketing, financial, and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA and EMA review process for our current and any future 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, if approved, commercialize our current and any future product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of clinical management 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 obtain marketing approval of our current and any future product candidates or otherwise advance our business. We cannot assure you that we will 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 successfully implement the tasks necessary to further develop and commercialize our current and any future product candidates and, accordingly, may not achieve our research, development, and commercialization goals.

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

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

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

Our anticipated international operations may expose us to business, tax, regulatory, political, operational, financial, pricing, and reimbursement risks associated with doing business outside of the United States.

Our business strategy incorporates potential international expansion as we seek to obtain regulatory approval for, and commercialize, our current and any future product candidates in patient populations outside the United States. If our product candidates are approved, we may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including:

- multiple, conflicting, and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- taxation of future foreign earnings may increase our effective tax rate**,** which could adversely affect our cash flows, and overall financial condition;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;

- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions;
- certain expenses including, among others, expenses for travel, translation, and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the FCPA, its accounting provisions or its anti-bribery provisions, or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our results of operations.

Risks Related to Intellectual Property

If we do not obtain, maintain or protect our intellectual property rights in products we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, third parties could develop and commercialize products and technology similar or identical to ours, and we may not compete effectively in our market.

Our success depends in significant part on our and our current or future licensors' ability to obtain, maintain and protect patents and other intellectual property rights and operate without infringing, misappropriating, or otherwise violating the intellectual property rights of others. We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have developed that are important to our business, including related to our product candidates. We have also licensed from third parties' rights to patents and other intellectual property, including from Epitomics, Inc., an Abcam Company ("Epitomics"), with respect to rabbit monoclonal antibodies generated using Epitomics' technology in the field of pharmaceutical products for human or veterinary use. If we or our licensors are unable to obtain or maintain patent protection with respect to such inventions and technology, our business, financial condition, results of operations, and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming, and complex, and we and our current or future licensors may not prepare, file, prosecute, maintain, and enforce all necessary or desirable patent applications at a reasonable cost or in a timely manner. Patents may be invalidated and patent applications may not be granted for a number of reasons, including known and unknown prior art, deficiencies in the patent applications or the lack of novelty of the underlying inventions or technology. It is also possible that we or our current and future licensors will fail to identify patentable aspects of inventions made in the course of research, development and commercialization activities in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research, development, and commercialization activities, such as our employees, collaborators, CROs, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such activities before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our current or future licensors were the first to make the inventions claimed in our owned or any licensed patents or patent applications, or that we or our current or future licensors were the first to file for patent protection of such inventions.

Moreover, in some circumstances, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering products or technology that we license from third parties and are reliant on our current and future licensors. For example, pursuant to our license agreement with Epitomics, Inc., Epitomics is responsible for the filing, prosecution and maintenance of the patents and patent applications licensed to us. Therefore, these patents and applications may not be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our current or future licensors fail to prosecute, maintain, enforce or defend such patents and other intellectual property rights, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected.

The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' patent rights are highly uncertain. Our and our current or future licensors' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Moreover, the patent examination process may require us or our current and future licensors to narrow the scope of the claims of our or our current and future licensors' pending and future patent applications, which may limit the scope of patent protection that may be obtained. Additionally, the scope of patent protection can be reinterpreted after issuance. Even if our or our current or future licensors' pending and future patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold or in-license may be challenged, narrowed, circumvented, or invalidated by third parties in court or in patent offices in the United States and abroad. Our and our current or future licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. Our competitors or other third parties may also circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

We cannot assure you that we have found all of the potentially relevant prior art relating to our patents and patent applications. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. For example, there are a number of third-party patents and patent applications relating to the engineering of antibodies, including with respect to the CD40 binding and fragment crystallizable ("Fc") domains, that may have earlier priority or publication dates and may be asserted as prior art against our patents and patent applications. Even if our patents do issue and even if such patents cover our product candidates, third parties may initiate oppositions, interferences, re-examinations, post-grant reviews, inter partes reviews, nullification or derivation actions in court or before patent offices, or similar proceedings challenging the inventorship, validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. An adverse determination in any such proceeding or litigation could reduce the scope of, or invalidate, the patent rights we own or license, allow third parties to commercialize our technology or products and compete directly with us, without payment to us.

Moreover, we, or our current or future licensors, may have to participate in interference proceedings declared by the United States Patent and Trademark Office ("USPTO") to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. 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 technology and product candidates, including sotigalimab. 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. Consequently, we do not know whether any of our technology or product candidates will be protectable or remain protected by valid and enforceable patents.

Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our current and future licensors were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs. Even where we have a valid and enforceable patent, we may not exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

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

Filing, prosecuting, enforcing, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our or our current and future licensors' intellectual property rights may not exist in some countries outside the United States or may be less extensive in some countries than 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 and our current and future licensors may not prevent third parties from practicing our and our current or future licensors' inventions in all countries outside the United States, or from selling or importing products made using our and our current or future licensors' inventions in and into the United States or other jurisdictions. Competitors may use our and our current or future licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our current and future licensors have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our and our current or future licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us and our current and future licensors to stop the infringement of our and our current or future licensors' patents or marketing of competing products in violation of our and our current or future licensors' intellectual property and proprietary rights generally. Proceedings to enforce our and our current or future licensors' intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our and our current or future licensors' efforts and attention from other aspects of our business, could put our and our current or future licensors' patents at risk of being invalidated or interpreted narrowly, could put our and our current or future licensors' patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our current and future licensors. We or our current and future licensors may not prevail in any lawsuits that we or our current and future licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Some jurisdictions may refuse to honor intellectual property rights due to legislation or geopolitical reasons, such as Russia recently stating that it will not honor patent rights of companies from countries that have imposed sanctions on Russia in response to the war in Ukraine. Accordingly, our and our current and future licensors' efforts to enforce intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming, and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act ("Leahy-Smith Act"), could increase those uncertainties and costs. The Leahy-Smith Act includes provisions that affect the way patent applications are prosecuted, redefine prior art, and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and may also 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 post-grant review, inter partes review, and derivation proceedings. In addition, assuming that other requirements for patentability are met, prior to March 15, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 15, 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, 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 patents that we might obtain in the future.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by 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 government fees on any issued patent or patent application are due to be paid to the USPTO and various government patent agencies outside of the United States in several stages over the lifetime of our owned or licensed patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent lapse can, in some cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. If we or our current and future licensors fail to maintain the patents and patent applications covering our product candidates, our patent protection could be reduced or eliminated and our competitors might be better able to enter the market with competing products or technology, which could have a material adverse effect on our business, financial condition, results of operation, and prospects.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose the ability to continue the development and commercialization of our product candidates.

We are a party to a number of intellectual property and technology licenses that are important to our business. For example, Apexigen obtained an exclusive license from Epitomics under certain intellectual property related to rabbit monoclonal antibodies generated using Epitomics' technology in the field of pharmaceutical products for human or veterinary use that has certain ongoing payment and other obligations even though the license agreement has now expired. In addition, if we fail to comply with our obligations under these technology agreements, including payment and diligence terms, or other specified events occur such as our insolvency, our current and future licensors may have the right to terminate these agreements, in which event we may not develop, manufacture, market or sell any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could adversely affect the value of the technology or product candidate being developed or licensed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our existing collaborative development relationships and any collaboration relationships we might enter into in the future;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current and future licensors and us; and

- the priority of invention of patented technology.

In addition, the agreements under which Apexigen licenses intellectual property or technology from third parties are generally 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, result 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 candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

We may not succeed in obtaining necessary rights to any product candidates we may develop through acquisitions and in-licenses.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our current or future product candidates. In order to avoid infringing these third-party patents, we may find it necessary or prudent to obtain licenses from such third-party intellectual property holders. Moreover, we may need to obtain additional licenses from our existing licensors and others to advance our research or allow commercialization of product candidates we may develop. In addition, with respect to any patents we co-own with third parties, we may require licenses to such co-owners' interest to such patents. However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for product candidates we develop. 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 established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development or commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. As a result, we may be unable to obtain any such licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them, or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. In addition, even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Third parties may initiate legal proceedings against us alleging that we infringe, misappropriate, or otherwise violate their intellectual property rights, or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain and could have an adverse effect on the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our and our current or future licensors' proprietary technologies without infringing, misappropriating, or otherwise violating the intellectual property rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Third parties may initiate legal proceedings against us or our current and future licensors alleging that we or our current and future licensors infringe, misappropriate, or otherwise violate their intellectual property rights. In addition, we or our current and future licensors may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, reexaminations, inter partes reviews, or derivation proceedings in the United States or other jurisdictions. These proceedings can be expensive and time-consuming, and many of our or our current and future licensors' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our current and future licensors.

There are third-party patents and, if issued as patents, patent applications relating to the engineering of antibodies, including with respect to CD40 and Fc domains, that may be construed to cover our product candidates, including sotigalimab. The third parties that control these patents may allege that our product candidates, including sotigalimab, infringe these patents. Parties making infringement, misappropriation, or other intellectual property claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. In addition, even if we believe any third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of validity, enforceability, priority, or non-infringement. A court of competent jurisdiction could hold that such third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any of our products or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such third-party U.S. patents in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. An unfavorable outcome could require us or our current and future licensors to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our current and future licensors a license on commercially reasonable terms or at all. Even if we or our current and future licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our current and future licensors, and it could require us to make substantial licensing and royalty payments. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement, misappropriation, or other violation of third-party intellectual property could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects.

We may be subject to claims by third parties asserting that we or our employees, consultants, or advisors have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants, and advisors, including our senior management, were previously employed at other biopharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure, and/or non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

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

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Trade secrets can be difficult to protect. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not obtain adequate remedies for such breaches. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have a material adverse effect on our business. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent information and techniques and we cannot guarantee that our competitors will not independently develop substantially equivalent information and techniques. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us. Failure on our part to adequately protect our trade secrets and our confidential information would harm our business and our competitive position.

Issued patents covering one or more of our product candidates or technologies could be found invalid or unenforceable if challenged in court.

To protect our competitive position, we may from time to time need to resort to litigation in order to enforce or defend any patents or other intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. Enforcement of intellectual property rights is difficult, unpredictable, and expensive, and many of our or our licensors' or collaboration partners' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaboration partners can. Accordingly, despite our or our licensors' or collaboration partners' efforts, we or our licensors or collaboration partners may not prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the European Union and the United States. We may fail in enforcing our rights—in which case our competitors may be permitted to use our technology without being required to pay us any license fees. In addition, however, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our products or use our technologies, including our APXiMAB platform, and then compete directly with us, without payment to us.

If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering one of our products, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States or in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. A claim for a validity challenge may be based on failure to meet any of several statutory requirements, for example, lack of novelty, obviousness, or non-enablement. A claim for unenforceability could involve an allegation that someone connected with prosecution of the patent withheld relevant information from the European Patent Office or the USPTO or made a misleading statement, during prosecution. Third parties may also raise similar claims before the USPTO or an equivalent foreign body, even outside the context of litigation. Potential proceedings include re-examination, post-grant review, inter partes review, interference proceedings, 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 in such a way that they no longer cover our technology or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a defendant 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 one or more of our product candidates or certain aspects of our APXiMAB platform technologies. Such a loss of patent protection could have a material adverse impact on our business, financial condition, results of operations, and prospects. Further, litigation could result in substantial costs and diversion of management resources, regardless of the outcome, and this could harm our business and financial results. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

We may become involved in disputes or lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming, unsuccessful, and lead to challenges to our intellectual property ownership.

Competitors and other third parties may infringe, misappropriate, or otherwise violate our issued patents or other intellectual property or the patents or other intellectual property of our licensors, or we or our licensors may be required to defend against claims of infringement, misappropriation, or other violation. In addition, our patents or the patents of our licensors may become involved in inventorship or priority disputes. Other disputes may arise related to intellectual property rights that we believe are derived from, or related to, our patents or technology, including with respect to sotigalimab. For example, we are aware of certain patent applications filed by a former collaborator covering biomarkers and patient selection discoveries related to our sotiga program. We believe that we own the intellectual property covered by these provisional patent applications. We are in discussions with the former collaborator to assign their rights in this intellectual property to us, but there is no guarantee that we will come to a satisfactory resolution of this matter.

To counter infringement, misappropriation, or other unauthorized use, we or our licensors may be required to negotiate a solution to such dispute or file infringement claims, either of which can be expensive and time-consuming. Any claims we or our licensors assert against perceived infringers could provoke these parties to assert counterclaims against us or our licensors alleging that we or our licensors infringe their patents or that our or our licensors' patents are invalid or unenforceable. In a patent infringement proceeding, a court may decide that a patent of ours or one of our licensors' is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our owned or licensed patents at risk of being invalidated, held unenforceable, or interpreted narrowly.

We may find it impractical or undesirable to enforce our intellectual property against some third parties. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Interference 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 or our licensors' patents or patent applications. If we or our licensors are unsuccessful in any interference proceedings to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents owned or licensed or our owned or licensed patent claims may be narrowed, invalidated, or held unenforceable. If we or our licensors are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority of inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or narrowing of our owned or licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products.

Any of the foregoing intellectual property disputes or litigation could result in a material adverse effect on our business, financial condition, results of operations, or prospects.

Intellectual property litigation or proceedings could cause us to spend substantial resources and distract our personnel.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims could result in substantial costs and diversion of management resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs or in-license needed technology or other product candidates. There could also be public announcements of the results of the hearing, motions or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. 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. Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not prevent third parties from infringing upon, misappropriating, or otherwise violating our intellectual property. Any of the foregoing events could harm our business, financial condition, results of operations, and prospects.

If we do not obtain patent term extension or data exclusivity for any product candidates we may develop, our business may be materially harmed.

Patents have a limited lifespan. Due to 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 owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including biosimilar or generic medications. For example, certain of our owned patents that cover sotigalimab will begin to expire in 2032, absent extensions, in the United States and similar patent applications are pending in foreign jurisdictions. At the time of the expiration of the relevant patents, the underlying technology covered by such patents can be used by any third party, including competitors. Although the patent term extensions under the Drug Price Competition and Patent Term Restoration Action of 1984 ("Hatch-Waxman Act") in the United States may be available to extend the patent term, we cannot provide any assurances that any such patent term extension will be obtained and, if so, for how long.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for 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, only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

If our trademark and tradenames are not adequately protected, then we may not build name recognition in our markets and our business may be adversely affected.

We cannot assure you that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks. We cannot assure you that any future trademark applications that we will file will be approved. During trademark registration proceedings, we may receive rejections and although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and in proceedings before comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. An opposition or cancellation proceeding may be filed against our trademarks and our trademarks may not survive such proceedings, which may force us to rebrand our name.

Intellectual property rights do not necessarily address all potential threats.

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 make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or may own in the future;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we may not develop additional proprietary technologies that are patentable; and
- 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, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our 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 our clinical trials. We currently rely on third parties to conduct clinical trials of its product candidates, including ISTs sponsored by third parties; these third parties also include CROs, clinical data management organizations, medical institutions and clinical investigators. We expect to continue to rely upon third parties to conduct additional clinical trials of our product candidates. Third parties have a significant role in the conduct of our 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, we have limited ability to control the amount or timing of resources that any such third party will devote to our clinical trials. In some cases, these third parties may not provide us with information about the ongoing clinical trials on a timely basis. The third parties may also violate the terms of the agreements governing such clinical trials in various ways, including asserting intellectual property rights that contractually belong to us. Some of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it will delay our drug development activities.

Our reliance on these third parties for research and 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 clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. 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 clinical trials may be deemed unreliable and the FDA, EMA, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current GMP regulations. Our failure or the failure of the third parties we engage to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process. We also are 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.

The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

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

We do not currently have the infrastructure or internal capability to manufacture our product candidates for use in clinical development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates in compliance with GMP requirements for clinical trials under the guidance of members of our organization. We currently rely on a single third-party manufacturer, WuXi Biologics (Hong Kong) Limited (“WuXi”), for the manufacture of our product candidates sotiga and APX601. We expect the quantity and stability of our current supply of sotiga, which was produced by a prior third-party manufacturer, will be sufficient to supply our currently ongoing clinical trials through mid-2023.

WuXi has successfully manufactured sotiga drug substance and drug product for clinical trial use and we expect to have labeled and packaged material ready for use in clinical trials by mid-2023. We continue to work with the FDA to complete a plan to demonstrate comparability of the WuXi-generated drug product with the sotiga drug product we have used in clinical trials historically, which was produced by a prior third-party manufacturer. If FDA or other relevant regulatory authorities do not accept our comparability protocol or we do not adequately demonstrate the comparability of the WuXi-generated drug product with the drug product we have used in past clinical trials, we may not be able to rely on clinical trial data we have generated to date using the drug product from that prior third-party manufacturer.

The manufacture of biologic therapeutics is complex. It is anticipated that during development from early clinical trials to commercialization that changes to the manufacturing cell line, manufacturing process or analytical methods will occur. These changes carry the risk that the intended goals of such changes are not achievable and that further development work may be needed to reach these goals, which may delay our ability to meet clinical or commercial supply needs. Our change in the manufacturing site, cell line, process and analytical methods for sotiga represent a specific elevated risk for the sotiga program. However, we currently have no alternative manufacturer in place for sotiga and APX601 drug substance and drug product. For the APX601 product candidate, we have successfully completed drug substance and drug product runs at WuXi. We have not yet performed labelling and packaging runs for APX601 and will need to do so prior to initiating any clinical development of APX601.

If we were to experience an unexpected loss of supply of our product candidates for any reason, whether as a result of manufacturing, supply, or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials, such as occurred with the prior switchover by us to a new contract manufacturer. Replacement of our sole manufacturer would likely result in substantial delay and could interrupt our clinical trials if we had not previously obtained enough supply of our product candidates.

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

- the possible failure of the third party to manufacture our product candidates according to our specifications;
- the possible failure of the third party to manufacture our product candidate according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the possible failure of our third-party manufacturer to procure raw materials from third-party suppliers and potential exposure to supply chain issues impacting delivery dates, quality, quantity and pricing of raw materials, including due to the COVID-19 pandemic, which may result in additional costs and delays in production of clinical trial materials, commercial product and regulatory approvals;
- the possible termination or nonrenewal of agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the possible breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or, following approval by regulatory authorities, of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

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

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

We may not gain the efficiencies we expect from further scale-up of manufacturing of our product candidates, and our third-party manufacturers may be unable to successfully scale up manufacturing in sufficient quality and quantity for our product candidates, which could delay or prevent the conducting of our clinical trials or the development or commercialization of our other product candidates.

We expect that our third-party manufacturer, WuXi, will manufacture our product candidates at a scale and on a timeline that is sufficient for us to complete our planned clinical trials and, if we receive marketing approval, to commercialize our product candidates, including sotigalimab, for the indications we are currently targeting. However, we may consider increasing the batch scale to gain cost efficiencies. If our current manufacturer or any other manufacturer we use is unable to scale-up the manufacture of our product candidates at such time, we may not gain such cost efficiencies and may not realize the benefits that would typically be expected from further scale-up of manufacturing. In addition, quality or other technical issues may arise during scale-up activities. If our third-party manufacturers are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

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

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

We have and may in the future enter into additional agreements with third parties under which those parties have or will be granted a license to develop product candidates discovered using our APXiMAB platform. If any such programs are not successful or if disputes arise related to such programs, we may not realize the full commercial benefits from such programs.

Our APXiMAB platform has enabled the discovery of several product candidates with potential utility in multiple therapeutic areas and has resulted in five programs that have been licensed to third parties, including larger global biopharmaceutical companies and mid-sized regional or China-focused companies. Our likely counterparties for future licensing and collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, and biotechnology companies. Such arrangements generally allow the licensing parties to control the amount and timing of resources that they dedicate to the development or potential commercialization of any product candidates they develop from the technology we have licensed to them, subject to any territorial or field of use restrictions in the license. In addition, we partnered with ESBATech AG, which was acquired by Alcon and later Novartis to provide rabbit monoclonal antibodies in order to develop product candidates for certain diseases.

We typically negotiate milestone payments and royalty fees from our licensees that will require various levels of success with their product candidate development program in order for us to generate revenue from them. Our ability to generate revenue from these licensing arrangements will depend on our counterparties' abilities to successfully develop and commercialize the product candidates they are developing. We cannot predict the success of any licensing program that we enter into or whether such program will lead to any meaningful milestone or royalty revenue to us.

Licensing programs involving third-party development of product candidates derived from our licensed technology pose the following risks to us:

- counterparties generally have significant discretion, if not total control, in determining the efforts and resources that they will apply to these development efforts;
- counterparties may not properly or adequately obtain, maintain, enforce, or defend intellectual property or proprietary rights relating to our intellectual property or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property-related proceedings, including proceedings challenging the scope, ownership, validity, and enforceability of our intellectual property;
- counterparties may own or co-own with us intellectual property covering their product candidates, and, in such cases, we typically will not have the exclusive right to commercialize such intellectual property or their product candidates based on the terms of the licensing agreement;
- we may need the cooperation of these counterparties to enforce or defend any intellectual property we contribute to the program;
- counterparties typically will control the interactions with regulatory authorities related to their product candidates, which may impact our ability to obtain and maintain regulatory approval of our own product candidates;
- disputes may arise between the counterparties and us that result in the delay or termination of the research, development, or commercialization of our product candidates or research programs or that result in costly litigation or arbitration that diverts management attention and resources;
- counterparties may decide to not pursue development and commercialization of any product candidates that are derived from our licensed technology, or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the counterparties' strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities, or counterparties may elect to fund or commercialize a competing product;
- counterparties could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates or research programs if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- counterparties may not commit sufficient resources to the marketing and distribution of their product candidates, resulting in lower royalties to us;

- counterparties may grant sublicenses to our technology or undergo a change of control, and the sublicensees or new owners may decide to pursue a strategy with respect to the program which is not in our best interest;

- counterparties may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, know-how, or intellectual property of the counterparty relating to our technology in relation to the terms of the licensing agreement;

- if these counterparties do not satisfy their obligations under our agreements with them, or if they terminate our licensing agreements with them, we may be adversely impacted; and

- licensing agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

Beovu® is a drug product developed by Novartis covered under the ESBATech Agreement with us. Novartis obtained approval for Beovu for use in neovascular (wet) age-related macular degeneration ("AMD") and as a treatment of visual impairment due to diabetic macular edema, Novartis continues to develop Beovu for other indications. Under the terms of the ESBATech agreement, Novartis is obligated to pay us a very low single-digit royalty on worldwide net sales of Beovu. However, Novartis has disputed its obligation to pay royalties to us under the agreement and continues to pay such royalties under protest. As a result, we have determined that any sales-based royalties received from Novartis for Beovu are currently fully constrained, and we have recorded the royalty proceeds as deferred revenue on our consolidated balance sheet, with the amounts totaling $5.7 million and $3.6 million as of December 31, 2022 and 2021, respectively. If the dispute with Novartis regarding their royalty obligations is not settled favorably through negotiation or if the parties escalate the dispute through arbitration or litigation, there is no guarantee that we will recognize such historic and future royalty revenue in part or at all, we may be required to return the cash received to date for the constrained royalty payments, we may not receive future payments, and we may incur substantial costs and distraction of management related to such dispute. While this dispute continues, the Beovu royalty rights will be impaired which will limit our ability to exercise ownership over or monetize this royalty stream, all of which could have an adverse effect on our business, financial condition, and results of operations.

Many of the risks relating to product development, intellectual property, regulatory approval, and commercialization described in this "*Risk Factors*" section also apply to the activities of our licensees and any negative impact on these counterparties and their product development programs may adversely affect us.

If we seek to establish additional collaborations, but are unable to do so, 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 are currently seeking to engage a global collaboration partner to advance the development of sotigalimab and may seek to selectively form other collaborations to expand our capabilities, potentially accelerate research and development activities, and provide for commercialization activities by third parties.

We face significant competition in seeking appropriate collaborators. 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 a collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate and document. 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 successfully enter 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 negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

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

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

- exposure to unknown liabilities;
- 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 costs and difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- impairment of relationships with key collaborators and other counterparties of any acquired businesses due to changes in management and ownership;
- 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 marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, 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. Moreover, we may not locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Other General Risks

The COVID-19 pandemic could adversely impact our business including our ongoing and planned clinical trials and preclinical research.

We are actively monitoring, evaluating and responding to developments relating to COVID-19, including new strains of the disease that have emerged, vaccination status both locally and globally, and other COVID-19 related protocols and travel restrictions as set forth by the CDC and other state, local and government authorities. In response to the COVID-19 pandemic in 2020, we implemented policies that enabled some of our employees to work remotely, and such policies may continue for an indefinite period. We also implemented various safety protocols for on-site personnel, including COVID-19 testing procedures and compliance measures for social distancing and continue to maintain appropriate protocols in accordance with federal, state and local regulation. Our priority is to protect the health and safety of our employees, community, partners and clinical trial participants, while working to ensure the sustainability of our business operations.

As the COVID-19 pandemic continues, we may experience disruptions that could severely impact our business, current and planned clinical trials and preclinical research, including:

- delays or difficulties in enrolling and retaining subjects in our ongoing clinical trials and our future clinical trials;
- delays or difficulties in clinical site initiation, including due to difficulties in staffing and recruiting at clinical sites;
- difficulties interpreting data from our clinical trials due to the possible effects of COVID-19 on subjects;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in resources, including our employees, that would otherwise be focused on the conduct of our business or our current or planned clinical trials or preclinical research, including because of sickness, the desire to avoid contact with large groups of people, or due to limitations on travel or other restrictions imposed or recommended by federal or state and local governments;
- interruptions, difficulties or delays arising in our existing operations and company culture as a result of some or all of our employees working remotely, including those hired during the COVID-19 pandemic;
- delays in receiving approval from regulatory authorities to initiate our clinical trials;
- interruptions in preclinical studies due to restricted or limited operations at the CROs conducting such studies;
- interruptions or delays in the operations of the FDA or other domestic or foreign regulatory authorities, which may impact review and approval timelines;
- delays in receiving the supplies, materials and services needed to conduct clinical trials and preclinical research;
- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs or require us to discontinue the clinical trial altogether;
- interruptions or delays to our development pipeline;
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside of the United States.

To the extent the COVID-19 pandemic continues to pose a threat on our ability to effectively conduct our business operations as planned, there can be no assurance that we will avoid a material impact on our business from the spread of COVID-19 or its consequences, including disruption to our business and downturns in business sentiment generally or in our industry or due to social or economic unrest caused by the ongoing COVID-19 pandemic.

Additionally, certain third parties with whom we engage or may engage, including collaborators, contract organizations, third-party manufacturers, suppliers, clinical trial sites, regulators and other third parties are similarly adjusting their operations and assessing their capacity in light of the COVID-19 pandemic. If these third parties experience continued business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. For example, as a result of the COVID-19 pandemic, there could be delays in the procurement of materials or manufacturing supply chains for one or more of our product candidates, which could delay or otherwise impact our preclinical studies and our planned clinical trials. Additionally, all of our preclinical studies are conducted by CROs, which could be discontinued or delayed as a result of the pandemic. It is also likely that the disproportionate impact of COVID-19 on hospitals and clinical sites will have an impact on recruitment and retention for our planned clinical trials. CROs have also made certain adjustments to the operation of such trials in an effort to ensure the monitoring and safety of patients and minimize risks to trial integrity during the pandemic in accordance with the guidance issued by the FDA and may need to make further adjustments in the future that could impact the timing or enrollment of our clinical trials. Many of these adjustments are new and untested, may not be effective, may increase costs and may have unforeseen effects on the enrollment, progress and completion of these trials and the findings from these trials. While we are currently continuing our clinical trials and preclinical studies, we may experience delays in the completion of our clinical trials, preclinical activities and subject enrollment, may need to suspend our clinical trials and may encounter other negative impacts to such trials due to the ongoing COVID-19 pandemic.

Due to the ongoing COVID-19 pandemic we may also be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus, which may include using telemedicine visits, remote monitoring of subjects and clinical sites and measures to ensure that data from clinical trials that may be disrupted as a result of the pandemic are collected pursuant to the study protocol and consistent with GCPs. Subjects who may miss scheduled appointments, any interruption in study drug supply, or other consequences that may result in incomplete data being generated during a clinical trial as a result of the pandemic must be adequately documented and justified. For example, since March 2020, the FDA has issued various COVID-19 related guidance, including guidance on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, and good manufacturing practice considerations for responding to COVID-19 infection in employees in drug product manufacturing, among other guidance documents. 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.

While the extent of the impact of the COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition and operating results.

To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this section and in this "*Risk Factors*" section.

Our internal computer systems, and those used by our third-party research institution collaborators, other contractors, and consultants, may fail or suffer other breakdowns, cyberattacks or information security breaches and incidents that could compromise the confidentiality, integrity and availability of such systems and data, result in material disruptions of our development programs and business operations, risk disclosure of confidential, financial or proprietary information, and affect our reputation.

Despite the implementation of security measures, our internal computer systems, and those used by our third-party research institution collaborators and other contractors or consultants, may be vulnerable to damage, compromise, disruption and unauthorized access owing to a variety of causes, including system malfunction, natural disasters, terrorism, war and telecommunication and electrical failure, cyberattacks by malicious third parties, and inadvertent or intentional actions by our employees, our third-party research institution collaborators, other contractors and consultants, and/or other third parties. As the cyber-threat landscape evolves, attacks are growing in frequency, sophistication, and intensity, and are becoming increasingly difficult to detect. These risks are increased given several of our personnel and those of our collaborators, contractors and consultants work remotely, and threats of cyberattacks by Russia and affiliated actors in response to the war in Ukraine. Such attacks could include the use of key loggers or other harmful and virulent malware, including ransomware or other means of effecting denials of service or unavailability of systems or data, and can be deployed through malicious websites, the use of social engineering, and/or other means. If a breakdown, cyberattack, or other information security breach or incident were to occur and cause interruptions in our operations or any loss, corruption, or unavailability of data, it could result in loss or misappropriation of confidential information, including trade secrets, other intellectual property, or financial information, and a material disruption of our development programs and our business operations, any of which could lead to significant delays or setbacks in our research and other further development and commercialization of our product candidates. 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 data.

Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. Any disruption or security breach or incident that we or our collaborators and other contractors and consultants suffer, including any such disruption, breach or incident resulting in a loss of, or damage to, data or systems, or inappropriate disclosure, access, loss, or other processing of confidential, financial, proprietary or personal information, including data related to our personnel, could result in loss, disclosure or other unauthorized processing of confidential, financial, proprietary, and personal information, could delay further development and commercialization of our product candidates, and any such event, or the perception any such event has occurred, 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. There can be no assurance that we or our collaborators, other contractors and consultants, or other business counterparties will be successful in efforts to detect, prevent, or otherwise respond to security breaches or incidents, or fully recover systems or data from all breakdowns, service interruptions, attacks, or other security breaches or incidents.

Further, notification 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. We expect to incur significant costs in an effort to detect and prevent security breaches and incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived disruption or security breach or other security incident.

Our insurance coverage may not be adequate to compensate us for the potential losses arising from any such disruption in or, failure or security breach or incident of or impacting, our systems or third-party systems where information important to our business operations or commercial development is stored or processed. 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 attention of management and technical personnel.

Our operations are subject to the effects of a rising rate of inflation.

The United States has recently experienced historically high levels of inflation. If the inflation rate continues to increase, for example due to increases in the costs of labor and supplies, it will affect our expenses, such as employee compensation and research and development charges. Research and development expenses account for a significant portion of our operating expenses. Such increased charges may not be readily recoverable during the period of time that we are bringing the product candidates to market. Additionally, the United States is experiencing an acute workforce shortage, which in turn, has created a very competitive wage environment that may increase our operating costs. To the extent inflation results in rising interest rates and has other adverse effects on the market, it may adversely affect our consolidated financial condition and results of operations.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third-party research institution and pharmaceutical company collaborators, manufacturers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical or public health crises, such as the COVID-19 pandemic, and other natural or man-made disasters or business interruptions, including terrorism and war. In addition, for some of our clinical trials, we rely on third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

The majority of our operations, including our corporate headquarters, are located in the San Francisco Bay Area of California. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain customary insurance coverage, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

In February 2022, Russia commenced a war against Ukraine. The sanctions announced by the U.S. and other countries against Russia as a result include restrictions on selling or importing goods, services, or technology in or from affected regions and travel bans and asset freezes impacting connected individuals and political, military, business, and financial organizations in Russia. The United States and other countries could impose wider sanctions and take other actions should the conflict further escalate. It is not possible to predict the broader consequences of this conflict, which could include further sanctions, embargoes, regional instability, threats of cyberattacks, prolonged periods of higher inflation, geopolitical shifts, and adverse effects on macroeconomic conditions, currency exchange rates, and financial markets, all of which could have a material adverse effect on our business, financial condition, and results of operations.

We are subject to governmental export and import controls that could impair our ability to compete in international markets or subject us to liability if we violate these controls.

Our products may be subject to U.S. export control laws and regulations including the Export Administration Regulations ("EAR") and trade and economic sanctions maintained by the Office of Foreign Assets Control ("OFAC"). As such, an export license may be required to export, reexport, or transfer our products to certain countries, end-users, and end-uses. If we were to fail to comply with such U.S. export controls laws and regulations, U.S. economic sanctions, or other similar laws, we could be subject to both civil and criminal penalties, including substantial fines, possible incarceration for employees and managers for willful violations, and the possible loss of our export or import privileges. Obtaining the necessary export license for a particular sale or offering may not be possible and may be time-consuming and may result in the delay or loss of sales opportunities. Furthermore, U.S. export control laws and economic sanctions prohibit the export of products to certain U.S. embargoed or sanctioned countries, governments, and persons, as well as for prohibited end-uses. Even though we take precautions to ensure that we and our partners comply with all relevant export control laws and regulations, any failure by us or our partners, including third party manufacturers, to comply with such laws and regulations could have negative consequences for us, including reputational harm, government investigations and penalties.

Changes in our products or changes in export and import regulations in such countries may create delays in the introduction of our products into international markets, prevent our end-customers with international operations from deploying our products globally or, in some cases, prevent or delay the export or import of our products to certain countries, governments or persons altogether. Any change in export or import laws or regulations, economic sanctions or related legislation, shift in the enforcement or scope of existing export, import or sanctions laws or regulations, or change in the countries, governments, persons, or technologies targeted by such export, import or sanctions laws or regulations, could result in decreased use of our products by, or in our decreased ability to export or sell our products to, existing or potential end-customers with international operations. Any decreased use of our products or limitation on our ability to export to or sell our products in international markets could adversely affect our business, financial condition, and results of operations.

Any legal proceedings or claims against us could be costly and time-consuming to defend and could harm our reputation regardless of the outcome.

We may in the future become subject to legal proceedings and claims that arise in the ordinary course of business, including intellectual property, collaboration, licensing agreement, product liability, employment, class action, whistleblower and other litigation claims, and governmental and other regulatory investigations and proceedings. Such matters can be time-consuming, divert management's attention and resources, cause us to incur significant expenses or liability, or require us to change our business practices. In addition, the expense of litigation and the timing of this expense from period to period are difficult to estimate, subject to change, and could adversely affect our financial condition and results of operations. Because of the potential risks, expenses, and uncertainties of litigation, we may, from time to time, settle disputes, even where we have meritorious claims or defenses, by agreeing to settlement agreements. Any of the foregoing could adversely affect our business, financial condition, and results of operations.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2022, we had federal net operating loss ("NOL") carryforwards totaling $137.3 million. Of the $137.3 million, $109.0 million are carried forward indefinitely, but are subject to an 80% of taxable income limitation, and $28.3 million which will begin to expire in 2033, if not utilized. As of December 31, 2022, we had state NOL carryforwards of $64.6 million, which will begin to expire in 2035, if not utilized. Under Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. As a result of previous transactions, including the Business Combination, we may have experienced such an ownership change. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. As a result, our ability to use our pre-change NOL carryforwards and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation.

Changes in tax law could materially impact our business, results of operations and financial condition.

Changes to U.S. federal, state, and local, and foreign tax laws, including those that may be enacted in the future could impact the tax treatment of our business operations. For example, the United States recently enacted the Inflation Reduction Act of 2022, which implements, among other changes, a 1% excise tax on certain stock buybacks. In addition, the Organization for Economic Cooperation and Development has proposed a number of tax provisions that could impact our business if we expand internationally. Further, on January 1, 2022, a provision of the Tax Cuts and Jobs Act of 2017 went into effect that eliminates the option to deduct domestic research and development costs in the year incurred and instead requires taxpayers to amortize such costs over five years. Such changes, among others, may adversely affect our effective tax rate, results of operation and general business condition.

Risks Related to Ownership of Our Common Stock

The price of shares of common stock may be volatile or may decline regardless of our operating performance. You may lose some or all of your investment.

The trading price of shares of our common stock is volatile. The stock market recently has experienced significant volatility. This volatility often has been unrelated or disproportionate to the operating performance of particular companies. You may not be able to resell your shares at an attractive price due to a number of factors such as those listed in "*Risks Related to Our Business, Financial Condition, and Need for Additional Capital*" and the following:

- the uncertainty surrounding our ability to continue as a going concern;
- our operating and financial performance and prospects;
- our quarterly or annual earnings or those of other companies in our industry compared to market expectations;
- conditions that impact demand for our products and/or services;
- future announcements concerning our business, our clients' businesses or our competitors' businesses;
- the public's reaction to our press releases, other public announcements and filings with the SEC;
- issuances, exchanges or sales, or expected issuances, exchanges or sales of our capital stock;
- changes in senior management or key personnel;
- the size of our public float;
- coverage by or changes in financial estimates by securities analysts or failure to meet their expectations;
- market and industry perception of our success, or lack thereof, in pursuing our growth strategy;
- strategic actions by us or our competitors, such as acquisitions or restructurings;
- changes in laws or regulations which adversely affect our industry or us;
- privacy and data protection laws, privacy or data breaches, or the loss of data;
- changes in accounting standards, policies, guidance, interpretations or principles;

- changes in general market, economic and political conditions in the United States and global economies or financial markets, including those resulting from the rising rate of inflation, natural disasters, terrorist attacks, acts of war and responses to such events.
- the impact of the COVID-19 pandemic on our financial condition and the results of operations;
- changes in our dividend policy;
- adverse resolution of new or pending litigation against us; and
- the market's reaction to our reduced disclosure and other requirements as a result of being an "emerging growth company" under the Jumpstart Our Business Startups Act (the "JOBS Act");

These broad market and industry factors may materially reduce the market price of shares of our common stock, regardless of our operating performance. In addition, price volatility may be greater if the public float and trading volume of our common stock is low. As a result, you may suffer a loss on your investment.

In the past, following periods of market volatility, stockholders have instituted securities class action litigation. If we were involved in securities litigation, it could have a substantial cost and divert resources and the attention of executive management from our business regardless of the outcome of such litigation.

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

The market price of our common stock has been volatile recently, trading below $1.00 on certain days. If we do not maintain a stock price over $1.00 per share for 30 consecutive business days, we would be at risk of delisting from the Nasdaq if we did not regain compliance. If Nasdaq delists our shares from trading on its exchange for failure to maintain compliance with the bid-price-rule or otherwise meet the listing standards, we and our stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities trading on the over-the-counter market;
- 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, possibly resulting in a reduced level of trading activity in the secondary trading market for shares of our common stock;
- a limited or no amount of analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Certain of our warrants are accounted for as a warrant liability and are recorded at fair value upon issuance with changes in fair value each period reported in earnings, which may have an adverse effect on the market price of our common stock.

As of July 29, 2022, the closing date for our Business Combination, we had 123,500 private placement warrants outstanding, which are exercisable under the resale registration statement filed in September 2022 and provided that a current prospectus relating to them is available and such shares are registered, qualified or exempt from registration under the securities, or blue sky, laws of the state of residence of the holder (or we permit holders to exercise their warrants on a cashless basis under certain circumstances). We may redeem outstanding warrants in certain circumstances. Under GAAP, we are required to evaluate contingent exercise provisions of these warrants and then their settlement provisions to determine whether they should be accounted for as a warrant liability or as equity. Any settlement amount not equal to the difference between the fair value of a fixed number of our equity shares and a fixed monetary amount precludes these warrants from being considered indexed to its own stock, and therefore, from being accounted for as equity. As a result of the provision that the private placement warrants, when held by someone other than the initial purchasers or their permitted transferees, will be redeemable by us, the requirements for accounting for these warrants as equity are not satisfied. Therefore, we are required to account for these private placement warrants as a warrant liability and record (a) that liability at fair value, and (b) any subsequent changes in fair value as of the end of each period for which earnings are reported. The impact of changes in fair value on earnings may have an adverse effect on the market price of our common stock.

Effective internal controls are necessary for us to provide reliable financial reports and prevent fraud.

Prior to the Business Combination, our predecessor, BCAC, had identified a material weakness in its internal controls over financial reporting in connection with the reclassification of the warrants. The material weakness was remediated as of December 31, 2022. If we identify further material weaknesses in our internal control over financial reporting, any such identified material weakness could limit our ability to prevent or detect a misstatement of our accounts or disclosures that could result in a material misstatement of our annual or interim consolidated financial statements. In such case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting and our stock price may decline as a result. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to avoid potential future material weaknesses.

We do not intend to pay dividends on shares of our common stock for the foreseeable future.

We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, we do not anticipate declaring or paying any cash dividends on shares of our common stock in the foreseeable future. Any decision to declare and pay dividends in the future will be made at the discretion of our Board and will depend on, among other things, our business prospects, results of operations, financial condition, cash requirements and availability, certain restrictions related to our indebtedness, industry trends and other factors that our Board may deem relevant. Any such decision will also be subject to compliance with contractual restrictions and covenants in the agreements governing our current and future indebtedness. In addition, we may incur additional indebtedness, the terms of which may further restrict or prevent us from paying dividends on our common stock. As a result, you may have to sell some or all of your shares of our common stock after price appreciation in order to generate cash flow from your investment, which you may not be able to do. Our inability or decision not to pay dividends, particularly when others in our industry have elected to do so, could also adversely affect the market price of shares of our common stock.

If securities analysts do not publish research or reports about us, or if they issue unfavorable commentary about us or our industry or downgrade our common stock, the price of shares of our common stock could decline.

The trading market for shares of our common stock will depend in part on the research and reports that third-party securities analysts publish about us and the industries in which we operate. We may be unable or slow to attract research coverage and if one or more analysts cease coverage of us, the price and trading volume of our securities would likely be negatively impacted. If any of the analysts that may cover us change their recommendation regarding our securities adversely, or provide more favorable relative recommendations about our competitors, the price of our securities would likely decline. If any analyst that may cover us ceases covering us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which could cause the price or trading volume of our securities to decline. Moreover, if one or more of the analysts who cover us downgrades our common stock, or if our reporting results do not meet their expectations, the market price of shares of our common stock could decline.

Our issuance of additional shares of common stock could make it difficult for another company to acquire us, may dilute your ownership of us and could adversely affect our stock price.

We filed a registration statement with the SEC on Form S-8 providing for the registration of shares of our common stock issued or reserved for issuance under our 2020 Plan, 2022 Plan and 2022 ESPP. Subject to the satisfaction of vesting conditions and the expiration of any applicable lockup agreements, shares registered under the registration statement on Form S-8 are available for resale immediately in the public market without restriction. In addition, under our purchase agreement dated March 17, 2022 with Lincoln Park (the "Lincoln Park Purchase Agreement"), we have the right to direct Lincoln Park to purchase an aggregate of up to $50,000,000 of our common stock from time to time, subject to certain limitations. As of December 31, 2022, we have issued 1,266,684 shares of our common stock under the Lincoln Park Purchase Agreement, including 150,000 on July 29, 2022, 500,000 shares of our common stock 90 calendar days after July 29, 2022 and 616,684 shares of common stock pursuant to purchases we directed under the Lincoln Park Purchase Agreement.

On January 30, 2023, we completed a private placement, issuing an aggregate of 1,995,708 shares of common stock and accompanying warrants to purchase the same number of shares, for approximately $2.8 million. From time to time in the future, we may issue additional shares of common stock or securities convertible into common stock pursuant to a variety of transactions, including acquisitions. The issuance by us of additional shares of common stock or securities convertible into common stock would dilute your ownership of us and the sale of a significant amount of such shares in the public market could adversely affect prevailing market prices of shares of our common stock.

In the future, we expect to obtain financing or to further increase our capital resources by issuing additional shares of our common stock or offering debt or other equity securities, including senior or subordinated notes, debt securities convertible into equity, or shares of preferred stock. Issuing additional shares of our common stock, other equity securities, or securities convertible into equity may dilute the economic and voting rights of our existing stockholders, reduce the market price of shares of our common stock, or both. Debt securities convertible into equity could be subject to adjustments in the conversion ratio pursuant to which certain events may increase the number of equity securities issuable upon conversion. Preferred stock, if issued, could have a preference with respect to liquidating distributions or a preference with respect to dividend payments that could limit our ability to pay dividends to the holders of our common stock. Our decision to issue securities in any future offering will depend on market conditions and other factors beyond our control, which may adversely affect the amount, timing or nature of our future offerings. As a result, holders of our common stock bear the risk that our future offerings may reduce the market price of shares of our common stock and dilute their percentage ownership.

Sales of our common stock, or the perception of such sales, by us or our existing stockholders in the public market could cause the market price for our common stock to decline and certain Selling Securityholders still may receive significant proceeds.

The sale of substantial amounts of shares of our common stock in the public market, or the perception that such sales could occur, could harm the prevailing market price of shares of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Resales of our common stock may cause the trading price of our securities to drop significantly.

All shares issued as merger consideration in the Business Combination are freely tradable without registration under the Securities Act and without restriction by persons other than our "affiliates" (as defined under Rule 144), including our directors, executive officers and other affiliates, and certain other former Legacy Apexigen stockholders.

Shares held by certain of our stockholders are eligible for resale, subject to, in the case of certain stockholders, volume, manner of sale and other limitations under Rule 144. In addition, pursuant to the Registration Rights and Lock-Up Agreement that we entered into with certain stockholders in connection with the Business Combination, we registered the sale of their shares of common stock under the Securities Act, and pursuant to the Registration Rights Agreement that we entered into with Lincoln Park, we registered the shares of our common stock issued to Lincoln Park pursuant to the Lincoln Park Purchase Agreement under the Securities Act.

Further, shares held by our stockholders who participated in our private placement in January 2023 will be eligible for resale, subject to applicable resale restrictions, and following the effectiveness of the resale registration statement we are obligated to file for such stockholders.

As restrictions on resale end or if these stockholders exercise their registration rights, the market price of shares of our common stock could drop significantly if the holders of these shares sell them or are perceived by the market as intending to sell them. These factors could also make it more difficult for us to raise additional funds through future offerings of shares of our common stock or other securities.

In addition, the shares of our common stock reserved for future issuance under the 2022 Plan and 2022 ESPP will become eligible for sale in the public market as those shares are issued, subject to provisions relating to various vesting agreements, and, in some cases, limitations on volume and manner of sale applicable to affiliates under Rule 144, as applicable.

Our management team has limited experience in operating a public company.

Our executive officers have limited experience in the management of a publicly traded company. Our management team may not successfully or effectively manage its transition to a public company that will be subject to significant regulatory oversight and reporting obligations under federal securities laws. For example, we failed to timely file our Form 10-Q for the quarter ended June 30, 2022. Their limited experience in dealing with the increasingly complex laws pertaining to public companies could be a significant disadvantage in that it is likely that an increasing amount of their time may be devoted to these activities which will result in less time being devoted to the management and growth of the company. We may not have adequate personnel with the appropriate level of knowledge, experience, and training in the accounting policies, practices or internal controls over financial reporting required of public companies in the United States. The development and implementation of the standards and controls necessary for us to achieve the level of accounting standards required of a public company in the United States may require costs greater than expected. It is possible that we will be required to expand our employee base and hire additional employees to support our operations as a public company which will increase our operating costs in future periods.

As a public reporting company, we are subject to rules and regulations established from time to time by the SEC regarding our internal control over financial reporting.

We are a public reporting company subject to the rules and regulations established from time to time by the SEC and Nasdaq. These rules and regulations require, among other things that we establish and periodically evaluate procedures with respect to our internal control over financial reporting. Reporting obligations as a public company are likely to place a considerable strain on our financial and management systems, processes and controls, as well as on our personnel.

In addition, as a public company, we are required to document and test our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act so that our management can certify as to the effectiveness of our internal control over financial reporting. The design of our internal controls over financial reporting post-Business Combination has required and will continue to require significant time and resources from management and other personnel. As a result, management was unable, without incurring unreasonable effort or expense, to conduct an assessment of our internal control over financial reporting as of December 31, 2022. Accordingly, we are excluding management's report on internal control over financial reporting in this Annual Report on Form 10-K pursuant to Section 215.02 of the SEC Division of Corporation Finance's Regulation S-K Compliance & Disclosure Interpretations. If we are not able to implement the requirements of Section 404, including any additional requirements once we are no longer an emerging growth company, in a timely manner or with adequate compliance, we may not be able to assess whether our internal control over financial reporting is effective, which may subject us to adverse regulatory consequences and could harm investor confidence and the market price of our common stock.

Additionally, once we are no longer an emerging growth company, we will be required to comply with the independent registered public accounting firm attestation requirement on our internal control over financial reporting. We will be an "emerging growth company" until the earlier of (1) the last day of the fiscal year (a) following February 2, 2026, the fifth anniversary of the BCAC IPO, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our prior second fiscal quarter, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. Until we cease being an emerging growth company stockholders will not have the benefit of an independent assessment of the effectiveness of our internal control environment.

As an "emerging growth company," we cannot be certain if the reduced disclosure requirements applicable to "emerging growth companies" will make our common stock less attractive to investors.

As an "emerging growth company," we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to obtain an assessment of the effectiveness of our internal controls over financial reporting from our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, which we have elected to do.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active market for our common stock, our share price may be more volatile and the price at which our securities trade could be less than if we did not use these exemptions.

Anti-takeover provisions in our governing documents and under Delaware law could make an acquisition of us more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Our amended and restated certificate of incorporation and bylaws and Delaware law contain provisions that could have the effect of rendering more difficult, delaying, or preventing an acquisition deemed undesirable by our Board. Among other things, our amended and restated certificate of incorporation and/or bylaws include the following provisions:

- a staggered board, which means that our Board is classified into three classes of directors with staggered three-year terms and directors are only able to be removed from office for cause;
- limitations on convening special stockholder meetings, which could make it difficult for our stockholders to adopt desired governance changes;

- a prohibition on stockholder action by written consent, which means that our stockholders are only be able to take action at a meeting of stockholders and are not able to take action by written consent for any matter;

- a forum selection clause, which means certain litigation against us can only be brought in Delaware;

- the authorization of undesignated preferred stock, the terms of which may be established and shares of which may be issued without further action by our stockholders; and

- advance notice procedures, which apply for stockholders to nominate candidates for election as directors or to bring matters before an annual meeting of stockholders.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the DGCL, which prevents interested stockholders, such as certain stockholders holding more than 15% of our outstanding common stock, from engaging in certain business combinations unless (i) prior to the time such stockholder became an interested stockholder, the Board approved the transaction that resulted in such stockholder becoming an interested stockholder, (ii) upon consummation of the transaction that resulted in such stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the common stock, or (iii) following Board approval, such business combination receives the approval of the holders of at least two-thirds of our outstanding common stock not held by such interested stockholder.

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

Our bylaws provide that the Court of Chancery of the State of Delaware is the sole and 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 employees.

Our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the (i) Court of Chancery (the "Chancery Court") of the State of Delaware (or, in the event that the Chancery Court does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (A) any derivative action, suit or proceeding brought on our behalf; (B) any action, suit or proceeding asserting a claim of breach of fiduciary duty owed by any of our directors, officers, or stockholders to us or to our stockholders; (C) any action, suit or proceeding asserting a claim arising pursuant to the DGCL, the our amended and restated charter or our amended and restated bylaws; or (D) any action, suit or proceeding asserting a claim governed by the internal affairs doctrine; and (ii) subject to the foregoing, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Notwithstanding the foregoing, such forum selection provisions shall not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts of the United States have exclusive jurisdiction. 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. Alternatively, if a court were to find the choice of forum provision contained in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition.

Additionally, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As noted above, our amended and restated bylaws provide that the federal district courts of the United States of America shall have jurisdiction over any action arising under the Securities Act. Accordingly, there is uncertainty as to whether a court would enforce such provision. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate headquarters are currently located in San Carlos, California, where we lease approximately 6,400 square feet of office, research and development and laboratory space pursuant to a lease agreement that will expire on March 31, 2023. We expect to enter into a six-month lease for office space that will begin in March 2023. We believe that these facilities will be adequate for our near-term needs. If required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock and public warrants have traded on The Nasdaq Capital Market under the symbols "APGN" and "APGNW," respectively, since July 30, 2022. Prior to July 30, 2022 and before the completion of the business combination with Brookline Capital Acquisition Corp., the common stock and warrants of Brookline Capital Acquisition Corp. traded on Nasdaq under the ticker symbols "BCAC" and "BCACW" and there was no public trading market for Legacy Apexigen's equity.

Holders

As of February 8, 2023, there were 179 registered stockholders of record of our common stock. Because most of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial stockholders represented by these holders of record.

Dividend Policy

We have never declared or paid any cash dividends on our common stock or other securities. We currently anticipate that we will retain all of our future earnings for use in the expansion and operation of our business and do not anticipate paying any cash dividends in the foreseeable future. We also may incur indebtedness in the future that may prohibit or effectively restrict the payment of dividends on our common stock. Any future determination related to our dividend policy will be made at the discretion of our Board of Directors.

Equity Compensation Plan Information

The information regarding our equity compensation plans and the securities authorized for issuance thereunder is set forth herein under Part III, Item 12 below

Unregistered Sales of Equity Securities and Use of Proceeds

On March 17, 2022, we entered into subscription agreements with certain investors for a private investment in public equity ("PIPE") transaction for $14.5 million, which transaction closed on July 29, 2022, in connection with the Business Combination. The PIPE investors received an aggregate of 1,452,000 units ("PIPE Units") at a purchase price of $10.00 per unit. Each PIPE Unit consists of one share of common stock and one-half of one warrant. Each whole warrant entitles its holder to purchase one share of common stock at an exercise price of $11.50 per share until the five-year anniversary of the Business Combination, or July 29, 2027.

We also entered into a committed purchase agreement with Lincoln Park Capital Fund, LLC on March 17, 2022. We issued 150,000 shares of common stock to Lincoln Park as an initial fee on July 29, 2022, and 500,000 additional shares of common stock to Lincoln Park on October 29, 2022 as an additional commitment fee, for its commitment to purchase shares of our common stock under the committed investment agreement. During the year ended December 31, 2022, we directed Lincoln Park to purchase 616,684 shares of common stock under the committed purchase agreement, which resulted in proceeds of $2.5 million to us.

In August 2022, we received approximately $17,000 from the exercise of options to purchase 3,628 shares of common stock.

On January 23, 2023, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional and accredited investors (the "Investors") pursuant to which we issued and sold to the Investors in a private placement (the "Private Placement") an aggregate of 1,995,708 shares of our common stock and accompanying warrants (the "Warrants") to purchase an aggregate of up to 1,995,708 additional shares of common stock at a price of $1.40 per share and accompanying Warrant. The exercise price of the Warrants is $1.40 per share. The Warrants are exercisable at any time on or after the date that is six months following the date of the issuance of the Warrants and will expire five and one-half years from the date of issuance. Brookline Capital Markets, a division of Arcadia Securities, LLC, has acted as our placement agent for the Private Placement (the "Placement Agent").

We also entered into a letter agreement (the "Engagement Agreement") with the Placement Agent, pursuant to which the Placement Agent agreed to serve as the exclusive placement agent for us in connection with the Private Placement. Pursuant to the Engagement Agreement, the Placement Agent received warrants to purchase up to 99,785 shares of Common Stock (the "Placement Agent Warrants") on substantially the same terms as the Warrants, except that the Placement Agent Warrants have an exercise price equal to 125% of the price paid by Investors in the Private Placement, or $1.75 per share of Common Stock.

Each of the foregoing issuances was made in a transaction not involving a public offering pursuant to an exemption from the registration requirements of the Securities Act in reliance upon Section 4(a)(2) of the Securities Act, or Regulation D or Regulation S promulgated under the Securities Act.

Item 6. [Reserved]

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

References included in this section to "Apexigen," "Apexigen's, "the Company," "the Company's," "we," "our," "us," and "its" refer to Legacy Apexigen prior to the consummation of the Business Combination and to Apexigen, Inc. following the Business Combination. The following discussion and analysis of the Company's financial condition and results of operations should be read in conjunction with "Special Note about Forward-Looking Statements," "Part 1, Item 1 Business," Part 1, Item 1A Risk Factors", and our consolidated financial statements and related notes thereto contained elsewhere in this report. Certain information contained in the discussion and analysis set forth below includes forward-looking statements that involve risks and uncertainties.

Overview

In 2022, Brookline Capital Acquisition Corp. ("BCAC") and Apexigen America, Inc., which was then known as Apexigen, Inc. ("Legacy Apexigen") entered into a definitive business combination agreement ("Business Combination Agreement"). Legacy Apexigen survived the business combination as a wholly-owned subsidiary of BCAC. Additionally, BCAC changed its name to Apexigen, Inc. and Legacy Apexigen changed its name to Apexigen America, Inc.

We are a clinical-stage biopharmaceutical company focusing on discovering and developing a new generation of antibody therapies for oncology, with an emphasis on new immuno-oncology agents designed to harness the patient's immune system to combat and eradicate cancer. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through the issuance of stock as well as through proceeds from license agreements and borrowings under a debt arrangement. Our net losses were $32.1 million and $28.9 million for the years ended December 31, 2022 and 2021. We expect to continue to incur significant losses for the foreseeable future. As of December 31, 2022, we had an accumulated deficit of $176.8 million.

We expect our operating expenses to increase as we continue to discover, develop, seek regulatory approvals for and prepare for potential commercialization of our product candidates, in particular to advance sotiga into additional and potentially registration-enabling clinical trials and, if we successfully execute a collaboration for the development and commercialization of sotiga. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We will need substantial additional funding to support our continuing operations, in addition to proceeds of $2.8 million from the private placement received in January 2023 (see Note 14), and to pursue our long-term development strategy. We may seek additional funding through the issuance of common stock, other equity or debt financings or collaborations or partnerships with other companies. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts for our product candidates and other research, development, manufacturing, and commercial activities.

Legacy Apexigen was incorporated in Delaware in 2010, the year Legacy Apexigen was spun off from Epitomics, Inc. ("Epitomics"), which was a California-based biotechnology company that was acquired by Abcam Plc ("Abcam") in 2012. Legacy Apexigen was spun off from Epitomics to focus on the discovery, development and commercialization of humanized monoclonal antibody therapeutics. Apexigen is headquartered in San Carlos, California.

Business Combination Agreement and Related Agreements

On March 17, 2022, BCAC and Legacy Apexigen entered into a Business Combination Agreement pursuant to which BCAC and Legacy Apexigen agreed to combine, with the equityholders of both entities holding equity in the combined company listed on the Nasdaq Stock Exchange (the "Combined Company") and with Legacy Apexigen's equityholders owning a majority of the equity in the Combined Company. The transactions contemplated under the Business Combination Agreement (the "Business Combination") closed on July 29, 2022. Legacy Apexigen equityholders received equity in the Combined Company in the form of common shares and warrants. Under the Business Combination Agreement, Legacy Apexigen was valued at $205.0 million on a fully diluted basis, net of exercise proceeds for Legacy Apexigen's pre-closing stock options. Concurrently with the execution of the Business Combination Agreement, BCAC entered into subscription agreements with certain investors for a private investment in public equity ("PIPE") transaction to close concurrently with the business combination. In addition, concurrent with the execution of the Business Combination Agreement, BCAC, Legacy Apexigen and Lincoln Park entered into a committed investment agreement under which the Combined Company has the right to direct Lincoln Park to purchase up to an aggregate of $50.0 million of our common stock over a 24-month period pursuant to the terms of a purchase agreement.

As a result, the Combined Company received approximately $19.0 million in gross proceeds funded by approximately $4.5 million in cash held in BCAC's trust account net of redemption and $14.5 million from the PIPE. The Combined Company paid off the Extension and Working Capital Notes that totaled $0.9 million and incurred $9.2 million in transaction expenses relating to the Business Combination, consisting of banking, legal, and other professional fees. The PIPE investors received an aggregate of 1,452,000 units (each a "PIPE Unit") at a purchase price of $10.00 per unit. Each PIPE Unit consists of one share of common stock and one-half of one warrant. Each whole warrant entitles the PIPE Investor to purchase one share of common stock at an exercise price of $11.50 per share during the period commencing 30 days after July 29, 2022 and terminating on the five-year anniversary of July 29, 2022.

The merger is accounted for as a reverse recapitalization in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Under this method of accounting, BCAC was treated as the "acquired" company for financial reporting purposes. See Note 3, "*Business Combination*," to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further details. Accordingly, for accounting purposes, the merger was treated as the equivalent of Legacy Apexigen issuing stock for the net assets of BCAC, accompanied by a recapitalization. The net assets of BCAC are stated at historical cost, with no goodwill or intangible assets recorded.

Components of Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of sotiga, our lead product candidate, as well as APX601 and other preclinical product candidates. We expense research and development costs as incurred. Nonrefundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. We expense the prepaid amounts as the related goods are delivered or the services are performed.

Research and development expenses include:

- Expenses incurred under agreements with third-party contract research organizations for clinical development;
- Costs related to production of drug substance, drug product and clinical supply, including fees paid to third-party contract manufacturers;
- Laboratory and vendor expenses related to the execution of preclinical activities;
- Employee-related expenses, which include salaries, benefits and stock-based compensation; and
- Facilities, depreciation and amortization, insurance and other direct and allocated expenses incurred in our research and development activities

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

	Year Ended December 31,	
	2022	2021
Clinical development	$ 5,982	$ 7,745
Contract manufacturing	9,693	5,344
Discovery and non-clinical	1,120	2,907
Personnel costs	4,840	4,444
Other allocated indirect costs	1,400	1,224
Total research and development expenses	$ 23,035	$ 21,664

We expect our research and development expenses to decrease in the near-term as we complete the clinical trials that have been ongoing and we begin to realize the effects of cost-reduction efforts in personnel costs, discovery and nonclinical expenses undertaken in 2022 and early 2023. Also, we expect our contract manufacturing costs in the near-term to be lower than in 2022 and 2021 as we have completed the drug substance and drug product manufacturing activities for sotiga and APX601 that were underway in 2022 and 2021, and we do not expect to initiate any new drug substance or drug product manufacturing runs in the near term. We anticipate the clinical development of sotiga, including potentially into a registration-enabling clinical trial, will involve significant costs. To support the advancement of the sotiga clinical development program, we are actively seeking a global development and commercialization collaboration partner. We believe that such a global collaboration would substantially reduce our development and manufacturing costs related to the sotiga program, which would provide us with the opportunity to advance certain other product candidates in our pipeline. If we successfully execute such a collaboration for the development and commercialization of sotiga, we expect to then invest in advancing APX601 through an IND filing and into Phase 1 clinical development, and begin IND-enabling activities for our APX801 program.

The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and Administrative Expenses

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

We expect that our general and administrative expenses will increase as we anticipate to incur expenses related to compliance with the rules and regulations of the SEC, Sarbanes-Oxley Act and the listing standards of Nasdaq, additional corporate, director and officer insurance expenses, increased legal, audit and consulting fees and greater investor relations expenses. As a result, we expect that the general and administrative expenses will increase in future periods in the near-term.

Other Income, Net

Other income, net primarily relates to interest income on our cash, cash equivalents and short-term investments, change in fair value of derivative warrant liabilities, change in fair value of common stock liability, and fees related to our short-term investments.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table presents our consolidated statement of operations data for the years ended December 31, 2022 and 2021, and the dollar and percentage change between periods (in thousands):

	Year Ended December 31,			
	2022	2021	$ Change	% Change
Operating expenses:				
Research and development	$ 23,035	$ 21,664	$ 1,371	6%
General and administrative	9,651	7,293	2,358	32%
Total operating expenses	32,686	28,957	3,729	13%
Loss from operations	(32,686)	(28,957)	(3,729)	13%
Other income, net	617	41	576	1405%
Net loss	$ (32,069)	$ (28,916)	$ (3,153)	11%

Costs and Expenses

Research and Development

Research and development expenses increased by $1.4 million, or 6%, to $23.0 million for the year ended December 31, 2022 from $21.7 million for the year ended December 31, 2021. The increase primarily relates to an increase of $4.3 million in contract manufacturing expenses and an increase of $0.4 million in compensation expenses, partially offset by a decrease of $1.7 million in clinical development expenses and a decrease of $1.6 million in discovery and other non-clinical expenses.

The $4.3 million increase in contract manufacturing expenses was primarily due to a $6.0 million increase related to sotigalimab manufacturing costs, partially offset by a $1.5 million decrease related to APX601 and a $0.2 million decrease related to another preclinical program, APX701.

General and Administrative

General and administrative expenses increased by $2.4 million, or 32%, to $9.7 million for the year ended December 31, 2022 from $7.3 million for the year ended December 31, 2021. The increase is primarily attributable to a $1.4 million increase in compensation expenses, a $0.6 million increase in business insurance expenses, and $0.7 million increase in amortization of deferred financing costs, partially offset by the $0.2 million decrease in spending on professional services and $0.1 million decrease in rent expense from an office lease expiration.

Other Income, Net

Other income, net, increased by $0.6 million to $0.6 million for the year ended December 31, 2022 from approximately $41,000 for the year ended December 31, 2021. The increase is primarily attributable to the increase in interest income of $0.3 million, a $0.1 million change in fair value of derivative warrant liabilities and a $0.2 million change in fair value realized upon issuance of common stock as a commitment fee to Lincoln Park.

Liquidity and Capital Resources

Since inception through December 31, 2022, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. Our net losses were $32.1 million and $28.9 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $176.8 million. We have funded our operations to date primarily through the issuance of stock as well as through proceeds from license agreements and borrowings under a debt arrangement. We will continue to be dependent upon equity and debt financings or collaboration-related revenue until we are able to generate positive cash flows from our operations. As of December 31, 2022, we had $16.8 million in cash, cash equivalents and short-term investments and expect to fund our operations into the third quarter of 2023 based on current operations without receiving any additional proceeds under our equity line with Lincoln Park or any proceeds from any other potential financing or business development transactions. Our cash and cash equivalents consist primarily of bank deposits and money market funds. Our short-term investments consist of U.S treasury securities. Based on our research and development activities and plans, there is uncertainty regarding our ability to maintain liquidity sufficient to operate the business effectively, which raises substantial doubt as to our ability to continue as a going concern.

Funding Requirements

Our primary use of cash, cash equivalents, and short-term investments is to fund operating expenses, which consist primarily of research and development expenditures related to our programs, and to a lesser extent, general and administrative expenditures. We plan to increase our research and development expenses for the foreseeable future as we continue the clinical development of our current and future product candidates. At this time, due to the inherently unpredictable nature of clinical development and the impact of the COVID-19 pandemic, we cannot reasonably estimate the costs we will incur and the timelines required to complete development, obtain marketing approval, and commercialize our current product candidate or any future product candidates. For the same reasons, we are also unable to predict when, if ever, we will generate revenue from product sales or our current or any future license agreements that we may enter into or whether, or when, if ever, we may achieve profitability. Clinical and preclinical development timelines, the probability of success, and development costs can differ materially from expectations. In addition, we cannot forecast the timing and amounts of milestone, royalty and other revenue from licensing activities, which future product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our future funding requirements will depend on many factors, including the following:

- the progress, timing, scope, results and costs of our clinical trials and preclinical studies for our product candidates, including the ability to enroll patients in a timely manner for our clinical trials;
- the costs of obtaining clinical and commercial supplies and validating the commercial manufacturing process for sotigalimab and any other product candidates;
- our ability to successfully commercialize sotigalimab and any other product candidates;

- the cost, timing and outcomes of regulatory approvals;
- the extent to which we may acquire or in-license other product candidates and technologies;
- the timing and amount of any milestone, royalty or other payments we are required to make pursuant to any current or future collaboration or license agreement;
- the extent to which we receive royalty payments though our current or any future partnership arrangements;
- our ability to attract, hire and retain qualified personnel;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

Due to our significant research and development expenditures, we have generated operating losses in all periods presented. We expect to incur substantial additional losses in the future as we expand our research and development activities. Based on our research and development plans, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt as to our ability to continue as a going concern. There can be no assurance that such additional capital, whether in the form of debt or equity financing, will be sufficient or available and, if available, that such capital will be offered on terms and conditions acceptable to us.

In addition to the proceeds that we received from the private placement in January 2023, we may seek additional funds through the sale and issuance of shares of our common stock in private or public offerings, other equity or debt financings, our committed purchase agreement with Lincoln Park, collaborations or partnerships with third parties, or other transactions to monetize assets, including our right to receive milestone payments and royalties under our out-license arrangements. We cannot assure that we will succeed in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials or preclinical studies or research and development programs. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amount of increased capital outlays and operating expenditures associated with our current and planned research, development and manufacturing activities.

To the extent that we raise additional capital through strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams or research programs or to grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our then-existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Cash Flows

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

	Year Ended December 31,	
	2022	**2021**
Net cash used in operating activities	$ (30,693)	$ (23,902)
Net cash provided by investing activities	10,955	22,024
Net cash provided by financing activities	11,097	37

Comparison of the Years Ended December 31, 2022 and 2021

Operating Activities

For the year ended December 31, 2022, cash used in operating activities was $30.7 million, which consisted of a net loss of $32.1 million and a net change of $2.0 million in our net operating assets and liabilities, partially offset by non-cash charges of $3.4 million. The change in our net operating assets and liabilities was primarily due a $3.1 million decrease in accrued expenses and a $0.8 million decrease in prepaid expenses and other current assets, partially offset by a $2.0 million increase in deferred revenue. The non-cash charges are primarily comprised of $1.9 million for stock-based compensation expense, $0.3 million for expense from vesting of restricted stock units, $0.7 million for amortization of deferred financing costs, and $0.4 million for non-cash lease expense.

For the year ended December 31, 2021, cash used in operating activities was $23.9 million, which consisted of a net loss of $28.9 million, partially offset by non-cash charges of $2.0 million and a net change of $3.0 million in our net operating assets and liabilities. The non-cash charges are primarily comprised of $1.1 million for stock-based compensation expense, and $0.5 million for non-cash lease expense. The change in our net operating assets and liabilities was primarily due an increase of $1.7 million from proceeds recorded to deferred revenue and an increase of $1.5 million from the change of accrued expenses.

The change in cash flows from operating activities was principally from the increase in net losses, decrease in accrued expense offset by the increase in stock-based compensation expense. Changes in prepaid expenses and other current assets, accounts payable and accrued liabilities were generally due to the advancement of our research programs and the timing of vendor payments.

Investing Activities

For the years ended December 31, 2022 and 2021, cash provided by investing activities was $11.0 million and $22.0 million, respectively. The change in cash flows from investing activities was primarily due to the timing of sales and purchases of marketable securities.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2022 was $11.0 million and consisted primarily of proceeds from the business combination and private offering and proceeds from common stock issued to Lincoln Park during the period, partially offset by the payments of deferred transaction costs and financing costs. Net cash used in financing activities for the year ended December 31, 2021 was not significant.

Contractual Obligations

We lease our principal facility under a non-cancelable operating lease agreement with a lease term ending on March 31, 2023.

In addition, we have entered into certain licensing agreements pursuant to which we will owe royalty payments if and when we sublicense or commercialize certain of our products, as well as certain collaboration agreements pursuant to which we may in the future owe certain amounts to our collaboration partners upon the achievement of certain milestones. Because these obligations are uncertain, and their timing and amount are not known, they are not included in the table above. These agreements are described in more detail in the section titled "*Licensing and Other Arrangements*" below.

We also enter into agreements in the normal course of business with contract research organizations for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes, which are generally cancelable upon written notice. These obligations and commitments are also not included in the table above.

Licensing and Other Arrangements

We have entered into royalty-bearing license agreements and partnership agreements. Under the terms of these agreements described below, we have the right to collect, or are obligated to pay, certain milestone payments upon the achievement of specified pre-clinical, clinical or commercial milestones.

Beovu® and Antibody Candidate Discovery and Development Agreement with Novartis

We have an agreement with Novartis relating to antibodies that Epitomics generated that target certain molecules which were used to develop antibody product candidates. Under the agreement, Novartis has a non-exclusive, irrevocable, worldwide, sublicensable, royalty-bearing and perpetual license to our rights in certain intellectual property to develop and commercialize those drug product candidates. Pursuant to the terms of the agreement, the upfront fee and all milestone payments due upon the achievement of certain pre-clinical and clinical development milestones have been paid. Novartis remains obligated to pay us a very low single-digit royalty on net sales of the Beovu (brolucizumab-dbll) product for therapeutic uses by Novartis, its affiliates or licensees.

In October 2019, Novartis' Beovu product was approved for commercial sale. Novartis has disputed its obligation to pay Beovu royalties to us and continues to pay us royalties under protest. As a result, we have determined that any sales-based royalty revenue that we may earn under this agreement is currently fully constrained. We have recorded the Beovu royalty proceeds as deferred revenue in the consolidated balance sheets. Deferred revenue totaled $5.7 million and $3.6 million as of December 31, 2022 and 2021, respectively.

Other Agreements

We have entered into certain other partnership program agreements that may eventually lead to royalty payments or other payments to us, but we do not anticipate any potential payments under these agreements in the foreseeable future, if at all.

Clinical Collaborations

We have entered into a number of collaboration arrangements for the clinical development of sotigalimab with companies and academic and non-profit institutions. These arrangements specify whether we or the collaborator bears the cost of the clinical trials, and in the case of combination therapies, typically the collaborators provide the supply of such drug products while we supply sotigalimab. Our applicable share of the costs of these clinical collaborations are reflected as research and development expenses.

Upon achievement of certain regulatory and clinical milestones related to the development of sotigalimab in pancreatic cancer, we will be obligated to pay an aggregate of up to $9.5 million in cash and shares of common stock. Because we are not currently advancing the development of sotiga in pancreatic cancer, none of these milestones were probable as of December 31, 2022, and no amounts have been recognized.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future significant effect on our financial condition, results of operations, liquidity or cash flows.

Major Vendor

We had a major vendor that accounted for approximately 39.9% and 23.2% of the research and development expenses for the years ended December 31, 2022 and 2021, respectively. The same vendor also accounted for approximately 24.8% and 28.1% of the total accounts payable and accrued liabilities as of December 31, 2022 and 2021, respectively. Moreover, there is another vendor that accounted for approximately 33.6% and 27.7% of the total accounts payable and accrued liabilities as of December 31, 2022 and 2021, respectively, but we did not incur any expenses with this vendor during the years ended December 31, 2022 and 2021.

We had an additional vendor in 2021 that accounted for approximately 12.4% of the research and development expenses for the year ended December 31, 2021. The same vendor did not account for a major portion of accounts payable and accrued liabilities as of December 31, 2021.

Emerging Growth Company

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). We may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies. Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until those standards would otherwise apply to private companies. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our consolidated financial statements with another public company, which is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period, difficult or impossible because of the potential differences in accounting standards used.

Critical Accounting Policies and Estimates

We prepare our consolidated financial statements in accordance with GAAP. The preparation of the consolidated financial statements in conformity with GAAP requires our management to make a number of estimates and assumptions relating to the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the period. We evaluate our significant estimates on an ongoing basis, including estimates related to accruals for research and development costs, stock-based compensation and uncertain tax positions. We base our estimates on historical experience 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 value of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

We believe that the accounting policies described below involve a significant degree of judgment and complexity. Accordingly, we believe these are the most critical to aid in fully understanding and evaluating our financial condition and results of operations. For further information, see Note 2, *Summary of Significant Accounting Policies*, to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Revenue Recognition

Under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*, we recognize revenue when we transfer promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. We have not commenced sales of our product candidates and do not have a product approved for sale as of December 31, 2022.

We have other license agreements with third parties, under which we may also earn contingent fees including milestone payments based on counterparty performance and royalties on sales. We recognize milestone payments as revenue once the underlying events are probable of being met and there is not a significant risk of reversal. We recognize sales-based royalties as revenue when the underlying sales occur.

For more information on revenue recognition, see Note 2, *Summary of Significant Accounting Policies*, to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Research and Development Expenses

We expense research and development costs as incurred. Research and development consist of costs incurred for the development of sotiga, our lead product candidate, as well as APX601 and other preclinical product candidates. Research and development costs consist primarily of external costs related to clinical development, contract manufacturing, preclinical development and discovery as well as personnel costs and allocated overhead, such as rent, equipment, depreciation and utilities. Personnel costs consist of salaries, employee benefits and stock-based compensation.

We estimate external research and development expenses based on the services performed, pursuant to contracts with commercial and academic institutions that conduct and manage research and development services on our behalf. We record the costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in accrued liabilities in the consolidated balance sheets. These costs are a component of our research and development expenses. We accrue these costs based on factors such as the number of subject visits, the number of active patients, the number of patients enrolled, and estimates of the work completed and other measures in accordance with agreements established with our third-party service providers. As actual costs become known, we adjust our accrued liabilities. We have not experienced any significant differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed may vary from our estimates, resulting in adjustments to expenses in future periods. Changes in these estimates that result in significant changes to our accruals could significantly affect our results of operations.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development are capitalized and then expensed as the related goods are delivered or the services are performed. We evaluate such payments for current or long-term classification based on when they will be realized.

Stock-based Compensation

Stock-based compensation, inclusive of stock options with only a service condition, and stock options with performance conditions, are awarded to our officers, directors, employees, and certain non-employees, in addition to the estimated shares of common stock to be purchased under our Employee Stock Purchase Plan.

We account for stock-based compensation in accordance with ASC Topic 718, "*Compensation—Stock Compensation*." We measure all equity awards granted to employees and non-employees based on the estimated grant date fair value. For awards subject to service-based vesting conditions, we recognize stock-based compensation expense on a straight-line basis over the requisite service period, which is generally the vesting term. For awards subject to performance-based vesting conditions, we recognize stock-based compensation expense using the accelerated attribution method when it is probable that the performance condition will be achieved. We recognize forfeitures as they occur.

We calculate the fair value of stock options using the Black-Scholes option pricing model and recognize expense using the straight-line attribution approach. The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including the fair value of our common stock, the expected term of the awards, expected stock price volatility, the risk-free interest rate for a period that approximates the expected term of the awards and our expected dividend yield.

Expected Term—We determine the expected life of options granted using the "simplified" method. Under this approach, we presume the expected terms to be the mid-point between the weighted-average vesting term and the contractual term of the option. The simplified method makes the assumption that the award recipient will exercise share options evenly over the period when the share options are vested and ending on the date when the share options would expire.

Risk-Free Interest Rate—We base the risk-free interest rate from the U.S. Treasury yield curve in effect at the measurement date with maturities approximately equal to the expected term.

Expected Volatility—Because our stock is recently traded in an active market, we calculate volatility by using the historical volatilities of the common stock of comparable publicly traded companies. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.

Expected Dividends—We have never paid cash dividends on our common stock and do not have plans to pay cash dividends in the future. Therefore, we use an expected dividend yield of zero.

As of December 31, 2022, the unrecognized stock-based compensation expense related to equity awards was $4.2 million and is expected to be recognized as expense over a weighted-average period of approximately 2.6 years.

For more information, see Note 9, *Equity Plans and Related Equity Activities*, to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

New Accounting Pronouncements

See Note 2, *Summary of Significant Accounting Policies*, to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

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

We are exposed to certain credit and interest rate risks as part of our ongoing business operations.

Credit Risk

We are exposed to credit risk on our investment portfolio. Investments that potentially subject us to credit risk consist principally of cash, cash equivalents and short-term investments. We place our cash, cash equivalents and short-term investments with financial institutions with high credit standing and our excess cash in marketable investment grade securities. Our short-term investments consist of government debt securities, corporate debt securities, commercial paper, and asset backed securities.

Interest Rate Risk

We had cash, cash equivalents and short-term investments of $16.8 million and $36.4 million as of December 31, 2022 and 2021, respectively. The primary goals of our investment policy are liquidity and capital preservation. We do not enter into investments for trading or speculative purposes. We believe that we do not have any significant exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash and cash equivalents. Declines in interest rates, however, would reduce future investment income. A hypothetical 1.00% (100 basis points) increase in interest rates would not have materially impacted the fair value of our short-term investments as of December 31, 2022 and 2021. If overall interest rates had increased or decreased by 1.00% (100 basis points), our interest income would not have been materially affected during the year ended December 31, 2022 or year ended December 31, 2021.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development contracts. We do not believe that inflation has had a significant effect on our financial results during the periods presented. However, to the extent that the inflation the United States has recently experienced results in rising interest rates and has other adverse effects on the market, it may adversely affect our future consolidated financial condition and results of operations.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements, together with the report of our independent registered public accounting firms, appear beginning on page 96 of this Annual Report on Form 10-K for the years ended December 31, 2022 and 2021.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Report of Independent Registered Public Accounting Firm (Moss Adams LLP, San Francisco, CA, PCAOB ID: 659)	97
Consolidated Balance Sheets	98
Consolidated Statements of Operations and Comprehensive Loss	99
Consolidated Statements of Stockholders' Equity	100
Consolidated Statements of Cash Flows	101
Notes to Consolidated Financial Statements	102

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Apexigen, Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, stockholders' equity, 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 consolidated financial position of the Company as of December 31, 2022 and 2021, and the consolidated 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.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to this matter are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Reverse Recapitalization

As discussed in Note 3 to the consolidated financial statements, the Company completed the Business Combination on July 29, 2022, which was accounted for as a reverse recapitalization.

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

/s/ Moss Adams LLP

San Francisco, CA
February 22, 2023

We have served as the Company's auditor since 2021.

APEXIGEN, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 14,802	$ 23,443
Short-term investments	1,997	12,917
Prepaid expenses and other current assets	2,618	1,681
Deferred financing costs, current	1,776	-
Total current assets	21,193	38,041
Property and equipment, net	150	245
Right-of-use assets	100	483
Deferred financing costs, non-current	1,036	-
Other assets	376	327
Total assets	$ 22,855	$ 39,096
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,343	$ 4,487
Accrued liabilities	5,359	8,488
Deferred revenue	5,659	3,610
Lease liabilities, current portion	106	369
Total current liabilities	16,467	16,954
Derivative warrant liabilities	11	-
Lease liabilities, less current portion	-	141
Total liabilities	16,478	17,095
Commitment and contingencies (Note 10)		
Stockholders' equity:		
Common stock, $0.0001 par value; 1,000,000,000 and 23,563,040 shares authorized as of December 31, 2022 and 2021, respectively; 22,646,015 and 18,051,592 shares issued and outstanding as of December 31, 2022 and 2021, respectively[(1)]	2	2
Additional paid-in capital	183,168	166,727
Accumulated deficit	(176,793)	(144,724)
Accumulated other comprehensive loss	-	(4)
Total stockholders' equity	6,377	22,001
Total liabilities and stockholders' equity	$ 22,855	$ 39,096

(1) The balance sheet as of December 31, 2021 presented above reflects the retrospective application of recapitalization as if the Business Combination had occurred on January 1, 2021. See Note 1, 3, and 7.

See accompanying notes to consolidated financial statements.

APEXIGEN, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	$ 23,035	$ 21,664
General and administrative	9,651	7,293
Total operating expenses	32,686	28,957
Loss from operations	(32,686)	(28,957)
Other income, net	617	41
Net loss	$ (32,069)	$ (28,916)
Net loss per share	$ (1.62)	$ (1.60)
Weighted-average common shares used to compute net loss per share, basic and diluted	19,787,212	18,034,092
Comprehensive Loss:		
Net loss	$ (32,069)	$ (28,916)
Other comprehensive loss		
Unrealized gain (loss) on marketable securities	4	(7)
Comprehensive loss	$ (32,065)	$ (28,923)

See accompanying notes to consolidated financial statements.

APEXIGEN, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share amounts)

	Year Ended December 31, 2022							
	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amounts	Shares	Amounts	Capital	Deficit	Income (Loss)	Equity (Deficit)
Balance at January 1, 2022, as previously reported	145,130,628	$ 158,707	31,070,665	$ 31	$ 7,991	$ (144,724)	$ (4)	$ (136,706)
Retroactive application of recapitalization	(145,130,628)	(158,707)	(13,019,073)	(29)	158,736	-	-	158,707
Balance at January 1, 2022, as adjusted	-	-	18,051,592	2	166,727	(144,724)	(4)	22,001
Merger and private offering, net of transaction costs of $9,232	-	-	3,143,464	-	8,468	-	-	8,468
Common stock issuance to Lincoln Park	-	-	1,266,684	-	5,410	-	-	5,410
Vesting of restricted stock units			80,668	-	326			326
Vesting of restricted stock awards	-	-	23,518	-	242	-	-	242
Exercise of stock options	-	-	75,550	-	110	-	-	110
Exercise of common stock warrant	-	-	4,539	-	-	-	-	-
Reclassification of preferred stock warrant	-	-	-	-	2	-	-	2
Stock-based compensation	-	-	-	-	1,883	-	-	1,883
Net loss	-	-	-	-	-	(32,069)	-	(32,069)
Other comprehensive loss	-	-	-	-	-	-	4	4
Balance at December 31, 2022	-	$ -	22,646,015	$ 2	$ 183,168	$ (176,793)	$ -	$ 6,377

	Year Ended December 31, 2021							
	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amounts	Shares	Amounts	Capital	Deficit	Loss	Equity (Deficit)
Balance at January 1, 2021, as previously reported	145,130,628	$ 158,707	30,521,693	$ 31	$ 6,750	$ (115,808)	$ 3	$ (109,024)
Retroactive application of recapitalization	(145,130,628)	(158,707)	(12,526,339)	(29)	158,736	-	-	158,707
Balance at January 1, 2021, as adjusted	-	-	17,995,354	2	165,486	(115,808)	3	49,683
Exercise of stock options	-	-	56,238	-	98	-	-	98
Stock-based compensation	-	-	-	-	1,143	-	-	1,143
Net loss	-	-	-	-	-	(28,916)	-	(28,916)
Other comprehensive loss	-	-	-	-	-	-	(7)	(7)
Balance at December 31, 2021	-	$ -	18,051,592	$ 2	166,727	$ (144,724)	$ (4)	$ 22,001

See accompanying notes to consolidated financial statements.

APEXIGEN, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (32,069)	$ (28,916)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	110	105
Stock-based compensation	1,883	1,143
Expense from vesting of restricted stock units	326	-
Expense from vesting of restricted stock awards	242	-
Accretion of discount and amortization of premiums on marketable securities	(31)	204
Amortization of deferred financing costs	740	-
Change in fair value of derivative warrant liabilities	(78)	-
Change in fair value of liability for common stock to be issued	(205)	-
Non-cash lease expense	401	522
Other	-	6
Changes in current assets and liabilities:		
Prepaid expenses and other current assets	(759)	(352)
Other assets	(70)	(168)
Accounts payable	317	841
Accrued expenses	(3,127)	1,521
Deferred revenue	2,049	1,723
Lease liabilities	(422)	(531)
Net cash used in operating activities	(30,693)	(23,902)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(57)	(54)
Purchases of marketable securities	(18,945)	(20,179)
Sales of marketable securities	29,957	42,257
Net cash provided by investing activities	10,955	22,024
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from merger and private offering	18,094	-
Payments of deferred transaction costs	(9,221)	(61)
Proceeds from common stock issuance to Lincoln Park	2,500	-
Payments of financing costs	(386)	-
Proceeds from exercise of stock options	110	98
Net cash provided by financing activities	11,097	37
Net decrease in cash and cash equivalents	(8,641)	(1,841)
Cash and cash equivalents, beginning of period	23,443	25,284
Cash and cash equivalents, end of period	$ 14,802	$ 23,443
Supplemental disclosure of non-cash investing and financing activities:		
Purchase of equipment included in accounts payable	$ -	$ 43
Transaction costs in accounts payable and accrued liabilities at period end	$ -	$ 364
Financing costs in accounts payable and other accrued liabilities	$ 261	$ -
Common stock issuance to Lincoln Park for commitment fees	$ 2,910	$ -
Reclassification of warrant	$ 2	$ -

See accompanying notes to consolidated financial statements.

1. Organization and Description of the Business

Description of Business

Apexigen, Inc. (“Apexigen” or "we") is a clinical-stage biopharmaceutical company focused on discovering and developing antibody therapeutics for oncology, with an emphasis on new immuno-oncology agents designed to harness the patient’s immune system to combat and eradicate cancer. Our lead product candidates are sotigalimab (“sotiga” or “APX005M”), which is a CD40 agonist antibody, and APX601, which is a TNFR2 antagonist antibody. We also have out-license arrangements for a number of programs. Since inception, we have devoted substantially all of our resources to performing research, development, and manufacturing activities in support of our product candidates. In October 2019, the first of our out-licensed product candidates was approved for commercial product sale. Apexigen is headquartered in San Carlos, California.

On March 17, 2022, Brookline Capital Acquisition Corp. (“BCAC”) and Apexigen America, Inc., which was then known as Apexigen, Inc. ("Legacy Apexigen") entered into a business combination agreement (“Business Combination Agreement”) pursuant to which BCAC and Legacy Apexigen agreed to combine, with the former equityholders of both entities holding equity in the combined public company listed on the Nasdaq Stock Exchange ("Nasdaq") and with Legacy Apexigen’s existing equityholders owning a majority of the equity in the combined public company. Existing Legacy Apexigen equityholders received equity in the combined public company in the form of common shares, stock options and warrants. Under the Business Combination Agreement, the transaction valued Legacy Apexigen at $205.0 million on a fully diluted basis, net of exercise proceeds for Legacy Apexigen’s pre-closing stock options. Concurrently with the execution of the Business Combination Agreement, BCAC entered into subscription agreements with certain investors for a private investment in public equity (“PIPE”) transaction to close concurrently with the merger (see Note 3), and BCAC and Legacy Apexigen entered into a committed investment agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park") (see Note 7) to allow the combined company to direct Lincoln Park to make certain equity purchases during the 24 months following the business combination subject to certain limitations.

The transactions contemplated under the Business Combination Agreement (the “Business Combination”) closed on July 29, 2022 ("Closing" or the "Closing Date"). As a result, the combined public company received approximately $19.0 million in gross proceeds funded by $4.5 million in cash held in BCAC’s trust account net of redemption and $14.5 million from the PIPE. The combined public company paid off the outstanding convertible and non-convertible unsecured promissory notes in the aggregate amount of $0.9 million held by Brookline Capital Holdings, LLC, the sponsor of BCAC (the “Extension and Working Capital Notes”), and incurred $9.2 million in transaction expenses relating to the merger, consisting of banking, legal, and other professional fees. The PIPE investors received an aggregate of 1,452,000 units (each a “PIPE Unit”) at a purchase price of $10.00 per unit. Each PIPE Unit consists of one share of BCAC Common Stock and one-half of one warrant. Each whole warrant entitles the PIPE Investor to purchase one share of BCAC Common Stock at an exercise price of $11.50 per share during the period commencing 30 days after July 29, 2022 and terminating on the five-year anniversary of July 29, 2022.

Legacy Apexigen was incorporated in Delaware in 2010, the year Legacy Apexigen was spun-out of Epitomics, Inc. (“Epitomics”), which was a California-based biotechnology company that was acquired by Abcam plc in 2012. Legacy Apexigen was spun-out of Epitomics to focus on the discovery, development, and commercialization of humanized monoclonal antibody therapeutics.

Liquidity and Capital Resources

As of December 31, 2022, we had approximately $16.8 million of cash, cash equivalents, and short-term investments and expect to fund our operations into the third quarter of 2023 based on current operations assuming no additional proceeds from our equity line with Lincoln Park or any other potential financing or business development transactions. We have incurred substantial losses and negative cash flows from operations since inception and had an accumulated deficit of $176.8 million as of December 31, 2022. Since inception through December 31, 2022, we have funded operations primarily through the issuance of equity, proceeds from collaborative research and development agreements, and borrowings under a debt arrangement. Due to our significant research, development, and manufacturing expenditures, we have generated operating losses in all periods presented. We expect to incur substantial additional losses in the future as we advance and expand our research and development activities and prepare to pursue the potential regulatory approval and commercialization of our product candidates. Based on our research and development activities and plans, there is uncertainty regarding our ability to maintain liquidity sufficient to operate the business effectively, which raises substantial doubt as to our ability to continue as a going concern.

We may seek additional funds through the sale and issuance of shares of our common stock in private or public offerings, other equity or debt financings, collaborations, or partnerships with third parties, or other transactions to monetize assets, including our right to receive milestone payments and royalties under our out-license arrangements. We cannot assure that we will succeed in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials or preclinical studies or research and development programs. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amount of increased capital outlays and operating expenditures associated with our current and planned research, development, and manufacturing activities.

To the extent that we raise additional capital through strategic alliances, licensing arrangements or other monetization transactions with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of the then-existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting the ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.

2. Summary of Significant Accounting Policies

Basis of Presentation

We prepare our consolidated financial statements and accompanying notes in accordance with accounting principles generally accepted in the United States of America ("GAAP").

Principles of Consolidation

The consolidated financial statements include the accounts of Apexigen and its wholly owned subsidiary. All significant inter-company transactions and balances have been eliminated in consolidation.

Emerging Growth Company

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies. Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Securities Exchange Act of 1934 (the "Exchange Act")) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our consolidated financial statements with another public company, which is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period, difficult or impossible because of the potential differences in accounting standards used.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts expensed during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to accruals for research and development costs, stock-based compensation, uncertain tax positions and fair values of common stock. We adjust such estimates and assumptions when facts and circumstances dictate. Changes in those estimates resulting from continuing changes in the economic environment will be reflected in the consolidated financial statements in future periods. As future events and their effects cannot be determined with precision, actual results could materially differ from those estimates and assumptions.

Segment Reporting

We have one operating segment, which is the business of researching, developing and commercializing antibody therapeutics for oncology. Our chief operating decision maker, Chief Executive Officer, manages our operations on an aggregated basis for the purposes of allocating resources and evaluating financial performance.

Cash and Cash Equivalents

We consider all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market funds and corporate debt securities. The carrying amount of cash equivalents approximates their fair value.

Short-Term Investments

Short-term investments consist of debt securities with original maturities of greater than three months from the date of purchase but less than one year from the balance sheet date. Such investments are considered available-for-sale and reported at fair value with unrealized gains and losses included as a component of stockholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included as other income, net in the consolidated statements of operations and comprehensive loss. Realized gains and losses and declines in fair value determined to be other-than-temporary, if any, on investments are included in other income, net. We determine the cost of securities sold using the specific identification method.

Fair Value Measurements

We apply fair value accounting to all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the consolidated financial statements on a recurring basis. The carrying amount of our financial assets and liabilities, including accounts payable and accrued expenses, approximate their fair values due to their short-term maturities.

Concentrations of Credit and Other Risks

Financial instruments that potentially subject us to a concentration of credit risk consist primarily of cash and cash equivalents and short-term investments. We hold our bank deposits at accredited financial institutions and these deposits may at times exceed insured limits. We are exposed to credit risk in the event of a default by the financial institutions holding our cash and cash equivalents to the extent of the amounts held in excess of federally insured limits. We limit our credit risk associated with cash and cash equivalents by placing them with financial institutions we believe are of high quality. We have not experienced any losses on our deposits of cash. Our investment policy limits investments to certain types of securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. As of December 31, 2022 and 2021, we had no off-balance sheet concentrations of credit risk.

We are subject to a number of risks similar to other early-stage biopharmaceutical companies, including the need to obtain adequate additional funding, possible failure of clinical trials, the need to obtain marketing approval for our product candidates, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of our products, and protection of proprietary technology. If we do not successfully develop, obtain regulatory approval for, commercialize or partner our product candidates, we will be unable to generate revenue from product sales or achieve profitability.

Property and Equipment, Net

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets. The estimated useful life of laboratory equipment, furniture and fixtures, office equipment, and software ranges from two to five years. We expense maintenance, repair and calibration costs as incurred.

Impairment of Long-Lived Assets

Our long-lived assets are comprised principally of our property and equipment and right-of-use lease assets. We periodically evaluate our long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets or group of assets may not be fully recoverable. We deem a long-lived asset impaired when the undiscounted future cash flows expected to be generated by the asset or group of assets is less than the carrying amount of the assets. If there is an impairment, we would reduce the carrying amount of the assets through an impairment charge, to their estimated fair values based on a discounted cash flow approach or, when available and appropriate, to comparable market values. We recorded no impairment of long-lived assets during the year ended December 31, 2022.

Deferred Transaction Costs

Deferred transaction costs consist of direct legal, accounting, filing and other fees and costs directly attributable to the merger (see Note 3). We capitalized deferred transaction costs prior to the close of the Business Combination and included in prepaid expenses and other current assets. We reclassified the deferred transaction costs related to the Business Combination to additional paid-in capital to offset the proceeds received upon closing of the Business Combination. There were deferred transaction costs of $0.5 million on the consolidated balance sheet as of December 31, 2021. Upon the close of the Business Combination, we reclassified transaction costs of $9.2 million to additional paid-in capital to offset the proceeds received, where we paid transaction costs of approximately $11,000 in 2021, and paid $9.2 million in 2022 (see Note 3).

Deferred Financing Costs

Deferred financing costs consist of direct costs and commitment fees directly attributable to the commencement of the equity line of credit from Lincoln Park Capital Fund, LLC upon closing of the Business Combination (see Note 7). We capitalize deferred financing costs and amortize these costs over 24 months of the equity line of credit. As of December 31, 2022, deferred financing costs totaled $2.8 million. Amortization expense for deferred financing costs was $0.7 million for the year ended December 31, 2022.

Revenue Recognition

Under Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 606, *Revenue from Contracts with Customers*, we recognize revenue when we transfer promised goods or services to customers in an amount that reflects the consolidated balance sheets to which we expect to be entitled in exchange for those goods or services. We have not commenced sales of our drug candidates and did not have a product approved for marketing as of December 31, 2022.

We may also earn contingent fees, including milestone payments based on counterparty performance and royalties on sales, from collaborations and other out-license arrangements. We will recognize milestone payments as revenue once the underlying events are probable of being met and there is not a significant risk of reversal. We will recognize sales-based royalties as revenue when the underlying sales occur. In October 2019, Novartis’ Beovu® product, which is covered by one of our license agreements, was approved for commercial product sale. Under this agreement, Novartis is obligated to pay us a very low single-digit royalty on net sales of the Beovu product. However, Novartis has disputed its obligation to pay us royalties on Beovu sales under this agreement. As a result, we have determined that any sales-based Beovu product royalty revenue that we may earn under this agreement is currently fully constrained. We have recorded the royalty proceeds as deferred revenue in the consolidated balance sheets. As of December 31, 2022 and 2021, deferred revenue totaled $5.7 million and $3.6 million, respectively.

Lease

We determine if an arrangement is a lease at inception and if so, we determine whether the lease qualifies as an operating or a finance lease. We include operating lease in operating lease right-of-use (“ROU”) assets and lease liabilities in our consolidated balance sheets. We did not have any finance leases as of December 31, 2022 or 2021. ROU assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. We recognize operating lease ROU assets and liabilities at the lease commencement date based on the present value of lease payments over the lease term. When a lease does not provide an implicit rate, we use an incremental borrowing rate based on the information available at the commencement date to determine the present value of lease payments. We use the implicit rate when readily determinable. The operating lease ROU assets also include any lease payments made and exclude lease incentives when paid by us or on our behalf. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. We recognize lease expense for lease payments on a straight-line basis over the lease term. We also made an accounting policy election to recognize lease expense for short-term leases with a term of 12 months or less on a straight-line basis over the lease term and not to recognize ROU assets or lease liabilities for such leases.

We lease our facility under a non-cancelable operating lease agreement and recognize related rent expense on a straight-line basis over the terms of the leases. As an implicit interest rate is not readily determinable in our lease, the incremental borrowing rate is based on information available on the adoption date in determining the present value of lease payments. The lease term for our operating lease includes the non-cancellable period of the lease plus any additional periods covered by its option to extend the lease that we are reasonably certain to exercise.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses are primarily for the development of sotiga, our lead product candidate, as well as APX601 and other preclinical product candidates. Research and development costs consist primarily of external costs related to clinical development, contract manufacturing, preclinical development and discovery as well as personnel costs and allocated overhead, such as rent, equipment, depreciation, and utilities. Personnel costs consist of salaries, employee benefits and stock-based compensation.

We estimate external research and development expenses based on the services performed, pursuant to contracts with commercial and academic institutions that conduct and manage research and development services on our behalf. We record the costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in accrued liabilities in the consolidated balance sheets. These costs are a component of our research and development expenses. We accrue these costs based on factors such as the number of patient visits, the number of active patients, the number of patients enrolled, estimates of the work completed and other measures in accordance with agreements established with our third-party service providers under the service agreements. As actual costs become known, we adjust our accrued liabilities. We have not experienced any significant differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed may vary from our estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in significant changes to our accruals could significantly affect our results of operations.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are capitalized and then expensed as the related goods are delivered or the services are performed. We evaluate such payments for current or long-term classification based on when they will be realized.

Common Stock Warrant

We record at fair value freestanding puttable or redeemable warrants, or warrants which are not considered to be indexed to our stock and include this amount in accrued expenses on our consolidated balance sheets as of December 31, 2021. On the closing date of the merger (see Note 3), the preferred stock warrant that was outstanding immediately before closing became a common stock warrant. We adjusted the carrying value of such warrant to its estimated fair value at the closing date of the merger based upon the value of our common stock warrant and reclassified estimated fair value at the closing date of the merger from accrued expenses to additional paid-in capital on the closing date of the merger. This common stock warrant of 4,321 shares is outstanding as of December 31, 2022.

Public Warrants

The public warrants, issued in connection with the BCAC's initial public offering prior to the merger and the PIPE transaction completed in July 2022, are classified as equity (see Note 8).

Derivative Warrant Liabilities

We account for the private placement warrants (see Note 8) issued in connection with the initial public offering as derivative warrant liabilities in accordance with FASB ASC Topic 815, "*Derivative and Hedging*". Accordingly, we recognize the private placement warrants as liabilities at fair value and adjust the instruments to fair value at each reporting period. The liabilities are subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized and included as other income, net in the consolidated statements of operations and comprehensive loss. We measured the fair value of the private placement warrants using a Black-Scholes option-pricing model. The determination of the fair value of the warrant liabilities may be subject to change as more current information becomes available and accordingly the actual results could differ significantly. As of December 31, 2022, deferred warrant liabilities were approximately $11,000. Change in fair value of derivative warrant liabilities was approximately $78,000 for the year ended December 31, 2022.

Stock-Based Compensation

We measure all equity awards granted to employees and non-employees based on the estimated grant date fair value. For awards subject to service-based vesting conditions, we recognize stock-based compensation expense on a straight-line basis over the requisite service period, which is generally the vesting term. For awards subject to performance-based vesting conditions, we recognize stock-based compensation expense using the accelerated attribution method when it is probable that the performance condition will be achieved. We recognize forfeitures as they occur.

We use the Black-Scholes option-pricing model to estimate the fair value of equity awards and recognize expense using the straight-line attribution approach. The Black-Scholes option-pricing model requires assumptions to be made related to the expected term of the awards, expected stock priced volatility, risk-free rate for a period that approximates the expected term of the awards and the expected dividend yield.

Income Taxes

We account for income taxes under the asset and liability method. Under this method, we recognize deferred tax assets and liabilities for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. We measure deferred tax assets and liabilities using enacted tax rates applied to taxable income in the years in which we expect to realize those temporary differences. We recognize the effect on deferred tax assets and liabilities of a change in tax rates as income or loss in the period that includes the enactment date. We establish a valuation allowance, when necessary, to reduce deferred tax assets to the amount we expect to realize. We recognize the financial statement effects of uncertain tax positions when it is more-likely-than-not, based on the technical merits of the position, that it will be sustained upon examination. We include interest and penalties related to unrecognized tax benefits within the provision of income tax. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Comprehensive Loss

Comprehensive loss includes net loss and certain changes in stockholders' equity that are excluded from net loss, primarily unrealized gains or losses on our marketable securities.

Net Loss per Share

We calculate basic net loss per share by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is the same as basic net loss per share for each period presented, since the effects of potentially dilutive securities are antidilutive given our net loss.

Major Vendor

We had a major vendor that accounted for approximately 39.9% and 23.2% of the research and development expenses for the years ended December 31, 2022 and 2021, respectively. The same vendor also accounted for approximately 24.8% and 28.1% of the total accounts payable and accrued liabilities as of December 31, 2022 and 2021, respectively. Moreover, there is another vendor that accounted for approximately 33.6% and 27.7% of the total accounts payable and accrued liabilities as of December 31, 2022 and 2021, respectively, but we did not incur any expenses with this vendor during the years ended December 31, 2022 and 2021.

We had an additional vendor in 2021 that accounted for approximately 12.4% of the research and development expenses for the year ended December 31, 2021. The same vendor did not account for a major portion of accounts payable and accrued liabilities as of December 31, 2021.

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued Accounting Standards Update ("ASU") No. 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), which simplifies the accounting for certain financial instruments including convertible instruments and contracts on an entity's own equity. It reduces the number of accounting models for convertible debt instruments and convertible preferred stock. In addition, it amends the guidance for the derivatives scope exception for contracts in an entity's own equity to reduce form-over-substance-based accounting conclusions. Early adoption is permitted. Apexigen adopted the new standard on January 1, 2022. The adoption of this standard did not have a significant impact to our consolidated financial statements.

In October 2020, the FASB issued ASU No. 2020-10, Codification Improvements, which improves consistency by amending the Codification to include all disclosure guidance in the appropriate disclosure sections. In addition, it clarifies application of various provisions in the Codification by amending and adding new headings, cross referencing to other guidance, and refining or correcting terminology. Early adoption is permitted. Apexigen adopted the new standard on January 1, 2022. The adoption of this standard did not have a significant impact to our consolidated financial statements.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, as clarified in subsequent amendments. The standard changes the impairment model for certain financial instruments. The new model is a forward-looking expected loss model and will apply to financial assets subject to credit losses and measured at amortized cost and certain off-balance sheet credit exposures. This includes loans, held-to-maturity debt securities, loan commitments, financial guarantees and net investments in leases, as well as trade receivables. For available-for-sale debt securities with unrealized losses, credit losses will be measured in a manner similar to the existing standard, except that the losses will be recognized as allowances rather than reductions in the amortized cost of the securities. The standard is effective for Apexigen for fiscal years and interim periods beginning January 1, 2023. Early adoption is permitted. We have not yet assessed the effect of adopting the standard on our consolidated financial statements.

3. Merger

On July 29, 2022, Legacy Apexigen and BCAC consummated the merger contemplated by the BCA, with Legacy Apexigen surviving the merger or business combination as a wholly-owned subsidiary of BCAC. As part of the consummation of the merger, BCAC changed its name to Apexigen, Inc. and Legacy Apexigen changed its name to Apexigen America, Inc.

Upon the closing of the merger, we amended and restated our certificate of incorporation to, among other things, increase the total number of authorized shares of capital stock to 1,020,000,000 shares, of which 1,000,000,000 shares were designated common stock, $0.0001 par value per share, and of which 20,000,000 shares were designated preferred stock, $0.0001 par value per share.

Immediately prior to the closing of the merger, each issued and outstanding share of Legacy Apexigen’s convertible preferred stock, was converted into shares of common stock based on a one-to-one ratio (see Note 7). The Business Combination is accounted for with a retrospective application of the Business Combination that results in 145,130,628 shares of convertible preferred stock converting into the same number of shares of Legacy Apexigen's common stock.

Upon the consummation of the merger, each share of Legacy Apexigen common stock issued and outstanding was canceled and converted into the right to receive 0.102448 shares (the “Exchange Ratio”) of our common stock (the “Per Share Merger Consideration”).

Outstanding stock options, whether vested or unvested, to purchase shares of Legacy Apexigen's common stock granted under the 2010 and 2020 Plan (“Legacy Options”) (see Note 9) converted into stock options for shares of our common stock upon the same terms and conditions that were in effect with respect to such stock options immediately prior to the merger, after giving effect to the Exchange Ratio.

Outstanding warrants to purchase shares of common stock remained outstanding after the closing of the merger. The warrants became exercisable 30 days after the completion of the merger, subject to other conditions, including with respect to the effectiveness of a registration statement covering the shares of common stock underlying such warrants, and will expire five years after the completion of the Business Combination or earlier upon redemption or liquidation (see Note 2 and Note 8).

In connection with the merger, certain stockholders exercised their right to redeem certain of their outstanding shares for cash, resulting in the redemption of 4,618,607 shares of common stock for gross redemption payments of $47.2 million. In addition, a number of investors purchased an aggregate of 1,452,000 shares of common stock (the “PIPE Shares”), for a purchase price of $10.00 per share, as applicable, for an aggregate purchase price of $14.5 million pursuant to separate subscription agreements. The PIPE transaction closed simultaneously with the consummation of the Business Combination. In connection with the merger, we incurred direct and incremental costs of approximately $9.2 million related to the equity issuance, consisting primarily of investment banking, legal, accounting, and other professional fees, which we recorded to additional paid-in capital as a reduction of proceeds.

The merger is accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, BCAC was treated as the "acquired" company for financial reporting purposes. Accordingly, for accounting purposes, the Business Combination was treated as the equivalent of Legacy Apexigen issuing stock for the net assets of BCAC, accompanied by a recapitalization. The net assets of BCAC are stated at historical cost, with no goodwill or intangible assets recorded.

Prior to the merger, Legacy Apexigen and BCAC filed separate standalone federal, state, and local income tax returns. As a result of the merger, we will file a consolidated income tax return. Although, for legal purposes, BCAC acquired Legacy Apexigen, and the merger represents a reverse acquisition for federal income tax purposes. BCAC will be the parent of the consolidated group with Legacy Apexigen as a subsidiary, but in the year of the closing of the merger, Legacy Apexigen will file a full-year tax return with BCAC joining in the return the day after the closing date of the merger.

Upon closing of the merger, we received gross proceeds of $19.0 million from the Business Combination and PIPE financing, offset by transaction costs of $9.2 million recorded in 2022 and BCAC's Extension and Working Capital Notes repayment of $0.9 million. The following table reconciles the elements of the merger to the consolidated statements of cash flows and the consolidated statement of changes in stockholders' equity (in thousands):

Cash - BCAC's trust (net of redemption)	$ 4,435
Cash - Private offering	14,520
Less: BCAC's Extension and Working Capital Notes repayment in 2022	(861)
Proceeds from merger and private offering for the year ended December 31, 2022	18,094
Less: transaction costs paid in 2022	(9,221)
Net proceeds from merger and private offering for the year ended December 31, 2022	8,873
Less: transaction costs paid in 2021	(11)
Plus: net assets of BCAC	(394)
Merger and private offering for the years ended December 31, 2022	$ 8,468

The number of shares of common stock issued immediately following the Closing Date was:

Common stock, outstanding prior to merger	5,061,592
Less: redemption of BCAC shares	(4,618,607)
Common stock of BCAC	442,985
BCAC Sponsor shares	1,190,979
BCAC Representative shares	57,500
Shares issued in private offering	1,452,000
Business combination and private offering shares	3,143,464
Legacy Apexigen shares	18,147,032
Total shares of common stock immediately after merger	21,290,496
Exercise of Legacy Apexigen common stock warrant	4,539
Shares issued to Lincoln Park (Note 7)	150,000
Total shares of common stock on July 29, 2022	21,445,035

The number of Legacy Apexigen's shares was determined as follows:

	Legacy Apexigen Shares	Legacy Apexigen Shares, effected for Exchange Ratio
Balance as of December 31, 2020	30,521,693	3,126,980
Recapitalization applied to Convertible Preferred Stock outstanding at December 31, 2020	145,130,628	14,868,374
Exercise of common stock options - 2021	548,972	56,238
Exercise of common stock options - 2022 (pre-Closing)	702,074	71,922
Exercise of common stock restricted awards - 2022 (pre-Closing)	229,556	23,518
Total Legacy Apexigen shares as of July 29, 2022	177,132,923	18,147,032

4. Fair Value Measurement

We record financial assets and liabilities at fair value. The accounting guidance for fair value provides a framework for measuring fair value, clarifies the definition of fair value and expands disclosures about fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. We categorize assets and liabilities recorded at fair value in the consolidated financial statements based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical levels are directly related to the amount of subjectivity with the inputs to the valuation of these assets or liabilities as follows:

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

Level 2 – Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of December 31, 2022, our cash equivalents consisted of money market funds with less than a three-month maturity. Our short-term investments consisted of U.S. treasury securities, which we recorded as available-for-sale securities. Money market funds and U.S. treasury securities are classified as Level 1 because they are valued using quoted market prices. As of December 31, 2021, our short-term investments consisted of government debt securities, corporate debt securities, commercial paper, and asset backed securities, which we recorded as available-for-sale securities and government debt securities are classified as Level 2 because their value is based on valuations using significant inputs derived from or corroborated by observable market data.

In certain cases where there is limited activity or less transparency around the inputs to valuation, we classify securities as Level 3. Level 3 liabilities consist of derivative warrant liabilities and preferred stock warrant liability.

The following tables set forth the financial instruments that we measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 14,671	$ -	$ -	$ 14,671
U.S. treasury securities	1,997	-	-	1,997
Total	$ 16,668	$ -	$ -	$ 16,668
Financial liability:				
Derivative warrant liabilities	$ -	$ -	$ 11	$ 11
Total	$ -	$ -	$ 11	$ 11

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 18,526	$ -	$ -	$ 18,526
Commercial paper	-	5,498	-	5,498
Corporate debt securities	-	4,512	-	4,512
Government debt securities	-	1,503	-	1,503
Asset backed securities	-	1,404	-	1,404
Total	$ 18,526	$ 12,917	$ -	$ 31,443
Financial liability:				
Preferred stock warrant liability	$ -	$ -	$ 2	$ 2
Total	$ -	$ -	$ 2	$ 2

In 2021, the financial liability measured at fair value on a recurring basis is the derivative warrant liabilities and preferred stock warrant liability, a level 3 instrument.

The derivative warrant liabilities had a fair value of $11,000 as of December 31, 2022. We estimate the fair value of the derivative warrant liabilities using a Black-Scholes option-pricing model, which assumptions are related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. We estimate the volatility of our common stock warrants based on historical volatility of select peer company's common stock that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which we anticipate remaining at zero.

The preferred stock warrant liability had a fair value of $2,000 as of December 31, 2021. We estimate the fair value of the preferred stock warrant liability using the Black-Scholes option-pricing model, which requires inputs such as the expected volatility based on comparable public companies, the estimated fair value of the preferred stock, and the estimated time to liquidity. On the Closing of the Business Combination, the preferred stock warrant that was outstanding immediately before the Closing became a common stock warrant. We adjusted the carrying value of such warrant to its estimated fair value at the Closing based upon the value of our common stock warrant and reclassified from accrued expenses to additional paid-in capital on the date of closing of the merger.

The following tables summarize the estimated fair value of our marketable securities and the gross unrealized holding gains and losses (in thousands):

	December 31, 2022			
		Unrealized		
	Amortized Cost	Gains	Losses	Estimated Fair Value
Cash and cash equivalents:				
Cash	$ 131	$ -	$ -	$ 131
Money market funds	14,671	-	-	14,671
Total cash and cash equivalents	$ 14,802	$ -	$ -	$ 14,802
Marketable securities:				
U.S. treasury securities	$ 1,997	$ -	$ -	$ 1,997
Total marketable securities	$ 1,997	$ -	$ -	$ 1,997

	December 31, 2021			
		Unrealized		
	Amortized Cost	Gains	Losses	Estimated Fair Value
Cash and cash equivalents:				
Cash	$ 4,917	$ -	$ -	$ 4,917
Money market funds	18,526	-	-	18,526
Total cash and cash equivalents	$ 23,443	$ -	$ -	$ 23,443
Marketable securities:				
Commercial paper	$ 5,498	$ -	$ -	$ 5,498
Corporate debt securities	4,515	-	(3)	4,512
Government debt securities	1,503	-	-	1,503
Asset backed securities	1,405	-	(1)	1,404
Total marketable securities	$ 12,921	$ -	$ (4)	$ 12,917

5. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31,	
	2022	2021
Prepaid clinical development expenses	$ 1,128	$ 776
Prepaid insurance expenses	970	56
Deferred financing costs	261	467
Other prepaid expenses and current assets	259	382
Total prepaid expenses and other current assets	2,618	1,681

Property and Equipment, Net

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

	December 31,	
	2022	2021
Laboratory equipment	$ 909	$ 943
Furniture and fixtures	28	28
Office equipment	25	25
Software	12	12
Total property and equipment	974	1,008
Less: accumulated depreciation	(824)	(763)
Total property and equipment, net	$ 150	$ 245

Depreciation expense for property and equipment was $110,000 and $105,000 for the years ended December 31, 2022 and 2021, respectively.

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2022	2021
Accrued clinical trial and manufacturing costs	$ 4,340	$ 6,472
Accrued personnel costs	497	1,172
Other accrued liabilities	522	844
Total accrued liabilities	$ 5,359	$ 8,488

6. Lease

We lease our principal facility under a non-cancelable operating lease agreement with a lease term ending in March 2023. As our lease does not provide an implicit rate, we used our incremental borrowing rate as the discount rate to calculate the present value of lease payments. The incremental borrowing rate represents an estimate of the interest rate that would be required to borrow on a collateralized basis over a similar term at an amount equal to the lease payments in a similar economic environment. The weighted-average discount rate associated with operating lease modifications was 5.05%. As of December 31, 2022 and 2021, the right-of-use assets were $0.1 million and $0.5 million, respectively, and lease liabilities were $0.1 million and $0.5 million, respectively. Rent expense was $0.4 million and $0.6 million for the years ended December 31, 2022 and 2021, respectively.

Future minimum lease payments as of December 31, 2022, are as follows (in thousands):

	Operating Leases
Year ending December 31,	
2023	$ 106
Total undiscounted future lease payments	106
Less: imputed interest	-
Total lease liabilities	$ 106

7. Stockholder's Equity

Preferred Stock

As discussed in Note 3, *Business Combination*, we retroactively adjusted the shares issued and outstanding prior to July 29, 2022 to give effect to the exchange ratio established in the Business Combination Agreement to determine the number of shares of common stock into which they were converted.

Prior to the Business Combination, Legacy Apexigen had shares of $0.001 par value Series A-1, Series A-2, Series B, and Series C preferred stock outstanding, all of which were convertible into shares of common stock of Legacy Apexigen on a 1:1 basis, subject to certain anti-dilution protections. Upon the Closing, the outstanding shares of preferred stock were converted into common stock of Legacy Apexigen, and then into common stock of Apexigen at a ratio of 1:0.102448, the exchange rate established in the BCA.

	July 29, 2022 (Closing Date)		
Convertible Preferred Stock	**Preferred Stock Shares**	**Exchange Ratio**	**Common Stock Shares**
Series A-1 (pre-combination)	39,196,116	0.102448	4,015,564
Series A-2 (pre-combination)	12,625,343	0.102448	1,293,442
Series B (pre-combination)	14,218,546	0.102448	1,456,662
Series C (pre-combination)	79,090,623	0.102448	8,102,706
Total	145,130,628		14,868,374

As of December 31, 2022, we are authorized to issue 20,000,000 shares of preferred stock with a par value of $0.0001 per share. The board of directors (the "Board") has the authority to issue preferred stock and to determine the rights, privileges, preferences, restrictions, and voting rights of those shares. As of December 31, 2022, we had no shares of preferred stock outstanding.

Common Stock

The holders of common stock are entitled to one vote per share on all matters to be voted on by the stockholders of Apexigen. Subject to the preferences that may be applicable to any outstanding shares of the convertible preferred stock, the holders of the common stock are entitled to receive ratably such dividends, if any, as the Board may declare. The Board has declared no dividends to date.

At December 31, 2022, we had reserved the following shares of common stock for the following purposes:

Equity awards issued and outstanding	4,839,554
Equity awards available for future grants	1,065,423
Shares available for Employee Stock Purchase Plan	257,341
Common stock warrants	3,728,821
Total common stock reserved for issuance	9,891,139

Lincoln Park

In conjunction with the Business Combination (see Note 1), we entered into a purchase agreement (the “Lincoln Park Purchase Agreement”) and a registration rights agreement (“RRA”) with Lincoln Park in March 2022, which provides that we may sell to Lincoln Park up to $50.0 million of shares (the “Purchase Shares”) of our common stock. The aggregate number of shares that we can sell to Lincoln Park under the Lincoln Park Purchase Agreement may not exceed 4.99% of the outstanding common stock, subject to certain exceptions set forth in the Lincoln Park Purchase Agreement.

On the date of Closing, we issued 150,000 shares of common stock to Lincoln Park as an initial fee for its commitment to purchase shares of our common stock under the Lincoln Park Purchase Agreement. On the date that is 90 calendar days after the date of Closing, we were obligated to issue to Lincoln Park the lesser of (i) $1.5 million of shares of common stock at a price per share equal to the arithmetic average of the closing sale price for our common stock during the ten consecutive business days immediately preceding the share delivery date and (ii) 500,000 shares of common stock. We recorded the additional commitment shares as liability for common stock to be issued in the consolidated balance sheets upon the date of Closing. Liability for common stock to be issued was $1.4 million as of date of Closing. The liability is subject to re-measurement at each balance sheet date until issued, and any change in fair value is recognized and included as other income, net in the consolidated statements of operations and comprehensive loss. The additional commitment shares of 500,000 shares were issued in October 2022 and the liability was remeasured. Change in fair value of liability for common stock to be issued was approximately $205,000 for the year ended December 31, 2022.

Subject to the terms of the Lincoln Park Purchase Agreement, we have the right, in our sole discretion, to present Lincoln Park with a purchase notice (a "Regular Purchase Notice"), provided that the closing stock price of the common stock on the Nasdaq is not below $3.00 per share. Each Regular Purchase Notice would direct Lincoln Park to purchase up to $500,000 of Purchase Shares (a "Regular Purchase"), which amounts may be increased under certain circumstances. Lincoln Park's committed obligation under any single Regular Purchase generally will not exceed $1.0 million. The Lincoln Park Purchase Agreement provides for a purchase price per Purchase Shares for each Regular Purchase (the "Purchase Price") equal to the lesser of (i) the lowest sale price of the common stock on the Nasdaq on the purchase date of such shares; and (ii) the average of the three lowest closing sale prices for the common stock traded on the Nasdaq during the ten consecutive business days ending on the business day immediately preceding the purchase date of such shares.

In addition, on any date on which we submit a Regular Purchase Notice for the maximum amount allowed for such a Regular Purchase to Lincoln Park, we also have the right, in our sole discretion, to present Lincoln Park with an accelerated purchase notice (an "Accelerated Purchase Notice"), directing Lincoln Park to purchase an amount of Purchase Shares (an "Accelerated Purchase"), which number of Purchase Shares will not exceed the lesser of (i) 300% of the number of shares purchased pursuant to such Regular Purchase Notice and (ii) 30% of the total volume of shares of the common stock traded on the Nasdaq during the Accelerated Purchase period. The purchase price per Purchase Share for each such Accelerated Purchase will be equal to the lesser of 95% of (i) the volume-weighted average price of the common stock on the Nasdaq during the applicable Accelerated Purchase period on the applicable Accelerated Purchase date; and (ii) the closing sale price of the common stock on the Nasdaq on the applicable Accelerated Purchase date. Lincoln Park has no obligation to purchase shares under the Lincoln Park Purchase Agreement unless we comply with the terms of the RRA.

In September 2022, we received aggregate proceeds of $2.5 million from Regular Purchases of 616,684 shares of common stock under the Lincoln Park Purchase Agreement.

8. Public and Private Warrants

Prior to the merger, BCAC issued 2,875,000 shares of public warrants and 123,500 shares of private warrants in connection with the BCAC's initial public offering. In connection with the PIPE transaction closed on July 29, 2022 (Note 1), we issued 726,000 shares of public warrants. As of December 31, 2022, we had 3,601,000 public warrants and 123,500 private placement warrants outstanding, each with an exercise price of $11.50 per share. Each of these warrants became exercisable on August 28, 2022, which was 30 days after the Closing of the merger (see Note 3), and will expire on the fifth anniversary of the Business Combination, or earlier upon redemption or liquidation.

We may call the public warrants for redemption:

- in whole or in part;
- at a price of $0.01 per warrant;
- upon a minimum of 30 days' prior written notice of redemption; and
- if, and only if, the last reported closing price of the ordinary shares equals or exceeds $18.00 per share for any 20 trading days within a 30-trading day period on the third trading day prior to the date on which we send the notice of redemption to the warrant holders.

If we call the public warrants for redemption, management will have the option to require all holders that wish to exercise the public warrants to do so on a "cashless basis," as described in the warrant agreement.

The private placement warrants are identical to the public warrants, except that none of the private placement warrants will be redeemable so long as they are held by the initial purchasers or any of their permitted transferees.

The exercise price and number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a share dividend, recapitalization, reorganization, merger, or consolidation. However, the warrants will not be adjusted for issuance of common stock at a price below its exercise price.

9. Equity Plans and Related Equity Activities

Equity Incentive Plans

In December 2010, we adopted the 2010 Stock Incentive Plan and 2010 Equity Incentive Plan, which expired in 2020. In August 2020, we adopted the 2020 Equity Incentive Plan. Upon the close of the merger (see Note 3), we adopted the 2022 Equity Incentive Plan (the 2022 Plan, the 2020 Equity Incentive Plan, the 2010 Stock Incentive Plan and the 2010 Equity Incentive Plan, collectively, the "Plans"). No further grants will be made under the 2020 Equity Incentive Plan. The 2022 Equity Incentive Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit, performance stock awards, and other forms of equity awards as described in the 2022 Equity Incentive Plan.

Initially, the maximum number of shares of common stock that we may issue under the 2022 Equity Incentive Plan is 2,573,405 shares plus any shares that may be added to the 2022 Plan's reserve if awards from the 2010 Equity Incentive Plan or 2020 Equity Incentive Plan expire, are canceled or otherwise terminate, up to a maximum of 3,461,319 shares added from such expirations, cancellations, and terminations. As of December 31, 2022, Apexigen had reserved 5,904,977 shares of common stock for the issuance of incentive and non-statutory stock options to purchase common stock, stock awards, and restricted stock awards to employees, directors, and consultants under the Plans. The number of shares of common stock reserved for issuance under the 2022 Equity Incentive Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2023 through January 1, 2032, in an amount equal to the lesser of (1) 5.0% of the total number of shares of common stock outstanding on the last day of the calendar month before the date of each automatic increase, (2) 3,216,756 shares, or (3) such number of shares determined by the administrator of the 2022 Plan.

The Board determines the period over which options become exercisable and options generally vest over a four-year period. No option will become exercisable after the expiration of ten years from the date of grant. The term of an incentive stock option ("ISO") granted to a 10% stockholder will not exceed five years from the date of the grant. The exercise price of an ISO and non-statutory stock option ("NSO") will not be less than 100% of the estimated fair value of the shares on the date of grant, respectively, and the exercise price of an ISO and NSO granted to a 10% stockholder will not be less than 110% of the estimated fair value of the shares on the date of grant.

In February 2021, we entered into a consulting agreement with a Board member and granted an option (the "Stock Option") to acquire 20,489 shares of common stock. The Stock Option vests upon the achievement of certain performance milestones and has a ten-year term. Based on the guidance in ASC Topic 718, *Stock Compensation*, we concluded that the Stock Option is a performance-based stock option. As determined by the Board, we achieved one of the performance milestones under the Stock Option during 2021. As a result, 5,122 options were vested during the year ended December 31, 2021, and we recognized $20,000 of stock-based compensation expense in the year ended December 31, 2021. No other performance milestone was achieved as of December 31, 2022. The unrecognized stock-based compensation expense for this option as of December 31, 2022 is approximately $60,000.

In July 2022, we granted restricted stock awards for 23,518 shares of common stock to two former Board members of Legacy Apexigen. The weighted average grant date fair value per restricted stock awards was $10.30 and the fair value of these restricted stock awards is approximately $0.2 million. The restricted stock awards are fully vested upon grant date and $0.2 million was recorded as general and administrative expense during the year ended December 31, 2022.

In September 2022, we granted options to purchase 700,000 shares of common stock to our non-executive Board members at an exercise price of $2.65 per share pursuant to our Outside Directors Compensation Policy. These options vest over 3 years in equal annual installments. The weighted average grant date fair value per options was $1.96 and the fair value of these options is approximately $1.3 million. $0.1 million was recorded as stock-based compensation expense during the year ended December 31, 2022.

In October 2022, we granted restricted stock units for 243,618 shares of common stock to various employees. The weighted average grant date fair value per restricted stock units was $2.46 and the fair value of these restricted stock units is approximately $0.6 million. We amortize the fair value of the units on a straight-line basis over its vesting periods. The restricted stock units are 50% vested in December 2022 and 50% vested in June 2023. $0.3 million was recorded as operating expense during the year ended December 31, 2022. Tax related withholdings of restricted stock units was approximately $43,000 during 2022, which equivalent to 42,415 shares of restricted stock units forfeited to cover the tax related withholdings.

Equity Stock Purchase Plan

In August 2022, we adopted the Apexigen, Inc. 2022 Employee Stock Purchase Plan (the "ESPP"). The ESPP provides eligible employees with a means of acquiring shares of our common stock at a discounted purchase price using their own accumulated payroll deductions. Under the terms of the ESPP, eligible employees can elect to have up to 15% of their eligible compensation, up to a maximum of $25,000 per year, withheld to purchase shares of common stock for a purchase price equal to 85% of the lower of the fair market value per share of common stock on (i) the commencement date of the 24-month offering period or (ii) the respective purchase date.

The ESPP authorizes the issuance of 257,341 shares of common stock under purchase rights granted to our eligible employees or to eligible employees of any of our designated affiliates. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2023 through January 1, 2032, by the lesser of (1) 1.0% of the total number of shares of common stock outstanding on the last day of the calendar month before the date of the automatic increase, and (2) 536,126 shares; provided that before the date of any such increase, our Board may determine that such increase will be less than the amount set forth in clauses (1) and (2).

The initial offering period commenced in November 2022. As of December 31, 2022, no shares of common stock were purchased under the ESPP. There was approximately $39,000 of stock-based compensation expense related to the ESPP recognized during the year ended December 31, 2022. As of December 31, 2022, there was $0.3 million of unrecognized stock-based compensation cost related to ESPP, which we expect to recognize over a weighted average period of 1.9 years. As of December 31, 2022, 257,341 shares were available under the ESPP for future issuance.

Stock-Based Compensation

Stock-based compensation is included in the consolidated statements of operations and comprehensive loss in research and development and general and administrative expense depending on the nature of the services provided. The following table illustrates stock-based compensation expense related to equity awards granted under the Plans and ESPP recognized for years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,	
	2022	2021
Research and development	$ 583	$ 292
General and administrative	1,300	851
Total stock-based compensation	$ 1,883	$ 1,143

As of December 31, 2022, there was $4.2 million of unrecognized stock-based compensation cost related to equity awards granted to employees and others under the Plans and ESPP, which we expect to recognize over a weighted average period of 2.6 years.

Summary of Assumptions for Stock Options and ESPP

In determining the fair value of the stock options granted and ESPP, we used the Black-Scholes option-pricing model and the following assumptions:

	Year Ended December 31,	
	2022	2021
Option Grants:		
Expected term (years)	5.00 - 6.06	5.62 - 10.00
Expected volatility	71% - 86%	88%
Risk-free interest rate	0.53% - 4.07%	0.60% - 1.20%
Expected dividend	0%	0%
ESPP:		
Expected term (years)	0.50 - 2.00	
Expected volatility	83% - 93%	
Risk-free interest rate	4.37% - 4.60%	
Expected dividend	0%	

The assumptions used to determine the fair value of the equity awards are as follows:

- Expected volatility: Because our stock is recently traded in an active market, we calculate volatility by using the historical volatilities of the common stock of comparable publicly traded companies. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the equity awards.
- Risk-free interest rate: we base the risk-free interest rate from the U.S. Treasury yield curve in effect at the measurement date with maturities approximately equal to the expected term.
- Expected term: we determine the expected life of awards granted using the "simplified" method. Under this approach, we presume the expected term to be the mid-point between the weighted-average vesting term and the contractual term of the option. The simplified method makes the assumption that the award recipient will exercise share options evenly over the period when the share options are vested and ending on the date when the share options would expire.
- Expected dividend yield: we have never paid cash dividends on its common stock and do not have plans to pay cash dividends in the future. Therefore, we use an expected dividend yield of zero.

Equity Plans' Activities

The following table summarizes the activities under the Plans (in thousands, except share and per share amounts):

	Awards Available to Grant	Number of Awards Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Terms (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2021	888,435	3,536,715	$ 2.71		
Shares authorized added to 2022 Plan	2,573,405				
Shares not returned to plan	(913,842)				
Options Granted	(2,097,010)	2,097,010	$ 3.18		
Options Exercised	-	(75,550)	$ 1.45		
Options Cancelled	839,156	(839,156)	$ 2.43		
Restricted stock awards granted	(23,518)	23,518	$ -		
Restricted stock awards vested	-	(23,518)	$ -		
Restricted stock units granted	(243,618)	243,618	$ -		
Restricted stock units vested	-	(80,668)	$ -		
Restricted stock units forfeited	42,415	(42,415)	$ -		
Outstanding at December 31, 2022	1,065,423	4,839,554	$ 2.91	6.66	$ 82
Vested and exercisable at December 31, 2022		2,685,009	$ 2.75	4.41	$ -
Vested and expected to vest at December 31, 2022		4,824,187	$ 2.91	6.65	$ 82

The weighted average grant date fair value of options granted during 2022 and 2021 was $2.30 and $3.39, respectively.

The following table summarizes information about our outstanding options as of December 31, 2022 by range of exercise prices and excludes the 120,535 shares of restricted stock units outstanding as of December 31, 2022:

	Awards Outstanding			Awards Exercisable		
Range of Exercise Price	Number of Awards	Weighted-Average Remaining Contractual Term (Years)	Weighted Average Exercise Price per Share	Number of Awards	Weighted-Average Remaining Contractual Term (Years)	Weighted Average Exercise Price per Share
$1.27 to $2.65	3,103,997	6.12	$ 2.08	1,692,935	3.09	$ 1.68
$3.03 to $4.79	1,384,481	7.55	$ 4.38	820,036	6.72	$ 4.13
$6.54 to $7.62	230,541	6.83	$ 6.84	172,038	6.40	$ 6.69
	4,719,019	6.58	$ 2.99	2,685,009	4.41	$ 2.75

10. Commitments and Contingencies

Indemnification

As permitted under Delaware law and in accordance with our bylaws, we have agreed to indemnify our officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at our request in such capacity. The term of the indemnification period is equal to the officer's or director's lifetime.

The maximum amount of potential future indemnification is unlimited. However, we currently hold director and officer liability insurance, which limits our exposure and may enable us to recover a portion of any future amounts paid. We believe that the fair value of these indemnification obligations is minimal. Accordingly, we have not recognized any liabilities relating to these obligations for any period presented.

We have certain agreements with service providers and other parties with which we do business that contain indemnification provisions pursuant to which we have agreed to indemnify the party against certain types of third-party claims. It is not possible to determine the maximum potential amount under these indemnification agreements due to the limited history of prior indemnification claims and the unique facts and circumstances involved in each particular agreement. Since these agreements were effective after December 31, 2022, there were no payments made by us under these agreements as of December 31, 2022. As of December 31, 2022, there was not a reasonable possibility that we had incurred a material loss with respect to indemnification of such parties. We had not recorded any liability for costs related to indemnification through December 31, 2022.

Clinical Collaborations

We have entered into a number of collaboration arrangements for the clinical development of sotigalimab with companies and academic and non-profit institutions. These arrangements specify whether we or the collaborator bears the cost of the clinical trials, and in the case of combination therapies, typically the collaborators provide the supply of such drug products while we supply sotigalimab. Our applicable share of the costs of these clinical collaborations are reflected as research and development expenses.

Upon achievement of certain regulatory and clinical milestones related to the development of sotigalimab in pancreatic cancer, we will be obligated to pay an aggregate of up to $9.5 million in cash and shares of common stock. Because we are not currently advancing the development of sotiga in pancreatic cancer, none of these milestones were probable as of December 31, 2022, and no amounts have been recognized.

Other

No liabilities for loss contingencies arising from claims, assessments, litigation, fines, and penalties and other sources are recorded as it is not probable that a liability has been incurred and the amount cannot be reasonably estimated. Legal costs incurred in connection with loss contingencies are expensed as incurred. We enter into contracts in the normal course of business with contract research organizations for preclinical studies and clinical trials and contract manufacturing organizations for the manufacture of clinical trial materials.

11. Income Taxes

We recorded no provision for income taxes for the years ended December 31, 2022 and 2021 was zero. We incurred net operating losses for all the periods presented.

The effective tax rate of the provision for income taxes differs from the federal statutory rate as follows:

	Year Ended December 31,	
	2022	2021
Federal statutory income tax rate	21.0%	21.0%
Permanent differences	0.8%	-0.3%
Other credit	2.3%	3.2%
Other	-0.7%	-0.3%
Change in valuation allowance	-23.4%	-23.6%
	0.0%	0.0%

The components of deferred tax assets and liabilities are as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carry forwards	$ 33,333	$ 27,217
Tax credits	4,702	3,964
Section 174 R&D Capitalization	4,274	-
Depreciation and amortization	90	-
Stock-based compensation	666	-
Other reserves and accruals	1,462	1,334
Gross deferred tax assets	44,527	32,515
Deferred tax liabilities:		
Depreciation and amortization	-	(24)
Right-of-use assets	(21)	(101)
Gross deferred tax liabilities	(21)	(125)
Valuation allowance	(44,506)	(32,390)
Net deferred tax assets	-	-

Realization of the deferred tax assets depends upon future taxable income. Since the amount and timing of future income are uncertain, the net deferred tax assets as of December 31, 2022 and 2021 have been fully offset by a valuation allowance. The valuation allowance increased by $12.1 million and $6.8 million during the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, we had federal net operating loss (“NOL”) carryforwards totaling $137.3 million. Of the $137.3 million, $109.0 million related to NOLs generated after December 31, 2017 and are carried forward indefinitely but are subject to an 80% of taxable income limitation, and $28.3 million will begin to expire in 2033. On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”) permits NOL carryovers and carrybacks to offset 100% of taxable income for years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019 and 2020 to be carried back to each of the five preceding taxable years. The CARES Act did not have an impact to our NOLs. As of December 31, 2022, the Company had state NOL carryforward of $64.6 million, which will begin to expire in 2035. We also have federal and state research and development tax credits of $3.7 million and $2.5 million, respectively, as of December 31, 2022. The federal research credits will begin to expire in the year 2030, and the state research credits have no expiration date. We qualified for Federal Orphan Drug credit in 2020 and started to claim the credit for tax year 2021. As of December 31, 2022, we have federal Orphan Drug credits of $0.9 million, which will begin to expire in 2041. Our NOL and credit carryforwards may be subject to annual limitations due to ownership change provisions by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of NOLs and tax credits before utilization.

We elected to recognize, if incurred, interest and penalties related to liabilities for uncertain tax positions as a part of income tax expense. We have incurred no such interest and penalties to date.

We determine our uncertain tax positions based on whether and how much of a tax benefit taken by us in its tax filings is more likely than not to be sustained upon examination by the relevant income tax authorities.

A reconciliation of the beginning and ending amounts of unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Gross unrecognized tax benefit at January 1	$ 1,598	$ 1,181
Additions for tax provision taken in the current year	405	417
Gross unrecognized tax benefit at December 31	$ 2,003	$ 1,598

We do not expect the unrecognized tax benefits to change significantly over the next 12 months. We file income tax returns in the U.S. federal jurisdiction and various states jurisdiction. We are subject to examination by the Internal Revenue Service and the state jurisdictions for all tax years.

12. Net Loss Per Share

The following outstanding potentially dilutive common stock equivalents have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	December 31,	
	2022	2021
Equity awards	4,839,554	3,536,780
Common stock warrants	3,728,821	13,361
Total anti-dilutive securities	8,568,375	3,550,141

13. 401(k) Plan

We have a 401(k) retirement plan that covers all employees. The 401(k) plan provides for voluntary contributions by employees of up to 100% of their eligible compensation, subject to the maximum allowed by law. Apexigen matches employee contributions up to a maximum of 4% of their salary. Apexigen recognized related expense of $177,000 and $139,000 for the years ended December 31, 2022 and 2021, respectively.

14. Subsequent Events

On January 23, 2023, we entered into a Securities Purchase Agreement (the “Purchase Agreement”) with certain institutional and accredited investors (the “Investors”) pursuant to which we issued and sold to the Investors in a private placement (the “Private Placement”) an aggregate of 1,995,708 shares of our common stock, par value $0.0001 per share (“Common Stock”) and accompanying warrants (the “Warrants”) to purchase an aggregate of up to 1,995,708 additional shares of common stock at a price of $1.40 per share and accompanying Warrant. The exercise price of the Warrants is $1.40 per share. The Warrants are exercisable at any time on or after the date that is six months following the date of the issuance of the Warrants and will expire five and one-half years from the date of issuance. Brookline Capital Markets, a division of Arcadia Securities, LLC, has acted as our placement agent for the Private Placement (the “Placement Agent”).

We also entered into a letter agreement (the “Engagement Agreement”) with the Placement Agent, pursuant to which the Placement Agent agreed to serve as the exclusive placement agent for us in connection with the Private Placement. We agreed to pay the Placement Agent a cash fee equal to 7% of the gross proceeds from the sale of the shares and accompanying Warrants in the Private Placement. The Placement Agent received warrants to purchase up to 99,785 shares of Common Stock (the “Placement Agent Warrants”) on substantially the same terms as the Warrants, except that the Placement Agent Warrants have an exercise price equal to 125% of the price paid by investors in the Private Placement, or $1.75 per share of Common Stock.

On January 30, 2023, we received aggregate gross proceeds of $2.8 million before deducting placement agent fees and estimated offering expenses payable by us. We expect the net proceeds from the Private Placement to be used for working capital purposes.

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

There is no information to report pursuant to Item 304(b) of Regulation S-K. The information required by Item 304(a) of Regulation S-K was previously reported under Item 4.01 of our Current Report on Form 8-K filed on November 14, 2022 and Exhibit 16.1 thereto.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period ended December 31, 2022, as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer have concluded that during the period covered by this report, our disclosure controls and procedures were effective as of December 31, 2022 to ensure that information we are required to disclose in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and (ii) is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

As discussed elsewhere in this Annual Report on Form 10-K, we completed the Business Combination on July 29, 2022. Prior to the Business Combination, our predecessor, Brookline Capital Acquisition Corp. ("BCAC"), was a special purpose acquisition company formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or other similar business combination with one or more operating businesses. Moreover, BCAC had previously identified a material weakness in its internal controls over financial reporting in connection with the reclassification of the warrants. The material weakness was remediated as of December 31, 2022. Furthermore, BCAC's previously existing internal controls are no longer applicable or comprehensive enough as of the assessment date as BCAC's liabilities and operations prior to the Business Combination were insignificant compared to those of the consolidated entity post-Business Combination. The design of our internal controls over financial reporting post-Business Combination has required and will continue to require significant time and resources from management and other personnel. As a result, management was unable, without incurring unreasonable effort or expense, to conduct an assessment of our internal control over financial reporting as of December 31, 2022. Accordingly, we are excluding management's report on internal control over financial reporting pursuant to Section 215.02 of the SEC Division of Corporation Finance's Regulation S-K Compliance & Disclosure Interpretations.

Attestation Report of the Registered Public Accounting Firm

Our independent registered public accounting firm is not required to attest to the effectiveness of our internal control over financial reporting for as long as we are an "emerging growth company" pursuant to the provisions of the JOBS Act.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the year ended December 31, 2022 covered by this Annual Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Board of Directors

The business and affairs of the Company are managed under the direction of the board of directors ("Board"). Our Board currently consists of eight directors, seven of whom are independent under the listing standards of the Nasdaq Stock Market. There are no arrangements or understandings between any of our directors and any other person pursuant to when he or she is or was selected to be a director. The following table sets forth certain information as of February 1, 2023 for each of our directors.

Name	Age	Title
Xiaodong Yang, M.D., Ph.D.	63	Chief Executive Officer and Director
Herb Cross [(1)(3)]	51	Director
Jakob Dupont, M.D.[(2)]	57	Director
Meenu Karson	50	Director and Chair of the Board
Gordon Ringold, Ph.D.[(1)(3)]	71	Director
Scott Smith [(2)(3)]	60	Director
Samuel Wertheimer, Ph.D.[(4)]	63	Director
Dan Zabrowski, Ph.D.[(1)(2)]	63	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the corporate governance and nominating committee.

(4) Director of Brookline Capital Acquisition Corp. from January 2021 to July 2022.

***Xiaodong Yang, M.D., Ph.D.**, Chief Executive Officer and Director.* Dr. Yang has served as the Company's Chief Executive Officer and as a member of the Board since July 2022. He also served as the Company's President from July 2022 to February 2023. Dr. Yang has served as Legacy Apexigen's Chief Executive Officer since July 2010 and as a member of Legacy Apexigen's board of directors since July 2010. From December 2009 to May 2010, he served as Vice President, Preclinical Development at Silence Therapeutics plc, a biotechnology company that develops RNA-based therapeutics. Dr. Yang joined Silence Therapeutics in December 2009 through its acquisition of Intradigm Corporation, a biotechnology company, where he served as Vice President, Research and Preclinical Development from September 2006 to December 2009. Prior to joining Intradigm, Dr. Yang was Senior Director of Cancer Pharmacology at Amgen from March 2006 to August 2006 and at Abgenix which was acquired by Amgen, from 1995 to 2006. He holds an M.D. from Beijing Medical University and a Ph.D. in Immunology from the University of Bern.

We believe Dr. Yang is qualified to serve on the Board based on his extensive expertise in the fields of therapeutic antibody discovery and development, oncology, and immunology, and his tenure as a chief executive officer in the biotechnology field.

Herb Cross. Mr. Cross has served as a member of the Board since July 2022. Mr. Cross has served as a member of Legacy Apexigen's board of directors since October 2019. He has served as the Chief Financial Officer of Atreca, Inc., a biotechnology company, since February 2019. From November 2017 to June 2018, Mr. Cross served as Chief Financial Officer of ARMOBiosciences, Inc., a biotechnology company. From February 2016 to November 2017, Mr. Cross served as Chief Financial Officer of Balance Therapeutics, Inc., a biotechnology company. Prior to 2016, Mr. Cross served in senior roles at a variety of life sciences companies, including as Chief Financial Officer at KaloBios Pharmaceuticals and Affymax, and as Vice President of Finance at Neoforma, PDL BioPharma and Facet Biotech. Mr. Cross received a B.S. in Business Administration from the University of California, Berkeley and is a certified public accountant.

We believe Mr. Cross is qualified to serve on the Board because of his substantial experience in executive leadership roles at various life sciences companies, and his extensive knowledge of strategic financial management and corporate operations.

Jakob Dupont, M.D. Dr. Dupont has served as a member of the Board since July 2022. Dr. Dupont has served as a member of Legacy Apexigen's board of directors since August 2020. He has served as the Global Head of Research and Development and Executive Vice President at Atara Biotherapeutics, a biotechnology company, since May 2020. From December 2018 to May 2020, he served as Chief Medical Officer and from May 2020 to July 2021 as a consultant oncologist at Gossamer Bio Inc. From January 2017 to December 2018 he served as Vice President, Global Head Breast and Gynecologic Cancer Development at Genentech, a biotechnology company. Dr. Dupont served as Chief Medical Officer and Senior Vice President at OncoMed Pharmaceuticals, a biotechnology company, from October 2011 to December 2016. Dr. Dupont holds an A.B. in Philosophy from Vassar College, an M.A. in Philosophy from New York University and an M.D. from Cornell University.

We believe Dr. Dupont is qualified to serve on the Board because of his extensive experience in the biotechnology field and his knowledge and expertise in oncology drug development.

Meenu Karson. Ms. Karson has served as Chair of the Board since July 2022. She has served as the President and Chief Executive Officer of Onsero Therapeutics since July 2021 and prior to that, as Chief Executive Officer of Proteostasis Therapeutics, Inc., a clinical stage biopharmaceutical company focused on the discovery and development of novel therapeutics to treat cystic fibrosis (CF) from May 2014 until December 2020. She led Proteostasis through a successful IPO and raised over $300 million to advance the CF pipeline from discovery to successful completion of Phase 2 studies. From 2007 to 2014, Ms. Karson was President and Chief Executive Officer at Allozyne, Inc. Prior to her time at Allozyne, Inc., she served as the Chief Business Officer at BioXell SpA, a spin-off from Roche Pharmaceuticals, where she led corporate development and financing activities. Currently, she serves on the board of Fore Bio Inc., a clinical stage precision oncology company and Vallon Pharmaceuticals. She obtained her M.B.A. from York University and her B.Sc. from the University of Toronto.

We believe Ms. Karson is qualified to serve on the Board because of her extensive experience in various leadership roles including as chief executive officer in the life sciences and biotechnology industries.

Gordon Ringold, Ph.D. Dr. Ringold has served as a member of the Board since July 2022. Dr. Ringold has served as a member of Legacy Apexigen's board of directors since June 2020. He has served as the Chief Executive Officer of Quadriga Biosciences, an oncology start-up focused on developing targeted anti-cancer drugs, since January 2015. Between 1997 and 2015, Dr. Ringold served in various capacities as co-founder and/ or Chief Executive Officer of Maxygen, SurroMed, Alexza and Alavita. From 1991 to 2000, Dr. Ringold was the Chief Executive Officer and Scientific Director of Affymax Research, acquired by Glaxo in 1995. Dr, Ringold also serves on the boards of Sagimet, Rapafusyn and Okava Pharmaceuticals. Dr. Ringold holds an A.B.in Biology from the University of California, Santa Cruz and a Ph.D. in Microbiology from the University of California, San Francisco.

We believe Dr. Ringold is qualified to serve on the Board because of his extensive operational experience in the biotechnology field including as chief executive officer of multiple companies.

Scott Smith. Mr. Smith has served as a member of the Board since July 2022. Mr. Smith has served as a member of Legacy Apexigen's board of directors since September 2019. He has served as the President of BioAtla, Inc., a biotechnology company, since September 2018. From September 2008 to April 2018 Mr. Smith was with Celgene, a biotechnology company, where he served in various executive roles, most recently as President and Chief Operating Officer. He holds a B.Sc. in Chemistry and Biology and a H.B.Sc. in Pharmacology from Western University, and an M.B.A. from Thunderbird School of Global Management.

We believe Mr. Smith is qualified to serve on the Board because of his multiple years of executive level experience in the biotechnology field including in immunology and oncology.

Samuel Wertheimer, Ph.D. Dr. Wertheimer has served as a member of the Board since July 2022. Dr. Wertheimer has been an investor in the healthcare and life sciences sectors, entrepreneur, and scientist. He joined Brookline Capital Markets in 2017 as Senior Scientific Advisor. His role is to identify opportunities, diligence, structure investments, and raise capital for banking clients. From 2012 to 2016, he served as co-founder of Poliwogg, Inc. a financial services firm bringing innovation to healthcare investing. While at Poliwogg, he helped develop the Poliwogg Medical Breakthrough Index that serves as the underlying index for the ALPS Medical Breakthrough ETF (SBIO). From 2000 to 2011, Dr. Wertheimer was a Private Equity Partner at OrbiMed Advisors, LLC, one of the world's largest healthcare-dedicated investment firms. At OrbiMed, Dr. Wertheimer was involved in raising and investing four venture capital funds with more than $1.5 billion in committed capital. He previously served on the boards of multiple public and private companies, including Biodel (Nasdaq: BIOD); a developer of drug delivery technologies, from 2006 to 2009; ChemoCentryx (CCXI), a development stage biotechnology company, from 2001 to 2011; Corus Pharma (acquired by Gilead), a development stage biotechnology company from 2001 to 2006; InteKrin Therapeutics (acquired by Coherus), a development stage biotechnology company from 2007 to 2010; NeurAxon, a development stage biotechnology company, from 2007 to 2010; and Salmedix (acquired by Cephalon), a development stage biotechnology company, from 2004 to 2005. He helped bring to market several new drugs including Treanda®, Cayston®, and Orbactiv®. Dr. Wertheimer received his Doctor of Philosophy degree from New York University, his Master of Public Health, with Honors, from Yale University and his Bachelor of Arts from the Johns Hopkins University.

We believe Dr. Wertheimer is qualified to serve on the Board due to his extensive operational, board and investment experience in the life sciences industry.

Dan Zabrowski, Ph.D. Dr. Zabrowski has served as a member of the Board since July 2022. Dr. Zabrowski has served as a member of Legacy Apexigen's board of directors since July 2016. He has served as a venture partner at Decheng Capital, a venture capital firm, since July 2016. From April 1992 to February 2016 Dr. Zabrowski was with F. Hoffmann-La Roche AG, a healthcare company, where he served in various pharma executive roles and was a member of the Roche Executive Committee. Most recently, Dr. Zabrowski was President of the Roche Sequencing Unit and Tissue Diagnostics, from September 2013 to February 2016. He holds a B.A. in Chemistry from Saint Louis University and a Ph.D. in Organic Chemistry from Indiana University, Bloomington.

We believe Dr. Zabrowski is qualified to serve on the Board due to his lengthy experience as a pharma executive and in the venture capital field.

Executive Officers

The following table sets forth certain information about our executive officers as of February 1, 2023. There are no arrangements or understandings between any of our executive officers and any other person pursuant to which he or she is or was to be selected as an officer.

Name	Age	Title
Xiaodong Yang, M.D., Ph.D.	63	Chief Executive Officer and Director
William Duke, Jr.	50	Chief Financial Officer
Frank Hsu, M.D.	62	Chief Medical Officer
Francis Sarena	52	President and Chief Operating Officer
Amy Wong	57	Senior Vice President, Finance and Operations

Xiaodong Yang, M.D., Ph.D. Please see "Board of Directors" above for biographical information about Dr. Yang.

William Duke, Jr., *Chief Financial Officer.* Mr. Duke has served as the Company's Chief Financial Officer and as the Company's Principal Financial and Accounting Officer since July 2022. Mr. Duke has served as Legacy Apexigen's Chief Financial Officer since June 2022, and previously served as Chief Financial Officer of two Nasdaq-listed biopharmaceutical companies. Mr. Duke served as Chief Financial Officer of Kaleido Biosciences from November 2019 to April 2022, and as Chief Financial Officer of Pulmatrix, Inc. from June 2015 until November 2019. Prior to Pulmatrix, Mr. Duke served as Chief Financial Officer of Valeritas, Inc., a medical technology company, from January 2014 through June 2015, and as Vice President and Corporate Controller of Valeritas from July 2011 through December 2013. Prior to joining Valeritas, Mr. Duke was Senior Director, Finance for Genzyme Corporation from January 2010 to July 2011. Mr. Duke holds a B.S. in Accounting from Stonehill College and an M.B.A. with a concentration in Finance from Bentley University and is a Certified Public Accountant.

Frank Hsu, M.D, *Chief Medical Officer.* Dr. Hsu has served as the Company's Chief Medical Officer since July 2022. Dr. Hsu has served as Legacy Apexigen's Chief Medical Officer since August 2021. From August 2019 to March 2021, Dr. Hsu served as Chief Medical Officer at Oncternal Therapeutics, a biotechnology company. From October 2013 to October 2018, Dr. Hsu served as Vice President, Head of Oncology at Immune Design, a biotechnology company, and from June 2012 to June 2013, he served as Chief Medical Officer at Zyngenia, Inc. Dr. Hsu holds a B.S. in Biology from Stanford University and an M.D. from Harvard Medical School and the Health, Science and Technology Program (MIT).

Francis Sarena, *President and Chief Operating Officer.* Mr. Sarena has served as the Company's President since February 2023 and Chief Operating Officer since July 2022. Mr. Sarena has served as Legacy Apexigen's Chief Operating Officer since January 2022. From December 2010 to May 2021, Mr. Sarena was with Five Prime Therapeutics, Inc., a biotechnology company, where he served in various executive roles, most recently as Chief Strategy Officer and Secretary. From December 2008 to July 2010, he served as Vice President, General Counsel and Secretary at Facet Biotech Corporation, a biotechnology company. Mr. Sarena holds a B.S.in Finance from San Francisco State University and a J.D. from University of California, Berkeley.

Amy Wong, *Senior Vice President, Finance and Operations.* Ms. Wong has served as the Company's Senior Vice President, Finance and Operations since July 2022. Ms. Wong has served as Legacy Apexigen's Senior Vice President, Finance and Operations since February 2019 and previously served as Legacy Apexigen's Vice President, Finance from April 2014 to February 2019. From December 2012 to February 2014, she served as Vice President, Finance, Human Resources and Operations at Tobi.com, an online retailer. She holds a B.S.in Business Administration (Accounting) from California State University, Sacramento.

Board Composition

The Board consists of eight members. Pursuant to the Company's amended and restated certificate of incorporation, the Company's directors are elected as follows:

The number of directors is fixed by the Board, subject to the terms of the Company's amended and restated certificate of incorporation and amended and restated bylaws. Each of the Company's directors will continue to serve as a director until the election and qualification of their successor, or until their earlier death, resignation or removal.

The Company's amended and restated certificate of incorporation provides that the Company's directors are divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. The Company's directors will be divided among the three classes as follows:

- the Class I directors are Samuel Wertheimer, Xiaodong Yang and Dan Zabrowski and their terms will expire at the annual meeting of stockholders to be held in 2023;

- the Class II directors are Meenu Karson, Gordon Ringold and Scott Smith and their terms will expire at the annual meeting of stockholders to be held in 2024; and
- the Class III directors are Herb Cross and Jakob Dupont and their terms will expire at the annual meeting of stockholders to be held in 2025.

At each annual meeting of stockholders, upon the expiration of the term of a class of directors, the successor to each such director in the class will be elected to serve from the time of election and qualification until the third annual meeting following their election and until their successor is duly elected and qualified, in accordance with the Company's amended and restated certificate of incorporation. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of Company's directors.

This classification of the Company's directors may have the effect of delaying or preventing changes in control of the Company.

Role of the Board in Risk Oversight

The Board has an active role, as a whole and also at the committee level, in overseeing the management of the Company's risks. The Board is responsible for general oversight of risks and regular review of information regarding the Company's risks, including credit risks, liquidity risks, and operational risks. The compensation committee is responsible for overseeing the management of risks relating to the Company's executive compensation plans and arrangements. The audit committee is responsible for overseeing the management of risks relating to accounting matters and financial reporting and potential conflicts of interest. The corporate governance and nominating committee is responsible for overseeing the management of risks associated with the independence of the Board. Although each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire Board is regularly informed through discussions from committee members about such risks.

Board Committees

The Board has an audit committee, a compensation committee, and a corporate governance and nominating committee, each of which has the composition and the responsibilities described below.

Audit Committee

The members of the Company's audit committee are Herb Cross, Gordon Ringold and Dan Zabrowski. Mr. Cross is the chairperson of the audit committee and is the audit committee financial expert, as that term is defined under the SEC rules implementing Section 407 of Sarbanes-Oxley Act, and possesses financial sophistication, as defined under the rules of Nasdaq. The Company's audit committee oversees the Company's corporate accounting and financial reporting process and assists the Board in monitoring the Company's financial systems. The Company's audit committee also:

- selects and hires the independent registered public accounting firm to audit the Company's consolidated financial statements;
- helps to ensure the independence and performance of the independent registered public accounting firm;
- approves audit and non-audit services and fees;
- reviews and discusses the Company's annual audited and quarterly consolidated financial statements, the results of the independent audit and the quarterly reviews and the reports and certifications regarding internal controls over financial reporting and disclosure controls with management and the independent registered public accounting firm;
- prepares the audit committee report that the SEC requires to be included in the Company's annual proxy statement;
- reviews reports and communications from the independent registered public accounting firm;
- reviews the adequacy and effectiveness of the Company's internal controls and disclosure controls and procedure;
- reviews the Company's policies on risk assessment and risk management;
- reviews and monitor conflicts of interest situations, and approve or prohibit any involvement in matters that may involve a conflict of interest or taking of a corporate opportunity;
- reviews related party transactions; and
- establishes and oversees procedures for the receipt, retention, and treatment of accounting related complaints and the confidential submission by the Company's employees of concerns regarding questionable accounting or auditing matters.

The Company's audit committee operates under a written charter, which satisfies the applicable rules of the SEC and the listing standards of Nasdaq.

Compensation Committee

The members of the Company's compensation committee are Dan Zabrowski, Jakob Dupont and Scott Smith. Dr. Zabrowski is the chairperson of Company's compensation committee. The Company's compensation committee oversees Company's compensation policies, plans, and benefits programs. The compensation committee also:

- oversees the Company's overall compensation philosophy and compensation policies, plans, and benefit programs;
- reviews and approves or recommends to the board of directors for approval compensation for the
- Company's executive officers and directors;
- prepares the compensation committee report that the SEC will require to be included in the Company's annual proxy statement; and
- administers Company's equity compensation plans.

The Company's compensation committee operates under a written charter, which satisfies the applicable rules of the SEC and the listing standards of Nasdaq.

Corporate Governance and Nominating Committee

The members of the Company's corporate governance and nominating committee are Gordon Ringold, Herb Cross and Scott Smith. Dr. Ringold is the chairperson of the Company's corporate governance and nominating committee. The Company's corporate governance and nominating committee oversees and assists the Company's board of directors in reviewing and recommending nominees for election as directors. Specifically, the corporate governance and nominating committee:

- identifies, evaluates, and makes recommendations to the Company's board of directors regarding nominees for election to the Company's board of directors and its committees;
- considers and makes recommendations to the Company's board of directors regarding the composition of
- Company's board of directors and its committees;
- reviews developments in corporate governance practices;
- evaluates the adequacy of the Company's corporate governance practices and reporting; and
- evaluates the performance of the Company's board of directors and of individual directors.

The Company's corporate governance and nominating committee operates under a written charter, which satisfies the applicable rules of the SEC and the listing standards of Nasdaq.

Code of Business Conduct and Ethics

We have adopted a written Code of Business Conduct and Ethics for the Company that applies to the Company's directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller or, persons performing similar functions. The Company's Code of Business Conduct and Ethics is available on the investor relations section of our website at www.apexigen.com. We intend to disclose any amendments to or waivers of our Code of Business Conduct and Ethics in a Current Report on Form 8-K on our website identified above. Information contained on our website is not incorporated by reference into this prospectus and should not be considered to be part of this Annual Report on Form 10-K.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires that our directors and executive officers, and persons who own more than 10% of our common stock, file reports of ownership and changes in ownership with the SEC. Based on our review of such filings and written representations from certain reporting persons that no Form 5 is required, we believe that during the fiscal year ended December 31, 2022, all directors, executive officers and greater than 10% stockholders complied with all Section 16(a) filing requirements applicable to them, with the exception of one Form 4 filing for Samuel Wertheimer, which was inadvertently filed late due to administrative error.

Item 11. Executive Compensation.

Our named executive officers for the year ended December 31, 2022, which consisted of our principal executive officer and our next two most highly compensated executive officers, were:

- Xiaodong Yang, M.D., Ph.D., Chief Executive Officer;
- Frank Hsu, M.D., Chief Medical Officer; and
- Francis Sarena, President and Chief Operating Officer.

Summary Compensation Table

The following table sets forth information regarding the compensation of our named executive officers for the years ended December 31, 2022 and 2021.

Named Executive Officers and Principal Position	Year	Salary ($)	Bonus ($)	Stock options ($)[1]	Stock awards ($)[2]	All Other Compensation ($)[3]	Total ($)
Xiaodong Yang, M.D., Ph.D.	2022	516,667	-	528,525	99,600	16,322	1,161,114
Chief Executive Officer	2021	419,168	108,984	125,777	-	13,177	667,106
Frank Hsu, M.D.	2022	506,667	-	818,552	61,500	14,253	1,400,972
Chief Medical Officer	2021	170,513	37,917	-	-	3,763	212,193
Francis Sarena (4)	2022	465,000	-	926,300	98,400	9,193	1,498,893
President and Chief Operating Officer							

(1) The amounts reported represent the aggregate grant-date fair value of the stock options awarded to the directors in fiscal 2022. The aggregate grant-date fair value of the stock options is calculated in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"). Such grant-date fair value does not take into account any estimated forfeitures related to service-vesting conditions. The assumptions used in determining the grant date fair value of the stock options reported are set forth in Note 9 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(2) The amounts reported represent the aggregate fair market value of RSUs granted in the year ended December 31, 2022 and calculated based on the closing stock price times the numbers of shares vested in accordance with FASB ASC Topic 718 ("ASC Topic 718"). The assumptions used in determining the grant date fair value of the stock options reported are set forth in Note 9 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(3) The amounts include matching contributions under our 401(k) plan ($12,200 for Dr. Yang, $12,200 for Dr. Hsu and $6,975 for Mr. Sarena), life insurance premiums ($1,722 for Dr. Yang, $2,053 for Dr. Hsu and $2,218 for Mr. Sarena), and medical insurance opt-out for Dr. Yang in the amount of $2,400.

(4) Mr. Sarena joined Apexigen as Chief Operating Officer in January 2022, and was appointed President and Chief Operating Officer in February 2023.

Employment Arrangements with Our Named Executive Officers

Xiaodong Yang, M.D., Ph.D.

On June 24, 2022, Apexigen entered into a confirmatory employment letter with Dr. Yang, Apexigen's Chief Executive Officer and member of Apexigen's board of directors. The confirmatory employment letter has no specific term and provides that Dr. Yang is an at-will employee. Dr. Yang's annual base salary is currently $575,000 and his annual target bonus is 50% of his annual base salary. Dr. Yang's performance and Apexigen's performance are to be primary considerations in determining any such annual bonus, which is subject to his continuous employment through the bonus payment date.

Frank Hsu, M.D.

On June 24, 2022, Apexigen entered into a confirmatory employment letter with Dr. Hsu, Apexigen's Chief Medical Officer. The confirmatory employment letter has no specific term and provides that Dr. Hsu is an at-will employee. Dr. Hsu's annual base salary is $506,667 and his annual target bonus is 40% of his annual base salary. Dr. Hsu's performance and Apexigen's performance are primary considerations in determining any such annual bonus, which is subject to his continuous employment through the bonus payment date.

Francis Sarena

On June 24, 2022, Apexigen entered into a confirmatory employment letter with Mr. Sarena, Apexigen's President and Chief Operating Officer. The confirmatory employment letter has no specific term and provides that Mr. Sarena is an at-will employee. Mr. Sarena's annual base salary is $465,000 and annual target bonus is 40% of his annual base salary. Mr. Sarena's performance and Apexigen's performance are primary considerations in determining any such annual bonus, which is subject to his continuous employment through the bonus payment date.

Executive Change in Control and Severance Plan

Prior to the closing of the Business Combination, Apexigen adopted a change in control and severance plan (the "Severance Plan"). Each of Dr. Yang, Dr. Hsu and Mr. Sarena are a participant in the Severance Plan and thereby are eligible to receive certain severance and change of control benefits as described below. The severance payments and benefits under the Severance Plan will be in lieu of any other severance payments and benefits to which a named executive officer was entitled before signing his or her participation agreement.

The Severance Plan provides that if the employment of the applicable named executive officer is terminated outside the period beginning three months prior to the date of a change in control and ending 12 months following that change in control (the "change in control period") by Apexigen without "cause" (excluding by reason of death or "disability") or by the named executive officer for "good reason" (as such terms are defined in the Severance Plan), the named executive officer will receive the following benefits if he or she timely signs and does not revoke a separation and release of claims agreement:

- continuing payments of severance pay of the named executive officer's base salary as in effect immediately prior to such termination (or if the termination is due to a resignation for good reason based on a material reduction in base salary, then such executive's base salary in effect prior to the reduction) for a specified period of 12 months, in the case of Dr. Yang, and nine months, in the case of Dr. Hsu and Mr. Sarena;
- reimbursement of premiums for coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), for the named executive officer and his or her eligible dependents, if any, for up to 12 months, in the case of Dr. Yang, and nine months, in the case of Dr. Hsu and Mr. Sarena, or a taxable lump-sum payment for the equivalent period in the event payment of the COBRA premiums would violate applicable law; and
- vesting acceleration as to any of the named executive officer's Company time-based equity awards that are outstanding and unvested as of the date of such termination that were scheduled to vest during the 12-month period following the date of such termination.

The Severance Plan also provides that if during the change in control period, the employment of the applicable named executive officer is terminated by Apexigen without "cause" (excluding by reason of death or "disability") or by the named executive officer for "good reason" (as such terms are defined in the Severance Plan), the named executive officer will receive the following benefits if he or she timely signs and does not revoke a separation and release of claims agreement:

- a lump-sum payment equal to 24 months, in the case of Dr. Yang, and 18 months, in the case of Dr. Hsu and Mr. Sarena, of the named executive officer's annual base salary as in effect immediately prior to such termination (or if the termination is due to a resignation for good reason based on a material reduction in base salary, then such executive's base salary in effect prior to the reduction);
- a lump-sum payment equal to the named executive officer's target bonus for the fiscal year in which his or her termination occurs multiplied by a fraction, the numerator of which is the number of days the named executive officer was employed during the fiscal year in which the termination occurs and the denominator is the number of days in such fiscal year;
- reimbursement of premiums for coverage under COBRA, for the named executive officer and his or her eligible dependents, if any, for up to 24 months, in the case of Dr. Yang, and 18 months, in the case of Dr. Hsu and Mr. Sarena, or a taxable lump-sum payment for the equivalent period in the event payment of the COBRA premiums would violate applicable law; and
- vesting acceleration as to 100% of the then-unvested shares subject to all outstanding Company time- based equity awards held by such named executive officer.

In addition, if any of the payments or benefits provided for under the Severance Plan or otherwise payable to the named executive officer would constitute "parachute payments" within the meaning of Section 280G of the Code and could be subject to the related excise tax, the named executive officer will receive either full payment of such payments and benefits or such lesser amount that would result in no portion of the payments and benefits being subject to the excise tax, whichever results in the greater amount of after-tax benefits to them. The Severance Plan does not require us to provide any tax gross-up payments to the executive officers.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by each of our named executive officers as of December 31, 2022.

	Option Awards					Stock Awards	
		Number of Securities Underlying Unexercised					
Named Executive Officers	Grant Date [1]	Exercisable (#)	Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have not Vested (#)
Xiaodong Yang, M.D., Ph.D.	10/29/2013	219,950 [2]	-	1.27	10/29/2023	-	-
	6/25/2015	20,489 [2]	-	1.47	6/25/2025	-	-
	10/30/2015	461,015 [2]	-	1.66	10/30/2025	-	-
	12/16/2016	35,856 [2]	-	2.25	12/16/2026	-	-
	2/17/2017	30,734 [2]	-	2.25	2/17/2027	-	-
	5/22/2018	295,978 [2]	-	3.62	5/22/2028	-	-
	2/14/2019	95,233	4,140 [3]	6.54	2/14/2029	-	-
	2/20/2020	3	12,293 [4]	7.03	2/20/2030	-	-
	2/20/2020	67,235	12,671 [5]	4.59	2/20/2030	-	-
	2/12/2021	18,413	20,004 [6]	4.59	2/12/2031	-	-
	10/7/2022	69,896	235,104 [7]	2.46	10/7/2032	-	-
	10/7/2022	-	-	-	-	20,244 [11]	13,806
Frank Hsu, M.D.	1/23/2022	74,956	149,916 [8]	4.79	1/23/2032	-	-
	10/7/2022	6,188	20,812 [9]	2.46	10/7/2032	-	-
	10/7/2022	-	-	-	-	12,500 [11]	8,525
Francis Sarena	1/23/2022	-	269,847 [10]	4.79	1/23/2032	-	-
	10/7/2022	-	-	-	-	20,000 [11]	13,640

(1) Each of the outstanding equity awards with a grant date before August 1, 2020 was granted pursuant to our 2010 or 2020 Equity Plan; subsequent equity awards were granted pursuant to our 2022 Equity Plan.

(2) The shares underlying this option are fully vested and immediately exercisable.

(3) The shares underlying this option vest, subject to Dr. Yang's continued role as a service provider to Apexigen, in 48 equal monthly installments beginning on February 14, 2019.

(4) The shares underlying this option vest, subject to Dr. Yang's continued role as a service provider to Apexigen, in 48 equal monthly installments beginning on January 1, 2020.

(5) The shares underlying this option vest, subject to Dr. Yang's continued role as a service provider to Apexigen, in 48 equal monthly installments beginning on January 1, 2020.

(6) The shares underlying this option vest, subject to Dr. Yang's continued role as a service provider to Apexigen, in 48 equal monthly installments beginning on January 1, 2021.

(7) The shares underlying this option vest, subject to Dr. Yang's continued role as a service provider to Apexigen, in 48 equal monthly installments beginning on October 7, 2022.

(8) The shares underlying this option vest, subject to Dr. Hsu's continued role as a service provider to Apexigen, on the one-year anniversary of August 30, 2021, and in 36 equal monthly installments beginning on August 30, 2022.

(9) The shares underlying this option vest, subject to Dr. Hsu's continued role as a service provider to Apexigen, in 48 equal monthly installments beginning on October 7, 2022.

(10) The shares underlying this option vest, subject to Mr. Sarena's continued role as a service provider to Apexigen, on the one-year anniversary of January 3, 2022, and in 36 equal monthly installments beginning on January 3, 2023.

(11) The shares underlying this RSU vest, subject to named executive officer's continued role as a service provider to Apexigen, on June 15, 2023.

Stock Awards Vested in 2022

The following table sets forth the number of shares of common stock acquired during 2022 by our named executive officers upon the vesting of RSUs and the value realized upon such vesting.

	Stock Awards	
Named Executive Officers	Number of Securities Acquired on Vesting (#)	Value Realized on Vesting ($)
Xiaodong Yang, M.D., Ph.D.	20,244	21,256
Frank Hsu, M.D.	12,500	13,125
Francis Sarena	20,000	21,000

Director Compensation

The following table presents the total compensation for each of our non-employee directors for their service on the Board for the fiscal year ended December 31, 2022. Directors who are also our employees receive no additional compensation for their service as directors. Dr. Yang was our only employee director during 2022. See the section titled "*Executive Compensation*" for additional information regarding Dr. Yang's compensation.

Directors	Fees earned or paid in cash ($)	Stock options ($)[1]	Stock awards ($)[2]	Total ($)
Herb Cross	53,816	182,379	-	236,195
Jakob Dupont, M.D.	47,880	182,379	-	230,259
Kenneth Fong, Ph.D.	-	18,184	121,115	139,299
Meenu Karson	29,680	182,379	-	212,059
Gordon Ringold, Ph.D.	52,332	182,379	-	234,711
William J. Rutter, Ph.D.	-	18,184	121,115	139,299
Scott Smith	49,576	182,379	-	231,955
Samuel Wertheimer, Ph.D.	16,960	182,379	-	199,339
Dan Zabrowski, Ph.D.	24,380	182,379	-	206,759

(1) The amounts reported represent the aggregate grant-date fair value of the stock options awarded to the directors in fiscal 2022. The aggregate grant-date fair value of the stock options is calculated in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"). Such grant-date fair value does not take into account any estimated forfeitures related to service-vesting conditions. The assumptions used in determining the grant date fair value of the stock options reported are set forth in Note 9 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(2) The amounts reported represent the aggregate fair market value of RSUs granted in the year ended December 31, 2022 and calculated based on the closing stock price times the numbers of shares vested in accordance with FASB ASC Topic 718 ("ASC Topic 718"). The assumptions used in determining the grant date fair value of the stock options reported are set forth in Note 9 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Outside Director Compensation Policy

The Board reviews director compensation periodically to ensure that director compensation remains competitive such that the Company is able to recruit and retain qualified directors. The Board retained Compensia, a third-party compensation consultant, to provide the Board and its compensation committee with an analysis of publicly available market data regarding practices and compensation levels at comparable companies and assistance in determining compensation to be provided to the Company's non-employee directors. Based on the discussions with and assistance from the compensation consultant, the Board adopted an Outside Director Compensation Policy that provides for certain compensation to the Company's non-employee directors.

Cash Compensation

The Outside Director Compensation Policy provides for the following cash compensation program for the Company's non-employee directors:

- $40,000 per year for service as a non-employee director;
- $30,000 per year for service as non-employee chair of the Company Board;
- $15,000 per year for service as chair of the Company's audit committee;
- $7,500 per year for service as a member of the Company's audit committee;
- $10,000 per year for service as chair of the Company's compensation committee;
- $5,000 per year for service as a member of the Company's compensation committee;

- $8,000 per year for service as chair of the Company's nominating and corporate governance committee; and
- $4,000 per year for service as a member of the Company's nominating and corporate governance committee.

Each non-employee director who serves as a committee chair of the Board will receive the cash retainer fee as the chair of the committee but not the cash retainer fee as a member of that committee, provided that the non-employee director who serves as the non-employee chair of the Board will receive the annual retainer fees for such role as well as the annual retainer fee for service as a non-employee director. These fees to the Company's non-employee directors will be paid quarterly in arrears on a prorated basis. The above-listed fees for service as non-employee chair of the Board or a chair or member of any committee are payable in addition to the non-employee director retainer. Under the Outside Director Compensation Policy, the Company also will reimburse its non-employee directors for reasonable travel expenses to attend meetings of the Board and its committees.

Equity Compensation

Initial Award. Pursuant to the Outside Director Compensation Policy, each person who first becomes a non-employee director following the effective date of such policy and each individual who served as a non-employee director on the effective date of such policy will receive, on the first trading day after the later of the 2-month anniversary of such effective date or the date that the person first becomes a non-employee director, an initial award of stock options to purchase shares of the Company's common stock (the "Initial Award"), subject to such person continuing to be a non-employee director through the date the Initial Award is granted. The Initial Award will be a number of shares equal to the lesser of (i) 100,000 shares or (ii) such number of shares that results in the Initial Award having an aggregate grant date fair value (determined in accordance with U.S. GAAP) of $300,000, with the number of shares subject to the Initial Award rounded to the nearest whole share. The Initial Award will be scheduled to vest in equal installments as to one-third of the shares subject to the Initial Award on each anniversary of the date that the person first became or becomes a non-employee director, subject to continued services to the Company through the applicable vesting dates. If the person was a member of the Board and also an employee, then becoming a non-employee director due to termination of employment will not entitle the person to an Initial Award.

Annual Award. Each non-employee director will receive, on the first trading day after each annual meeting of the Company's stockholders (an "Annual Meeting") that occurs following the effective date of the Outside Director Compensation Policy, an annual award of stock options to purchase shares of the Company's common stock (the "Annual Award"). The Annual Award will have an aggregate grant date fair value (determined in accordance with U.S. GAAP) of $150,000 (provided that if an individual began service as a non-employee director after the date of the Annual Meeting that occurred immediately prior to such Annual Meeting (or if there is no such prior Annual Meeting, then after the date of the closing of the Business Combination), then the Annual Award granted to such non-employee director will be prorated based on the number of whole months that the individual served as a non-employee director prior to the Annual Award's grant date during the 12-month period immediately preceding such Annual Meeting), with the number of shares subject to the Annual Award rounded to the nearest whole share. Each Annual Award will be scheduled to vest as to all of the shares of subject to such award on the earlier of the 1-year anniversary of the grant date or the date of the next Annual Meeting after the grant date, subject to continued services to the Company through the applicable vesting date.

Other Award Terms. Each Initial Award and Annual Award will be granted under the 2022 Plan (or its successor plan, as applicable) and form of award agreement under such plan. These awards will have a maximum term to expiration of ten years from their grant and a per share exercise price equal to 100% of the fair market value of a share of the Company's common stock on the award's grant date.

Change in Control. In the event of the Company's change in control, as defined in the 2022 Plan, each non-employee director's then outstanding equity awards covering shares of the Company's common stock will accelerate vesting in full, provided that he or she remains a non-employee director as of immediately before such change in control.

Director Compensation Limits. The Outside Director Compensation Policy provides that in any fiscal year, a non-employee director may be paid cash compensation and granted equity awards with an aggregate value of no more than $750,000 (provided that this limit will be increased to $1,000,000 in the fiscal year of the individual's initial service as a non-employee director), with the value of each equity award based on its grant date fair value determined in accordance with U.S. GAAP for purposes of this limit. Equity awards granted or other compensation provided to a non-employee director for services provided as an employee or consultant (other than a non-employee director), or provided before the date of the closing of the Business Combination, will not count toward this annual limit.

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

The following table sets forth beneficial ownership of our common stock as of February 8, 2023, by:

- each person who is known to be the beneficial owner of more than 5% of our common stock;
- each of our named executive officers and directors; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security, including options and warrants that are currently exercisable or exercisable within 60 days of February 8, 2023.

The beneficial ownership percentages in the table below are based on 24,561,055 shares of our common stock outstanding as of February 8, 2023.

This table is based upon information supplied by officers, directors and principal stockholders and Schedules 13G or 13D filed with the SEC. Unless otherwise indicated, the Company believes that all persons named in the table below have sole voting and investment power with respect to the voting securities beneficially owned by them.

	Shares Beneficially Owned	Percent of Shares Beneficially Owned
	Shares	%
Greater than 5% Shareholders:		
Entities affiliated with Decheng Capital China Life Sciences USD Fund II, L.P.[1]	1,894,551	7.7%
Entities affiliated with Brookline Capital Holdings, LLC[2]	1,314,479	5.4%
Named Executive Officers and Directors[3]		
Xiaodong Yang, M.D., Ph.D.[4]	1,876,389	7.2%
Frank Hsu, M.D.[5]	105,625	*
Francis Sarena[6]	97,409	*
Herb Cross[7]	29,824	*
Jakob Dupont, M.D.[8]	27,136	*
Meenu Karson	-	*
Gordon Ringold, Ph.D.[9]	39,854	*
Scott Smith[10]	30,534	*
Samuel Wertheimer, Ph.D.	-	*
Dan Zabrowski, Ph.D.	-	*
All current executive officers and directors as a group (12 persons)[11]	2,667,052	10.0%

* Represents beneficial ownership of less than 1%

(1) Consists of shares held of record by Decheng Capital China Life Sciences USD Fund II, L.P. (Decheng Capital). Decheng Capital Management II (Cayman),LLC (Decheng Management) serves as the general partner of Decheng Capital and possesses the power to direct the voting and disposition of the shares owned by Decheng Capital. Dr. Min Cui, the founder and managing director of Decheng Capital, is the sole director and sole voting shareholder of Decheng Management and has sole voting and dispositive power over the shares held by Decheng Capital. The address for Decheng Capital is No. 6, 1006 Huashan Road, Shanghai 200050, China.

(2) Consists of 1,190,979 shares held of record by Brookline Capital Holdings, LLC (BCH) and 123,500 shares subject to Private Placement Warrants held by BCH that are exercisable within 60 days of February 8, 2023. William Buchanan, Jr. serves as the Managing Partner of Brookline Capital Markets, which is the managing member of BCH. Consequently, such person may be deemed the beneficial owner of the shares and warrants held by BCH and have voting and dispositive control over such securities. Such person disclaims beneficial ownership of any shares or warrants other than to the extent he may have a pecuniary interest therein, directly or indirectly. The address for BCH is 280 Park Avenue, Suite 43W, New York, NY10017.

(3) The business address of each of these individuals is at c/o Apexigen, Inc., 75 Shoreway Road, Suite C, San Carlos, CA 94070.

(4) Consists of 511,147 shares of Common Stock held by Dr. Yang, 10,000 shares subject to warrants held by Dr. Yang that are exercisable within 60 days of February 8, 2023, and 1,355,242 shares subject to options held by Dr. Yang that are exercisable within 60 days of February 8, 2023.

(5) Consists of 8,177 shares of Common Stock held by Dr. Hsu and 97,448 shares subject to options held by Dr. Hsu that are exercisable within 60 days of February 8, 2023.

(6) Consists of 13,084 shares of Common Stock held by Mr. Sarena and 84,325 shares subject to options held by Mr. Sarena that are exercisable within 60 days of February 8, 2023.

(7) Consists of 29,824 shares subject to options held by Mr. Cross that are exercisable within 60 days of February 8, 2023.

(8) Consists of 27,136 shares subject to options held by Dr. Dupont that are exercisable within 60 days of February 8, 2023.

(9) Consists of 10,000 shares of Common Stock held by Dr. Ringold, 5,000 shares subject to warrants held by Dr. Ringold that are exercisable within 60 days of February 8, 2023, and 24,854 shares subject to options held by Dr. Ringold that are exercisable within 60 days of February 8, 2023.

(10) Consists of 30,534 shares subject to options held by Mr. Smith that are exercisable within 60 days of February 8, 2023.

(11) Consists of 558,640 shares of Common Stock held by our executive officers and directors, 15,000 shares subject to warrants held by our executive officers and directors that are exercisable within 60 days of February 8, 2023, and 2,093,412 shares subject to options held by executive officers and directors that are exercisable within 60 days of February 8, 2023.

Equity Compensation Plan Information

The following table summarizes our equity compensation plan information as of December 31, 2022. Information is included for equity compensation plans approved by our stockholders. All of our equity compensation plans have been approved by our stockholders.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights		Weighted-Average Exercise Price of Outstanding Options and Rights[1]		Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans ($)	
Equity compensation plans approved by security holders	4,839,554	(1)	2.91	(2)	1,322,764	(3)
Equity compensation plans not approved by security holders	-		-		-	
Total	4,839,554		2.91		1,322,764	

(1) Consists of (i) options to purchase a total of 4,719,019 shares of our common stock under the 2010 Equity Incentive Plan, 2020 Equity Incentive Plan, or 2022 Equity Incentive Plan, and (ii) 120,535 shares of our common stock that are subject to outstanding RSUs under the 2022 Equity Incentive Plan. Excludes purchase rights currently accruing under ESPP.

(2) The weighted average exercise price is calculated based solely on outstanding stock options. It does not take into account the shares of our common stock subject to outstanding RSUs, which have no exercise price.

(3) Consists of 1,065,423 shares of our common stock reserved for issuance under our 2022 Equity Incentive Plan and 257,341 shares of our common stock reserved for issuance under our ESPP.

Our 2022 Equity Incentive Plan automatically increase on January 1 of each calendar year, starting on January 1, 2023 through January 1, 2032, in an amount equal to the lesser of (1) 5.0% of the total number of shares of common stock outstanding on the last day of the calendar month before the date of each automatic increase, (2) 3,216,756 shares, or (3) such number of shares determined by the administrator of the 2022 Plan.

Our ESPP automatically increases on January 1 of each calendar year, beginning on January 1, 2023 through January 1, 2032, by the lesser of (1) 1.0% of the total number of shares of common stock outstanding on the last day of the calendar month before the date of the automatic increase, and (2) 536,126 shares; provided that before the date of any such increase, our Board may determine that such increase will be less than the amount set forth in clauses (1) and (2).

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

The following is a description of certain relationships involving Apexigen, Legacy Apexigen or BCAC, and each transaction since January 1, 2021, and each currently proposed transaction, in which:

- we have been or are to be a participant;
- the amount involved exceeded or exceeds $120,000;
- any of our directors (including director nominees), executive officers, or beneficial holders of more than 5% of any class of our voting securities, or any immediate family member of, or person sharing the household with, any of these individuals or entities, had or will have a direct or indirect material interest.

Apexigen Relationships and Related Person Transactions – Subsequent to the Business Combination

2023 PIPE – Placement Agent Warrants

In January 2023, we issued and sold stock and warrants to certain investors in a private placement pursuant to a securities purchase agreement (“2023 PIPE”). Brookline Capital Markets acted as placement agent for the 2023 PIPE. In February 2023, we issued warrants to Brookline Capital Markets as part of its consideration for serving as placement agent in the transaction. Samuel Wertheimer, one of our directors, is a managing partner and senior scientific advisor at Brookline Capital Markets, a division of Arcadia Securities, LLC, an affiliate of BCAC.

Legacy Apexigen Relationships and Related Person Transactions – Prior to the Business Combination

The following is a description of certain relationships and transactions since January 1, 2020 involving Legacy Apexigen's directors, executive officers, or beneficial holders of more than 5% of Legacy Apexigen's capital stock. Compensation arrangements and indemnification arrangements with Legacy Apexigen's directors and officers are described in "*Director Compensation*" and "*Executive Compensation*."

Series C Preferred Stock Transaction

From November 2019 through March 2020, Legacy Apexigen issued and sold an aggregate of 41,756,143 shares of Legacy Apexigen Series C preferred stock at a purchase price of $1.54974 per share for an aggregate purchase price of approximately $64.7 million.

The following table presents the number of shares and the total purchase price paid by Legacy Apexigen's directors, executive officers, or beneficial holders of more than 5% of Legacy Apexigen's capital stock in the transaction:

Name	Number of Shares	Purchase Price
Entity affiliated with Oceanpine Capital[(1)]	9,679,042	$ 14,999,999
Entity affiliated with Decheng Capital[(1)(2)]	8,065,859	12,500,000
Kenneth Fong[(1)(3)]	193,580	299,999
Total	17,938,481	$ 27,799,998

(1) Additional details regarding this stockholder and the stockholder's equity holdings are provided in "*Security Ownership of Certain Beneficial Owners and Management.*"
(2) Dan Zabrowski is a venture partner at Decheng Capital and a current member of our Board.
(3) Kenneth Fong is the former Chair of Legacy Apexigen's board of directors.

Subscription Agreements

In connection with the execution of the Business Combination Agreement, BCAC and those certain investors who participated in the private placement of 1,502,000 shares of common stock at the closing of the Business Combination (the "PIPE Investors"), entered into Subscription Agreements, pursuant to which the PIPE Investors subscribed for an aggregate of 1,502,000 PIPE Units (consisting of one share of common stock and one-half of one whole warrant) at a purchase price of $10.00 per PIPE Unit for an aggregate purchase price of $15,020,000. The PIPE Units were sold concurrently with the closing of the Business Combination and the Company received $14,520,000 of the expected $15,020,000 from PIPE Investors.

The following table presents the number of PIPE Units and the total purchase price paid by Legacy Apexigen's directors, executive officers, or beneficial holders of more than 5% of Legacy Apexigen's stock in the transaction:

Name	Number of Shares	Purchase Price
Entity affiliated with Oceanpine Capital[(1)]	50,000	$ 500,000
Entity affiliated with 3E Bioventures Capital[(1)]	100,000	1,000,000
Entity affiliated with William J. Rutter[(1)(2)]	200,000	2,000,000
Xiaodong Yang[(1)(3)]	20,000	200,000
Gordon Ringold[(1)(4)]	10,000	100,000
Total	380,000	$ 3,800,000

(1) Additional details regarding this stockholder and the stockholder's equity holdings are provided in "*Security Ownership of Certain Beneficial Owners and Management.*"
(2) William J. Rutter is a member of Legacy Apexigen's board of directors.
(3) Xiaodong Yang is our Chief Executive Officer and a current member of our Board.
(4) Gordon Ringold is a current member of our Board.

Investors' Rights Agreement

Legacy Apexigen was a party to an investors' rights agreement, as amended, with certain holders of its capital stock, including an entity affiliated with Decheng Capital, an entity affiliated with Oceanpine Capital, Xiaodong Yang, Kenneth Fong, William J. Rutter and an entity affiliated with Dr. Rutter. Dr. Dan Zabrowski is a venture partner at Decheng Capital and is a member of Legacy Apexigen's board of directors, Dr. Xiaodong Yang is the Chief Executive Officer and was a director of Legacy Apexigen, Dr. Kenneth Fong was the former Chair of Legacy Apexigen's board of directors, and Dr. William J. Rutter was a director of Legacy Apexigen. Under the investors' rights agreement, certain holders of Legacy Apexigen's capital stock had the right to demand that Legacy Apexigen file a registration statement or request that their shares of Apexigen capital stock be covered by a registration statement that Apexigen is otherwise filing. This investors' rights agreement terminated in connection with the closing of the Business Combination.

Indemnification Agreements

Legacy Apexigen entered into separate indemnification agreements with each of its directors and executive officers, in addition to the indemnification provided for in its amended and restated certificate of incorporation and amended and restated bylaws. The indemnification agreements and its amended restated certificate of incorporation and amended and restated bylaws required Legacy Apexigen to indemnify its directors, executive officers, and certain controlling persons to the fullest extent permitted by Delaware law.

BCAC Relationships and Related Person Transactions

Legacy Apexigen Stockholder Support Agreement

In connection with the Business Combination, certain Legacy Apexigen Stockholders entered into the Apexigen Stockholder Support Agreement with Legacy Apexigen and BCAC, pursuant to which such stockholders agreed to, at any stockholder meeting of Legacy Apexigen called for the purpose of approving the Business Combination, and in connection with any action by written consent of the stockholders requested by Legacy Apexigen for the purposes of approving the merger, vote in favor of or consent to the merger, the Business Combination Agreement and any transactions contemplated thereby or under any other agreements executed and delivered in connection therewith.

Registration Rights and Lock-Up Agreement

Concurrently with the execution of the Business Combination Agreement, BCAC and certain stockholders of Legacy Apexigen entered into a Registration Rights and Lock-Up Agreement. Pursuant to the Registration Rights and Lock-Up Agreement, the Company agreed to file a shelf registration statement with respect to the registrable securities thereunder within 45 days of the closing of the Business Combination, and maintain the effectiveness of such registration statement, subject to the terms of the Registration Rights and Lock-Up Agreement. The lock-up period ended in January 2023. Stockholders to the agreement also have certain demand and piggyback registration rights with respect to the shares acquired in the Business Combination.

Founder Shares

On May 27, 2020, Brookline Capital Holdings, LLC (the "Sponsor") purchased 1,437,500 shares of BCAC Common Stock (“Founder Shares”) for an aggregate purchase price of $25,000, or approximately $0.017 per share. 57,500 Founder Shares were transferred to Ladenburg Thalmann & Co. Inc., the BCAC IPO underwriter, and certain of its employees (“Representative”). As of the closing of the Business Combination, 1,380,000 Founder Shares were outstanding and held by the Sponsor and 57,500 were held by Representative. As a result of the merger, the Sponsor forfeited 436,021 Founder Shares. Prior to the initial investment in BCAC of $25,000 by the Sponsor, BCAC had no assets, tangible or intangible. The per share price of the Founder Shares was determined by dividing the amount of cash contributed to BCAC by the number of Founder Shares issued. The number of Founder Shares issued was determined based on the expectation that the Founder Shares would, in the aggregate, represent 20% of the outstanding shares of common stock upon completion of the BCAC IPO.

BCAC IPO Placement Units

Simultaneously with the consummation of the BCAC IPO, BCAC consummated a private placement of an aggregate of 247,000 placement units to the Sponsor at a price of $10.00 per placement unit, generating total proceeds of $2,470,000. Of the gross proceeds received from the BCAC IPO and the placement units, $58,075,000 was placed into the trust account established by BCAC for the benefit of its stockholders at J.P. Morgan Chase Bank, N.A (“Trust Account”).

Trust Extension Payments

The BCAC IPO prospectus and Existing Charter provided that BCAC initially had until May 2, 2022 (the date which was 15 months after the consummation of the BCAC IPO) to complete a Business Combination. On April 26, 2022, BCAC’s stockholders approved the Extension Amendment.

In connection with the Extension Amendment, the Sponsor, or its designees, agreed to loan $0.033 for each Public Share that BCAC Public Stockholders did not elect to redeem in April 2022 (“Additional Contributions”) to BCAC by way of the Extension Note, commencing on May 2, 2022, and on the 2nd day of each subsequent month, or portion thereof, that was needed by BCAC to complete the Business Combination from May 2, 2022 until October 2, 2022. The amount of the Additional Contributions did not bear interest and became repayable by the Company to the Sponsor or its designees upon the closing of the Business Combination.

On May 2, 2022, BCAC issued the Extension Note in the principal amount of $0.1 million to the Sponsor. The Extension Note was subsequently amended and restated to reflect identical additional principal amounts on each of June 2, 2022 and June 29, 2022 (for an aggregate principal amount of $0.5 million). The Sponsor deposited such funds into the Trust Account. Also on May 2, 2022, BCAC issued the Working Capital Note in the aggregate principal amount of $0.4 million to the Sponsor. The Working Capital Note was issued to provide BCAC with additional working capital during the extended period during which BCAC had to complete its initial business combination, and was not deposited into the Trust Account. BCAC issued the Working Capital Note in consideration for a loan from the Sponsor to fund BCAC’s working capital requirements. The Working Capital

Note became convertible at the Sponsor's election upon the closing of the Business Combination. Upon such election, the Working Capital Note converted, at a price of $10.00 per unit, into units identical to the private placement units issued in connection with the BCAC IPO. The Extension and Working Capital Notes totaled $0.9 million and were repaid upon the closing of the Business Combination.

Procedures with Respect to Review and Approval of Related Person Transactions

The Board recognizes the fact that transactions with related persons present a heightened risk of conflicts of interests (or the perception thereof). Our audit committee has the primary responsibility for reviewing and approving or disapproving "related party transactions," which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed $120,000 and in which a related person has or will have a direct or indirect material interest. Our audit committee charter provides that the audit committee will review and approve in advance any related party transaction.

The Board has adopted a formal written policy regarding related person transactions, which provides that we are not permitted to enter into any transaction that exceeds $120,000 and in which any related person has a direct or indirect material interest without the consent of the audit committee. In approving or rejecting any such transaction, the audit committee is to consider the relevant facts and circumstances available and deemed relevant to the audit committee, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

Director Independence

The Board has determined that Herb Cross, Jakob Dupont, Meenu Karson, Gordon Ringold, Scott Smith, Samuel Wertheimer and Dan Zabrowski, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the Nasdaq rules.

In making these determinations, the Board considered the current and prior relationships that each non-employee director has with the Company and all other facts and circumstances that the Board deems relevant in determining their independence, including the beneficial ownership of the Company's capital stock by each non-employee director, and the transactions involving them described in this section above entitled "*Certain Relationships and Related Party Transactions*." There are no family relationships among any of the directors or executive officers of Company.

Item 14. Principal Accounting Fees and Services.

Professional Fees Rendered from the Independent Registered Public Accounting Firms

The following table presents fees for professional audit services and other services rendered to our Company by independent registered public accounting firms for the years ended December 31, 2022 and 2021.

	For the Years Ended	
Plan Category	**2022**	**2021**
Audit Fees[1]	$ 758,586	$ 312,618
Audit-Related Fees[2]	-	-
Tax Fees[3]	-	19,682
Total Fees	$ 758,586	$ 332,300

(1) "Audit Fees" consist of fees billed for professional services rendered in connection with the audit of our consolidated financial statements and review of our quarterly consolidated financial statements for those fiscal years. This category also includes $385,426 in fees for services incurred in connection with the transactions contemplated under the Business Combination Agreement closed on July 29, 2022.

(2) "Audit-Related Fees" consist of fees billed related to the business combination transaction.

(3) "Tax Fees" consist of fees for professional services for tax compliance, tax advice and tax planning.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

- Financial Statements

Our consolidated financial statements are listed in the Index to the Consolidated Financial Statements in Part II, Item 8.

- Financial Statement Schedules

All schedules have been omitted because they not required, not applicable or the required information is included in the consolidated financial statements or the notes thereto.

- Exhibits

The documents listed in the Exhibit Index below are incorporated by reference or are filed with this report, in each case as indicated herein (numbered in accordance with Item 601 of Regulation S-K).

Exhibit Index

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit No.	Filing Date
2.1†	Business Combination Agreement, dated as of March 17, 2022.	S-1/A	333-266846	2.1	September 1, 2022
2.2	Amendment No. 1 to Business Combination Agreement dated as of June 26, 2022 among Brookline Capital Acquisition Corp., a Delaware corporation, Project Barolo Merger Sub, Inc., a Delaware corporation, and Apexigen, Inc., a Delaware Corporation.	8-K	001-39488	2.1	June 27, 2022
3.1	Amended and Restated Certificate of Incorporation of the Company.	8-K	001-39488	3.1	August 4, 2022
3.2	Amended and Restated Bylaws of the Company.	8-K	001-39488	3.2	August 4, 2022
4.1	Specimen Common Stock Certificate.	S-1/A	333-246287	4.2	August 24, 2020
4.2	Specimen Warrant Certificate.	S-1/A	333-246287	4.3	August 24, 2020
4.3	Form of Common Stock Purchase Warrant.	8-K	001-39488	4.1	January 25, 2023
4.4	Form of Placement Agent Warrant.	8-K	001-39488	4.2	January 25, 2023
4.5	Amended and Restated Warrant Agreement, dated July 29, 2022, by and between BCAC and Continental Stock Transfer & Trust Company, LLC.	8-K	001-39488	4.3	August 4, 2022
4.6*	Description of Securities.				
10.1+	Apexigen, Inc. 2022 Equity Incentive Plan and forms of agreement thereunder.	8-K	001-39488	10.5	August 4, 2022
10.2+	Apexigen, Inc. 2022 Employee Stock Purchase Plan and forms of agreement thereunder.	8-K	001-39488	10.6	August 4, 2022
10.3	Purchase Agreement, dated as of March 17, 2022, by and among Brookline Capital Acquisition Corp., Apexigen, Inc., and Lincoln Park Capital Fund, LLC.	8-K	001-39488	10.5	March 18, 2022
10.4+	Apexigen, Inc. 2010 Equity Plan, as amended, and forms of agreement thereunder.	S-8	333-267765	4.2	October 7, 2022
10.5+	Apexigen, Inc. 2020 Equity Incentive Plan, as amended, and forms of agreement thereunder.	S-8	333-267765	4.3	October 7, 2022
10.6+	Confirmatory Employment Letter between Apexigen, Inc. and Xiaodong Yang.	S-4/A	333-264222	10.10	June 27, 2022
10.7+	Confirmatory Employment Letter between Apexigen, Inc. and Amy Wong.	S-4/A	333-264222	10.11	June 27, 2022
10.8+	Confirmatory Employment Letter between Apexigen, Inc. and Frank Hsu.	S-4/A	333-264222	10.12	June 27, 2022

10.9+	Confirmatory Employment Letter between Apexigen, Inc. and Francis Sarena.	S-4/A	333-264222	10.13	June 27, 2022
10.10+	Confirmatory Employment Letter between Apexigen, Inc. and William Duke Jr.	S-4/A	333-264222	10.14	June 27, 2022
10.11+	Change in Control and Severance Plan.	S-4/A	333-264222	10.15	June 27, 2022
10.12+	Form of Apexigen, Inc. Indemnification Agreement.	S-4/A	333-264222	10.9	June 14, 2022
10.13	Form of Securities Purchase Agreement.	8-K	001-39488	10.1	January 25, 2023
10.14	Form of Registration Rights Agreement.	8-K	001-39488	10.2	January 25, 2023
10.15	Stockholder Support Agreement, dated as of March 17, 2022, by and among Brookline Capital Acquisition Corp., Project Barolo Merger Sub, Inc. and the other parties thereto.	8-K	001-39488	10.1	March 18, 2022
10.16	Registration Rights and Lock-Up Agreement, dated as of March 17, 2022, by and among Brookline Capital Acquisition Corp. and certain stockholders of Apexigen, Inc. named therein.	8-K	001-39488	10.2	March 18, 2022
10.17	Sponsor Support Agreement, dated as of March 17, 2022, by and among Brookline Capital Acquisition Corp., Apexigen, Inc. and Brookline Capital Holdings, LLC.	8-K	001-39488	10.3	March 18, 2022
10.18	Form of PIPE Subscription Agreement.	8-K	001-39488	10.4	March 18, 2022
10.19	Registration Rights Agreement, dated as of March 17, 2022, by and among Brookline Capital Acquisition Corp., Apexigen, Inc. and Lincoln Park Capital Fund, LLC.	8-K	001-39488	10.6	March 18, 2022
16.1	Letter of Marcum LLP as to the change in certifying accountant, dated as of November 14, 2022.	8-K	001-39488	16.1	November 14, 2022
21.1*	List of Subsidiary.				
23.1*	Consent of Moss Adams.				
24.1*	Power of Attorney (included on the signature page to this Annual Report on Form 10-K).				
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1#*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2#*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				

101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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* Filed herewith.

† Certain portions of this exhibit (indicated by "[***]") have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is not material and is the type of information that the registrant treats as private or confidential.

+ Indicates management contract or compensatory plan.

The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Apexigen, Inc.

Date: February 22, 2023

By: /s/ Xiaodong Yang
Xiaodong Yang, M.D., Ph.D.
Chief Executive Officer

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Xiaodong Yang and William Duke, as his or her true and lawful attorney-in-fact, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments (including post-effective 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, 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 to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact, or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Xiaodong Yang Xiaodong Yang, M.D., Ph.D.	Chief Executive Officer and Director (Principal Executive Officer)	February 22, 2023
/s/ William Duke, Jr. William Duke, Jr.	Chief Financial Officer (Principal Financial and Accounting Officer)	February 22, 2023
/s/ Meenu Karson Meenu Karson	Director, Chair of the Board	February 22, 2023
/s/ Herb Cross Herb Cross	Director	February 22, 2023
/s/ Jakob Dupont Jakob Dupont, M.D.	Director	February 22, 2023
/s/ Gordon Ringold Gordon Ringold, Ph.D.	Director	February 22, 2023
/s/ Scott Smith Scott Smith	Director	February 22, 2023
/s/ Sam Wertheimer Sam Wertheimer, Ph.D.	Director	February 22, 2023
/s/ Dan Zabrowski Dan Zabrowski, Ph.D.	Director	February 22, 2023

EXHIBIT 4.6

DESCRIPTION OF SECURITIES

The following description of the capital stock of Apexigen, Inc. ("us," "our," "we" or the "Company") is a summary of the rights of our securities and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws as currently in effect. Because the following description is only a summary, it does not contain all the information that may be important to you. For a complete description of the matters set forth herein, you should refer to our amended and restated certificate of incorporation and bylaws, the other agreements described below, including the warrant and registration rights agreements, copies of which have been filed as exhibits to the Annual Report on Form 10-K of which this Exhibit is a part, and to the applicable provisions of the Delaware General Corporation Law (the "DGCL").

General

The Company's authorized capital stock consists of 1,020,000,000 shares, $0.0001 par value per share, of which:

- 1,000,000,000 shares are designated as common stock ("Common Stock"); and
- 20,000,000 shares are designated as preferred stock.

Common Stock

The holders of our Common Stock will be entitled to one vote for each share held of record on all matters submitted to a vote of stockholders. The holders of Common Stock will not have cumulative voting rights in the election of directors.

Preferred Stock

The Company has authorized 20,000,000 shares of preferred stock. There is no preferred stock outstanding. Our board of directors (the "Board") may designate the rights, preferences, privileges, limitations and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of the outstanding voting stock. Additionally, the issuance of preferred stock may adversely affect the holders of Common Stock by restricting dividends on the Common Stock, diluting the voting power or subordinating the liquidation rights of the Common Stock. As a result of these or other factors, the issuance of preferred stock could have an adverse impact on the trading price of our Common Stock.

Dividends

We have not paid any cash dividends to stockholders. The declaration of any future cash dividend will be at the discretion of our Board and will depend upon our earnings, if any, our capital requirements and financial position, our general economic conditions, and other pertinent conditions. It is our present intention to retain all available funds and any future earnings to fund the development and growth of the business, and therefore we do not anticipate declaring or paying any cash dividends in the foreseeable future.

Warrants

Public Warrants

Each whole warrant entitles the registered holder to purchase one share of our Common Stock at a price of
$11.50 per share, subject to adjustment. Pursuant to the terms of the Amended and Restated Warrant Agreement, dated as of July 29, 2022, by and between us and our transfer agent, Continental Stock Transfer & Trust Company (the "Warrant Agreement"), a warrantholder may exercise its warrants only for a whole number of shares of Common Stock. This means that only a whole warrant may be exercised at any given time by a warrantholder. The warrants will expire five years after the date of the Warrant Agreement, or earlier upon redemption or liquidation.

We will not be obligated to deliver any shares of Common Stock pursuant to the exercise of a warrant and will have no obligation to settle such warrant exercise unless a registration statement under the Securities Act of 1933, as amended (the "Securities Act") with respect to the shares of Common Stock underlying the warrants is then effective and a prospectus relating thereto is current, subject to our satisfying our obligations described below with respect to registration. No warrant will be exercisable and we will not be obligated to issue shares of Common Stock upon exercise of a warrant unless Common Stock issuable upon such warrant exercise has been registered, qualified or deemed to be exempt under the securities laws of the state of residence of the registered holder of the warrants. In the event that the conditions in the two immediately preceding sentences are not satisfied with respect to a warrant, the holder of such warrant will not be entitled to exercise such warrant and such warrant may have no value and expire worthless. In no event will we be required to net cash settle any of the public warrants (the "Public Warrants") issued in connection with initial public offering of our predecessor company, Brookline Capital Acquisition Corp. ("BCAC"), or the warrants purchased by certain investors pursuant to subscription agreements entered into with BCAC as part of the business combination (the "2022 PIPE Warrants").

Once the warrants become exercisable, we may call the warrants for redemption:

- in whole and not in part;
- at a price of $0.01 per warrant;
- upon no less than 30 days' prior written notice of redemption given after the warrants become exercisable (the "30-day redemption period") to each warrantholder; and
- if, and only if, the reported last sale price of the Common Stock equals or exceeds $18.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within a 30-trading day period commencing once the warrants become exercisable and ending three business days before we send the notice of redemption to the warrantholders.

Private Placement Warrants

Except as described below, the warrants issued in the private placement consummated in connection with BCAC's initial public offering (the "Private Placement Warrants") have terms and provisions that are identical to those of the Public Warrants, including as to exercise price, exercisability and exercise period. They are exercisable on a cashless basis and are not redeemable by us so long as they are held by BCH. If the Private Placement Warrants are held by holders other than BCH, the Private Placement Warrants will be redeemable by us and exercisable by the holders on the same basis as the Public Warrants.

2022 PIPE Warrants

The 2022 PIPE Warrants have terms and provisions that are identical to those of the Public Warrants.

2023 PIPE Warrants

Each whole warrant entitles the registered holder to purchase one share of our Common Stock at a price of $1.40 per share, subject to adjustment as discussed below, at any time commencing six months after the date of the warrants purchased pursuant to that certain Securities Purchase Agreement, dated January 23, 2023, by and between the Company and certain investors party thereto (the "Purchase Agreement," such transaction, the "2023 PIPE," and such warrants, the "2023 PIPE Warrants"). The 2023 PIPE Warrants will expire five years and six months after the date of the Securities Purchase Agreement, or earlier upon liquidation.

We will not be obligated to deliver any shares of Common Stock pursuant to the exercise of a warrant and will have no obligation to settle such warrant exercise if, to the extent that after giving effect to such exercise, such person (together with such person's affiliates), to the warrant agent's actual knowledge, would beneficially own in excess of 4.99% or 9.99% (or such other amount as a holder may specify) of the shares of Common Stock outstanding immediately after giving effect to such exercise.

If we, at any time while the 2023 PIPE Warrants are outstanding: (i) pay a stock dividend or otherwise makes a distribution or distributions on shares of our Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock, (ii) subdivide outstanding shares of Common Stock into a larger number of shares, (iii) combine (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issue by reclassification of shares of the Common Stock any shares of our capital stock, then in each case the exercise price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of the 2023 PIPE Warrants shall be proportionately adjusted such that the aggregate exercise price of the 2023 PIPE Warrants shall remain unchanged.

In addition, if we, at any time, grant, issue or sell any Common Stock equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the holders of 2023 PIPE Warrants will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate executed as indicated, accompanied by full payment of the exercise price (or on a cashless basis, if applicable), by certified or official bank check payable to us, for the number of warrants being exercised. The warrantholders do not have the rights or privileges of holders of Common Stock until they exercise their warrants and receive shares of Common Stock. After the issuance of shares of Common Stock upon exercise of the warrants, each holder will be entitled to one (1) vote for each share held of record on all matters to be voted on by stockholders. No fractional shares will be issued upon exercise of the warrants.

We have agreed that, subject to applicable law, any action, proceeding or claim against us arising out of or relating in any way to the Warrant Agreement will be brought and enforced in the state and federal courts of the City of New York, and we irrevocably submit to such jurisdiction, which jurisdiction will be the exclusive forum for any such action, proceeding or claim. This provision applies to claims under the Securities Act but does not apply to claims under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or any claim for which the federal district courts of the United States of America are the sole and exclusive forum.

Placement Agent Warrants

The warrants issued to certain affiliates of Brookline Capital Markets, a division of Arcadia Securities, LLC in connection with the 2023 PIPE (the "Placement Agent Warrants") entitle the registered holder to purchase one share of our Common Stock at a price of $1.75 per share, subject to adjustment. Other than the exercise price, the terms and provisions of the Placement Agent Warrants are identical to the 2023 PIPE Warrants.

Anti-Takeover Provisions

Our amended and restated certificate of incorporation and bylaws contain provisions that may delay, defer or discourage another party from acquiring control of us. We expect that these provisions, which are summarized below, will discourage coercive takeover practices or inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our Board, which we believe may result in an improvement of the terms of any such acquisition in favor of the stockholders. However, they also give the Board the power to discourage acquisitions that some stockholders may favor.

Authorized but Unissued Shares

The authorized but unissued shares of Common Stock and preferred stock are available for future issuance without stockholder approval, subject to any limitations imposed by the listing standards of Nasdaq Stock Market, LLC ("Nasdaq"). These additional shares may be used for a variety of corporate purposes, including corporate finance transactions, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved Company Common Stock and preferred stock could make more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Classified Board of Directors

Our amended and restated certificate of incorporation provides that our Board will be divided into three classes of directors, with the classes to be as nearly equal in number as possible, and with each director serving a three- year

term. As a result, approximately one-third of the Board will be elected each year. The classification of directors will have the effect of making it more difficult for stockholders to change the composition of our Board.

Stockholder Action; Stockholders' Meetings

Our amended and restated certificate of incorporation provides that stockholders may not take action by written consent but may only take action at annual or special meetings of stockholders. As a result, a holder controlling a majority of capital stock would not be able to amend the Company's bylaws or remove directors without holding a meeting of stockholders called in accordance with the Company's bylaws. Further, our amended and restated certificate of incorporation provides that only the chairperson of the Board, the Chief Executive Officer of the Company or a majority of the Board, by resolution, may call special meetings of the Company stockholders, thus prohibiting a Company stockholder from calling a special meeting of the Company stockholders. These provisions might delay the ability of the Company's stockholders to force consideration of a proposal or for the Company's stockholders controlling a majority of the Company's capital stock to take any action, including the removal of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

In addition, the Company's amended and restated bylaws include an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders. Generally, in order for any matter to be "properly brought" before an annual meeting, the matter must be (i) specified in a notice of meeting given by or at the direction of the Board, (ii) if not specified in a notice of meeting, otherwise brought before the meeting by or at the direction of the Company Board, or (iii) otherwise properly brought before the meeting by a stockholder present in person who (A) was a stockholder both at the time of giving the notice and at the time of the meeting, (B) is entitled to vote at the meeting, and (C) has complied with the advance notice procedures specified in the Company's amended and restated bylaws or properly made such proposal in accordance with Rule 14a-8 under the Exchange Act and the rules and regulations thereunder, which proposal has been included in the proxy statement for the annual meeting. Further, for business to be properly brought before an annual meeting by a stockholder, the stockholder must (i) provide Timely Notice (as defined herein) thereof in writing and in proper form to the secretary of the Company and (ii) provide any updates or supplements to such notice at the times and in the forms required by the Company's amended and restated bylaws. To be timely, a stockholder's notice must be received at, the Company's principal executive offices not less than 90 days nor more than 120 days prior to the one-year anniversary of the preceding year's annual meeting; *provided*, *however*, that if the date of the annual meeting is more than 30 days before or more than 30 days after such anniversary date, notice by the stockholder to be timely must be received, not later than the 90th day prior to such annual meeting or, if later, the 10th day following the day on which public disclosure of the date of such annual meeting was first made (such notice within such time periods, "Timely Notice").

Stockholders at an annual meeting or special meeting of the Company's stockholders may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the Board or by a qualified stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has delivered written Timely Notice in proper form to the Company's secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying stockholder actions that are favored by the holders of a majority of the outstanding voting securities until the next stockholder meeting.

Amendment of Charter or Bylaws

The Company's amended and restated bylaws may be amended or repealed by a majority vote of the Board or by the holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all of the then- outstanding shares entitled to vote generally in the election of directors, voting as a single class. The Company's amended and restated certificate of incorporation can be amended in accordance with the DGCL which requires approval by the Board and stockholders.

Limitations on Liability and Indemnification of Officers and Directors

The Company's amended and restated certificate of incorporation and amended and restated bylaws provide indemnification and advancement of expenses for the directors and officers to the fullest extent permitted by the DGCL, subject to certain limited exceptions. We have entered into, or will enter into, indemnification agreements with each of our directors and officers. Under the terms of such indemnification agreements, we are required to indemnify each of the directors and officers, if the basis of the indemnitee's involvement was by reason of the fact that the indemnitee is or was a director of officer of the Company or any of its subsidiaries or was serving at the request of the Company in an official capacity of another entity. In some cases, the provisions of those indemnification agreements may be broader than the specific indemnification provisions contained under Delaware law. In addition, as permitted by Delaware law, the Company's amended and restated certificate of incorporation and amended and restated bylaws include provisions that eliminate the personal liability of directors for monetary damages resulting from breaches of certain fiduciary duties as a director. The effect of this provision is to restrict our rights and the rights of our stockholders in derivative suits to recover monetary damages against a director for breach of fiduciary duties as a director.

These provisions may be held not to be enforceable for violations of the federal securities laws of the United States.

Dissenters' Rights of Appraisal and Payment

Under the DGCL, with certain exceptions, stockholders will have appraisal rights in connection with a merger or consolidation of the Company. Pursuant to Section 262 of the DGCL, stockholders who properly demand and perfect appraisal rights in connection with such merger or consolidation will have the right to receive payment of the fair value of their shares as determined by the Delaware Court of Chancery.

Stockholders' Derivative Actions

Under the DGCL, any stockholder may bring an action in the Company's name to procure a judgment in its favor, also known as a derivative action, provided that the stockholder bringing the action is a holder of the Company's shares at the time of the transaction to which the action relates.

Forum Selection

The Company's amended and restated bylaws provide that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for: (i) any derivative action brought by a stockholder on behalf of the Company, (ii) any claim of breach of a fiduciary duty owed by any of our directors, officers, stockholders, employees or agents to the Company's stockholders, or any claim for aiding and abetting any such alleged
breach, (iii) any claim against the Company, our directors, officers or employees arising under its charter, bylaws or the DGCL, (iv) any claim against us, our directors, officers or employees governed by the internal affairs doctrine or (v) any action asserting an "internal corporate claim" as such term is defined in Section 115 of the DGCL. The Company's amended and restated certificate of incorporation designates the federal district courts of the United States of America as the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

Restrictions on the Resale of our Securities

Rule 144

A person who has beneficially owned restricted shares of Common Stock or warrants for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least three months before the sale. Persons who have beneficially owned restricted shares of Common or restricted warrants for at least six months but who are our affiliates at the time of, or any time during the three months preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period a number of securities that does not exceed the greater of:

- 1% of the then outstanding equity shares of the same class; and
- the average weekly trading volume of our Common Stock or Warrants, as applicable, during the four calendar weeks preceding the date on which notice of the sale is filed with the SEC.

Sales by affiliates of Apexigen under Rule 144 are also subject to certain requirements relating to manner of sale, notice and the availability of current public information about Apexigen.

Restrictions on the Use of Rule 144 by Shell Companies or Former Shell Companies

Rule 144 is not available for the resale of securities initially issued by shell companies (other than business combination related shell companies) or issuers that have been at any time previously a shell company. However, Rule 144 also includes an important exception to this prohibition if the following conditions are met:

- the issuer of the securities that was formerly a shell company has ceased to be a shell company;
- the issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the
- Exchange Act;
- the issuer of the securities has filed all Exchange Act reports and material required to be filed, as applicable, during the preceding 12 months (or such shorter period that the issuer was required to file such reports and materials), other than Form 8-K reports; and
- at least one year has elapsed from the time that the issuer filed current Form 10 type information with the SEC reflecting its status as an entity that is not a shell company.

While we were formed as a shell company, since the closing of the business combination on July 29, 2022, we are no longer a shell company, and so, once the conditions set forth in the exceptions listed above are satisfied, Rule 144 will become available for the resale of the above noted restricted securities.

Lincoln Park Registration Rights Agreement

In connection with the Lincoln Park Purchase Agreement, the Company also entered into a registration rights agreement with Lincoln Park pursuant to which the Company agreed to file a resale registration statement covering the resale of the number of shares of Common Stock issued or issuable to Lincoln Park under the Lincoln Park Purchase Agreement, subject to certain exceptions. On August 12, 2022 the Company filed a registration statement on Form S-1, which was declared effective on September 9, 2022. The Company may also in the future file with the SEC a prospectus or prospectus supplement to be used in connection with the sales of the shares of Common Stock issued or issuable to Lincoln Park pursuant to the Lincoln Park Purchase Agreement.

Registration Rights and Lock-Up Agreement

Pursuant to the Registration Rights and Lock-Up Agreement, we agreed to file with the SEC a shelf registration statement registering the resale of certain shares of Common Stock from time to time, and to use commercially reasonable efforts to have the resale registration statement declared effective as soon as practicable after the filing thereof, subject to the provisions set forth in the Registration Rights and Lock-Up Agreement. We will also be required to file a registration statement upon written demand of a majority in interest of our then outstanding equity securities of (including the shares of Common Stock issued or issuable upon the exercise or conversion of any such equity security) held by holders who are parties to the Registration Rights and Lock-Up Agreement. We are obligated to effect up to two (2) registrations pursuant to such demand registration. In addition, the holders have certain “piggyback” registration rights with respect to registrations initiated by us.

The lock-up provisions pursuant to the Registration Rights and Lock-Up Agreement expired on January 29, 2023.

Private Placement Registration Rights Agreement

In connection with the Purchase Agreement, we entered into a Registration Rights Agreement with the investors that are party to the Purchase Agreement, pursuant to which, we agreed that within 30 days after the closing of the

Private Placement, we will file with the SEC (at our sole cost and expense) a shelf registration statement registering the resale of (i) the shares of Common Stock sold in the Private Placement and (ii) the shares of Common Stock underlying the 2023 PIPE Warrants from time to time, and we shall use commercially reasonable efforts to have the registration statement declared effective as promptly as possible after the filing thereof, subject to the provisions set forth in the Registration Rights Agreement.

Private Placement Lock-Up Agreement

Pursuant to the Purchase Agreement, we entered into Lock-Up Agreements with certain of our directors and executive officers. Subject to certain exceptions, our directors and officers agreed to a lock-up on their respective shares of Common Stock during the period beginning on January 30, 2023 and ending 90 days after January 30, 2023.

Transfer Agent and Registrar

The transfer agent and registrar for the Common Stock and warrant agent for the warrants is Continental Transfer & Trust Company, LLC. The transfer agent and registrar's address is 1 State Street, 30th Floor, New York, NY 10004.

Trading Symbol and Market

The Common Stock and warrants trade on the Nasdaq under the symbols "APGN" and "APGNW," respectively.

EXHIBIT 21.1

SUBSIDIARY OF THE COMPANY

Name	State of Incorporation
Apexigen America, Inc.	Delaware, U.S.A

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-267765) of Apexigen, Inc. (the "Company"), of our report dated February 22, 2023, relating to the consolidated financial statements of the Company (which report expresses an unqualified opinion and includes explanatory paragraphs relating to a going concern uncertainty and the reverse recapitalization transaction), appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2022.

/s/ Moss Adams LLP

San Francisco, California
February 22, 2023

EXHIBIT 31.1

**CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a)
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Xiaodong Yang, certify that:

1. I have reviewed this Annual Report on Form 10-K of Apexigen, 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 officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers 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 controls over financial reporting.

Apexigen, Inc.

Date: February 22, 2023

By: /s/ Xiaodong Yang
Xiaodong Yang, M.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

**CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a)
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, William Duke, Jr., certify that:

1. I have reviewed this Annual Report on Form 10-K of Apexigen, 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 officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers 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 controls over financial reporting.

Apexigen, Inc.

Date: February 22, 2023

By: /s/ William Duke, Jr.
William Duke, Jr.
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

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

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

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 22, 2023

By: /s/ Xiaodong Yang
Xiaodong Yang, M.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

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

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

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 22, 2023

By: /s/ William Duke, Jr.
William Duke, Jr.
Chief Financial Officer
(Principal Financial and Accounting Officer)