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, 2021

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 000-51531

VIRACTA THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**94-3295878**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2533 S. Coast Hwy. 101, Suite 210 Cardiff, California	**92007**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 400-8470

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	VIRX	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. ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market LLC on June 30, 2021, was approximately $312.6 million. Shares of the registrant's common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the registrant have been excluded from this computation. 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 March 4, 2022 was 37,485,823 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Part III of this Annual Report on Form 10-K is incorporated by reference from the registrant's definitive proxy statement for the registrant's 2022 annual meeting of stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the close of the registrant's fiscal year ended December 31, 2021.

Table of Contents

PART I

Forward-Looking Statements

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act") that are based on management's beliefs and assumptions and on information currently available to our management. The forward-looking statements are contained principally in the sections entitled "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Forward-looking statements include, but are not limited to, statements concerning the following:

- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results
- the timing, progress and results of preclinical studies and clinical trials for our current product candidates and other product candidates we may develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the studies or trials will become available, and our research and development programs;
- our future results of operations and financial position, including the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- the timing, scope and likelihood of regulatory filings and approvals in the United States and applicable foreign jurisdictions and our ability to obtain and maintain applicable regulatory approvals for our product candidates;
- our business strategy, including our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- our manufacturing, commercialization, and marketing capabilities and strategy;
- our ability to successfully identify and develop prospective product candidates;
- the timing and likelihood of success of our current and planned future research and development activities;
- our ability to successfully assess personnel requirements and hire and retain such personnel;
- our expectations regarding the impact of the COVID-19 pandemic on our business and our current and planned clinical trials;
- the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our competitive position and the success of competing therapies that are or may become available;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- our expectations regarding the approval and use of our product candidates in combination with other drugs and any potential requirements related to a companion diagnostic;
- plans relating to the further development of our product candidates, including additional indications we may pursue;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our current product candidates and other product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- our reliance on third parties to conduct clinical trials of our product candidates and for the manufacture of our product candidates for preclinical studies and clinical trials;
- our expectations regarding research and development costs;
- our ability to obtain the anticipated benefits of our existing collaboration agreement and to obtain, and negotiate favorable terms of, any additional collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- the pricing and reimbursement of our current or future product candidates, if approved;
- the rate and degree of market acceptance and clinical utility of our current of future product candidates, if approved;

- our estimates regarding expense, future revenue, capital requirements and needs for additional financing and our ability to obtain any such financing, on acceptable terms or at all; and
- plans and objectives of our management for future operations.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. You should read this Annual Report on Form 10-K completely. As a result of many factors, including without limitation those set forth under “Risk Factors” under Item 1A of Part I below, and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements. The forward-looking statements made in this Annual Report on Form 10-K relate only to events as of the date on which the statements are made. Except as required by applicable law, we undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

Unless the context requires otherwise, references in this Annual Report on Form 10-K to “Viracta,” “we,” “us” and “our” refer to Viracta Therapeutics, Inc and its subsidiaries.

Item 1. Business.

Overview

Viracta Therapeutics, Inc. (“Viracta”) or (the “Company”) is a clinical-stage, precision oncology company focused on advancing new medicines for the treatment of virus-associated malignancies. The association of viruses and cancer has been well characterized, and Viracta’s lead program is focused on cancers associated with the Epstein-Barr virus (“EBV”). EBV has been recognized as a Group 1 human carcinogen by the World Health Organization (“WHO”). Despite the association of EBV with cancer, there are currently no approved therapies for these cancers and attempts to develop vaccines have not proven successful. EBV enters periods of latency during which most viral genes are epigenetically suppressed. Likewise, the latently infected cell can evade the body’s immune surveillance mechanisms. In some stages of latency, viral proteins are not expressed on the cell surface, making it difficult to develop effective immunotherapies. EBV is estimated to be associated with approximately 2% of the global cancer burden with over 310,000 new cases of EBV-associated lymphoma, nasopharyngeal carcinoma (“NPC”) and gastric carcinoma (“GC”) cancers annually, which are responsible for over 180,000 deaths each year. Viracta’s novel synthetic lethality approach targets the EBV genome to enable the killing of the tumor cells by inducing the expression of certain viral kinase genes, which in-turn, activate an antiviral drug. The activated antiviral drug disrupts the DNA replication cycle of the target cells resulting in chain termination and killing of the tumor cells by inducing apoptosis, also known as programmed cell death. This synthetic lethality approach may also be applicable to other cancers associated with the herpes family of viruses, to which EBV belongs, such as glioblastoma associated with cytomegalovirus (“CMV”), Kaposi’s sarcoma with Kaposi’s sarcoma virus (“KSV”), and gastrointestinal carcinomas with Human Herpesvirus 6 (“HHV6”).

Viracta’s lead product candidate is an all-oral combination therapy of its proprietary investigational drug, nanatinostat, and the antiviral agent valganciclovir (collectively referred to as “Nana-val”). Nana-val is currently being evaluated in multiple ongoing clinical trials. In June 2021, Viracta initiated NAVAL-1, a pivotal, global, multicenter, open-label Phase 2 basket trial of Nan-val for the treatment of multiple subtypes of relapsed/refractory (“R/R”) EBV-positive (“EBV^+”) lymphoma. In October 2021, the Company initiated a multinational, open-label Phase 1b/2 trial of Nana-val for the treatment of EBV^+ recurrent or metastatic nasopharyngeal carcinoma (“R/M NPC”) and other EBV^+ solid tumors.

Viracta is also conducting a Phase 1b/2 trial of Nana-val for the treatment of EBV^+ R/R lymphoma, and final results from this trial were presented in an oral presentation at the 63rd American Society of Hematology (“ASH”) Annual Meeting in December 2021. The

data demonstrated promising activity in multiple subtypes of heavily pre-treated, R/R EBV$^+$ lymphoma patients, and a generally well-tolerated safety profile. Complete responses were observed in diffuse large B-cell lymphoma ("DLBCL"), T/NK-cell lymphoma ("T/NK-NHL"), and immunodeficiency-associated lymphoproliferative disorders ("IA-LPD"). The median duration of response was 10.4 months.

Viracta has received Fast Track Designation by the U.S. Food and Drug Administration (the "FDA") for the treatment of R/R EBV$^+$ lymphoid malignancies, in addition to orphan drug designations for the treatment of EBV$^+$ diffuse large B-cell lymphoma, not otherwise specified ("EBV$^+$ DLBCL,NOS"), post-transplant lymphoproliferative disorders ("PTLD"), plasmablastic lymphoma, and T-cell lymphomas.

The Viracta team possesses deep, cross-functional experience and a longstanding commitment to developing new medicines to benefit patients. Collectively, the Viracta management team has extensive industry experience in both private and publicly-traded companies, having co-founded companies, such as Hybritech, Inc. and IDEC Corporation, raised substantial debt and equity capital, conducted significant research and gained expertise on the role of viral biology in cancer, and discovered and developed oncology treatments at companies such as Novartis, Genentech, Medivation, and MorphoSys.

Merger Transaction between Private Viracta Therapeutics, Inc. and Sunesis Pharmaceuticals, Inc. and Name Change

On November 29, 2020, the Company, then operating as Sunesis Pharmaceuticals, Inc., entered into an agreement and plan of merger and reorganization (the "Merger Agreement") with privately-held Viracta Therapeutics, Inc. ("Private Viracta") and Sol Merger Sub, Inc., a wholly-owned subsidiary of the Company ("Merger Sub"). On February 24, 2021, the transactions contemplated by the Merger Agreement were completed, and Merger Sub merged into Private Viracta, with Private Viracta surviving the merger as a wholly owned subsidiary of the Company (the "Merger"). Sunesis changed its name to Viracta Therapeutics, Inc. On February 25, 2021, the combined company's common stock began trading on The Nasdaq Global Select Market under the ticker symbol "VIRX".

Except as otherwise indicated, references herein to "Viracta," the "Company," or the "combined company", refer to Viracta Therapeutics, Inc. on a post-Merger basis, and the term "Private Viracta" refers to the business of privately-held Viracta Therapeutics, Inc., prior to the completion of the Merger. References to "Sunesis" refer to Sunesis Pharmaceuticals, Inc. prior to completion of the Merger.

Pursuant to the terms of the Merger Agreement, each outstanding share of Private Viracta common stock outstanding immediately prior to the closing of the Merger was converted into approximately 0.1119 shares of Company common stock (the "Exchange Ratio"), after taking into account the Reverse Stock Split, as defined below. Immediately prior to the closing of the Merger, all shares of Private Viracta preferred stock then outstanding were exchanged into shares of common stock of Private Viracta. In addition, all outstanding options exercisable for common stock of Private Viracta and warrants exercisable for capital stock of Private Viracta became options and warrants exercisable for the same number of shares of common stock of the Company multiplied by the Exchange Ratio at an exercise price equal to the pre-Merger price divided by the Exchange Ratio. Immediately following the Merger, stockholders of Private Viracta owned approximately 86% of the outstanding common stock of the combined company.

This transaction was accounted for as a reverse asset acquisition in accordance with generally accepted accounting principles in the United States of America ("GAAP"), as Viracta was considered to be acquiring Sunesis and the Merger was accounted for as an asset acquisition, even though Sunesis was the legal acquirer and the issuer of the common stock in the Merger. This determination was primarily based on the facts that, immediately following the Merger: (i) Private Viracta's stockholders owned a substantial majority of the voting rights in the combined company, (ii) Private Viracta designated a majority of the members of the initial board of directors of the combined company, and (iii) Private Viracta's senior management holds all key positions in the senior management of the combined company. As a result, as of the closing date of the Merger, the net assets of Sunesis were recorded at their acquisition-date relative fair values in the accompanying consolidated financial statements of the Company and the reported operating results prior to the Merger are those of Private Viracta.

To determine the accounting for this transaction under GAAP, a company must assess whether an integrated set of assets and activities should be accounted for as an acquisition of a business or an asset acquisition. The guidance required an initial screen test to determine if substantially all of the fair value of the gross assets acquired was concentrated in a single asset or group of similar assets. The initial screen test was not met as there was no single asset or group of similar assets for Sunesis that represented a significant majority in this acquisition. However, at the time of the closing of the Merger, Sunesis did not have processes or an organized workforce that significantly contributed to its ability to create outputs, and substantially all of its fair value was concentrated in cash, working capital, and in-process research and development ("IPR&D"). As such, the acquisition was treated as an asset acquisition.

Concurrent with the execution of the Merger Agreement, Private Viracta entered into an agreement for the sale of common stock in a private placement, which was completed immediately prior to the close of the Merger and resulted in gross proceeds of approximately

$65.0 million. In connection with the closing of the Merger and the concurrent private placement of common stock, the holders of the Company's preferred stock waived their right to exchange their shares into any class of the Company's stock other than common stock.

On February 24, 2021, in connection with, and prior to the completion of, the Merger, the Company effected a 3.5-for-one reverse stock split of its then outstanding common stock (the "Reverse Stock Split"). The par value and the authorized shares of the common stock were not adjusted as a result of the Reverse Stock Split. Unless otherwise noted herein, references to share and per-share amounts give retroactive effect to the Reverse Stock Split and the Exchange Ratio which was effected upon the Merger.

Strategy

Viracta's strategy is to build a leading precision oncology company focused on virus-associated malignancies. While the association between viruses and cancer has been well characterized, there are currently no approved therapies that specifically target virus-harboring cancer cells. Viracta's lead program targets an area of high unmet medical need with no approved therapies. Viracta's current pipeline is derived from its ability to leverage its synthetic lethality and biomarker-driven approach. Viracta prioritizes virus-associated targets that it believes have the potential to change the paradigm of treatment in virus-associated cancers.
Key elements of Viracta's strategy are as follows:

- Rapidly advance Viracta's lead product candidate, Nana-val, through clinical development, initially in EBV^+ lymphomas;
- Expand development of Nana-val in other EBV^+ malignancies, beginning with solid tumors harboring the EBV genome;
- Leverage its synthetic lethality approach and evaluate other malignancies associated with other viruses in the herpes family;
- Evaluate opportunities to combine Nana-val or nanatinostat with other therapeutic modalities; and
- Evaluate other opportunities to expand Viracta's pipeline through licensing, acquisitions and/or partnerships.

Pipeline

The following figure summarizes Viracta's current development programs:

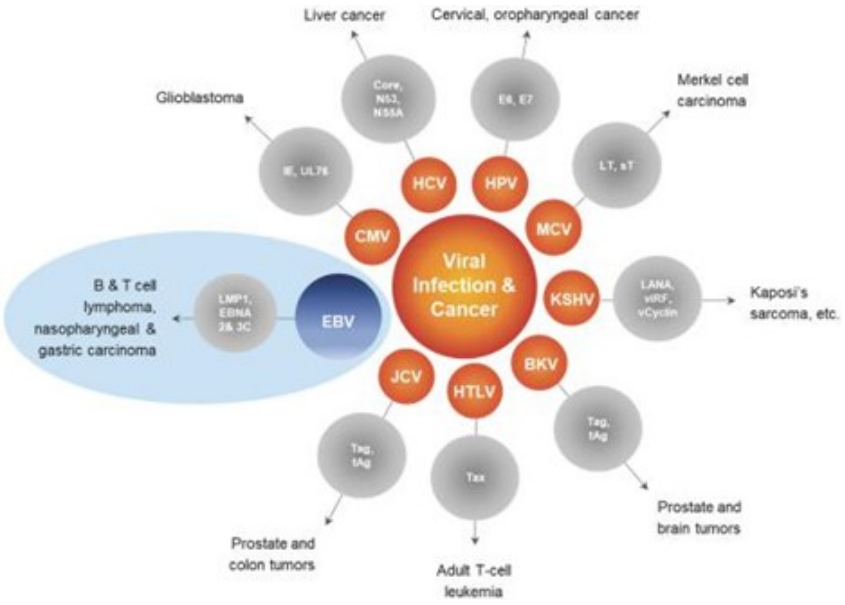
Figure 1: Pipeline

Scientific Background

Overview of Virus-associated Malignancies

The association of viruses and cancer has been well characterized. Despite knowing of EBV's association with cancer for over half a century, attempts to develop vaccines have not proven successful. The figure below illustrates the association of a number of viruses with various cancers.

Figure 2: Viral Infection and Cancer

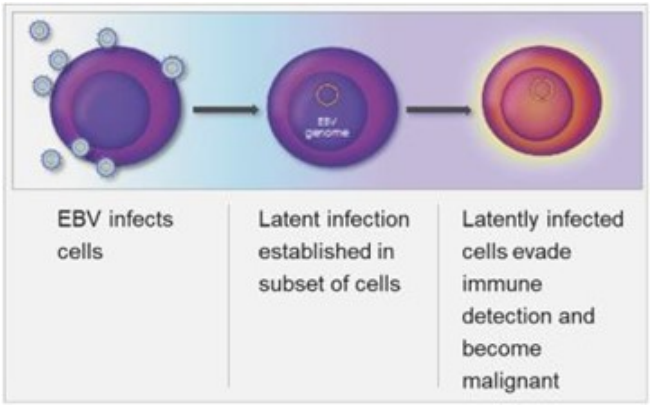


EBV, a member of the g-herpesvirus family, was the first virus directly implicated in the development of a human tumor and is formally classified as a Group 1 human carcinogen by the WHO. Primary infection with EBV typically occurs in childhood and is generally asymptomatic; however, infection later in life may manifest as infectious mononucleosis. Once infected, individuals remain life-long carriers of the virus, with approximately 95% of the world's adult population asymptomatically infected with EBV. The EBV genome can be detected in approximately one out of one million circulating B lymphocytes.

EBV Latency

EBV enters periods of latency during which most viral genes are epigenetically suppressed, as depicted in the figure below. In some stages, no viral proteins are expressed on the cell surface, making it difficult to develop broadly effective immunotherapies.

Figure 3: EBV Latency in Cells



Latent infection and intermittent reactivation are two important characteristics of the EBV lifecycle. The maintenance of latent EBV infection requires the expression of a small subset of genes, and specific expression patterns (Types I – III) of these genes are associated with specific EBV-driven malignancies. EBV has been shown to infect B-cells, T-cells, T/NK-cells and epithelial cells, though its greatest predilection is for B-cells. EBV has been associated with a wide spectrum of human malignancies, with B-cell lymphomas being the most common, and include EBV^+ diffuse large B cell lymphoma, not otherwise specified ("EBV^+ DLBCL,

NOS"), Burkitt's lymphoma ("BL"), post-transplant lymphoproliferative disorders ("PTLD"), and lymphomas associated with congenital and acquired immunodeficiencies, including HIV-related lymphomas.

Mechanism of Action of Nana-val

Nana-val utilizes a combination of Viracta's oral proprietary epigenetic drug, nanatinostat, in combination with the oral antiviral drug valganciclovir. Nanatinostat targets the EBV genome and induces the expression of certain viral kinase genes. Valganciclovir is converted to ganciclovir in the gut, and these EBV kinases then activate ganciclovir, which disrupts the DNA replication cycle, leading to DNA chain termination and killing of the tumor cells by inducing apoptosis. This type of killing can be considered a form of synthetic lethality, where neither drug alone would be as effective in killing the tumor cells, but together the two drugs are lethal to the tumor cells.

Epigenetic Re-Programming

EBV gene products can drive aberrant cell proliferation, inhibit programmed cell death and other mechanisms that promote formation of cancer. Viruses and cancers have also evolved mechanisms to evade immune detection by up-regulating immunosuppressive signals, including the induction of PD-L1. Due to these pleiotropic effects, so-called molecularly targeted approaches that target only one oncogenic activity have shown limited ability to impact these cancers.

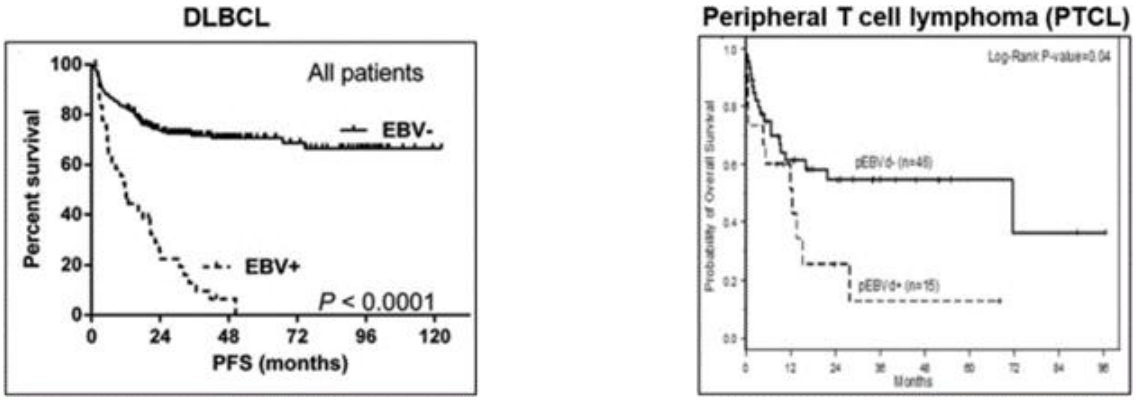
Epigenetics refers to mechanisms that control which genes or gene programs are turned on or which ones are silenced. Modification of gene promoter or histones, around which DNA is coiled, are major mechanisms by which gene expression is controlled.

EBV-Associated Lymphomas

EBV-associated lymphomas are a heterogeneous group of malignancies that harbor latent EBV within the tumor cells. Within a specific histologic subtype of lymphoma, the frequency of EBV positivity may vary considerably. EBV is associated with approximately 5% of DLBCL in Western countries and approximately 10%-15% in Asia and South America, whereas approximately 30% of peripheral T cell lymphoma ("PTCL") and HL within North America are EBV^+, and endemic BL are EBV^+ in approximately 95% of the cases. The risk for developing an EBV^+ lymphoma has been observed to be higher in the setting of immunodeficiency, including in patients with HIV, congenital immunodeficiencies and post-transplant immunosuppression. EBV-related lymphomas express a limited number of viral genes, with latency expression patterns associated with specific lymphoma subtypes. The limited expression of EBV genes may allow for persistence of the viral DNA in cells by restricting the visibility of the virus to the immune system. The observation that lymphomas in patients with impaired immune function are more likely to express a greater number of viral genes is supportive of this concept. EBV-related lymphoproliferative disease in immunosuppressed patients may respond to therapies that improve immune function, such as reduced immunosuppression (e.g., transplant patients) or adoptive immunotherapy. In contrast, EBV-related lymphomas that arise in immunocompetent patients generally express fewer viral genes and proteins, and as a result are less prone to immune attack.

While outcomes vary based on the specific malignancy, EBV-associated lymphomas (e.g., DLBCL, HL, BL, and a number of T-cell lymphomas) often present a treatment challenge as clinical outcomes such as progression free survival and overall survival are worse following standard of care regimens as compared to those for EBV-negative patients. The presence of EBV in lymphomas is therefore generally considered to be a poor prognostic indicator. As shown in the figure below, across a series of patients with DLBCL, those who were EBV^+ generally presented with more aggressive disease, had lower response rates to first-line therapy, and poorer progression free survival and overall survival. In a meta-analysis evaluating survival outcomes across several lymphoma types (HL, DLBCL, T/NKCL, PTCL), EBV^+ disease was associated with significantly worse overall survival.

Figure 4: Outcomes in EBV-negative vs EBV+ Lymphomas



Source: Lu TX, et al. Sci Rep 5,12168, 2015; Haverkos BM et al. Int J Cancer. 2017

EBV-positivity in tumor cells can be detected using in situ hybridization for EBV-encoded RNA (EBER-ISH). This is a clinical laboratory test that detects the presence of EBV in the cancer cell. This test is currently most often used to assist in the diagnosis of lymphoma subtypes. Because there has been a lack of actionable targeted therapies in the past, EBER-ISH has not been routinely used to guide course of treatment.

The evaluation of EBV utilizing either EBER-ISH and/or LMP-1 immunohistochemistry ("IHC") in the diagnostic workup of B and T cell lymphomas is included in the National Comprehensive Cancer Network ("NCCN") guidelines. Additionally, protocols established by the College of American Pathologists for both Hodgkin and non-Hodgkin lymphoma include the evaluation of EBV status. These laboratory developed tests are widely available in pathology labs, however the frequency at which the testing is performed varies by treatment center and disease type and is lower in community treatment centers compared to academic institutions. This is likely primarily due to the absence of an available EBV targeted therapy, which impacts the evaluation of treatment options for these patients.

Antivirals, including acyclovir and ganciclovir, are prodrugs that are specifically activated by herpesvirus kinases, such as thymidine kinase ("TK") and protein kinase ("PK"). These viral kinases are strictly expressed in the lytic phase of the viral life but not in the latent phase, which is the predominant phase in EBV associated tumors. To overcome this barrier, Viracta utilizes its proprietary epigenetic drug candidate, nanatinostat, to induce the expression of these viral kinase genes. Once induced, the viral kinases will phosphorylate and activate the antiviral prodrug in the tumor cell, resulting in the killing of the tumor cell. Viracta has determined that for EBV-associated malignancies, oral valganciclovir, which is converted to ganciclovir in the gut, is its preferred antiviral drug.

Nanatinostat belongs to a class of drugs known as histone deacetylase ("HDAC") inhibitors. HDAC inhibitors have been explored as anti-tumor agents. They were shown to have, in general, limited activity and in general, the efficacy they did exhibit was compromised by their adverse event profile. Nanatinostat is a highly potent class I HDAC inhibitor, specifically targeting those few HDAC isozymes required for silencing of EBV gene expression in tumors. Viracta has evaluated nanatinostat doses approximately 20-25% of the maximally tolerated dose (as determined in a previous Phase 1 study) to re-activate the latent EBV gene expression; the combination of nanatinostat with valganciclovir has thus far demonstrated a favorable safety and tolerability profile in a Phase 1b/2 clinical trial in patients with recurrent EBV+ lymphoma.

HDAC Enzymes and Inhibitors

Currently, 18 HDAC enzymes have been identified in mammalian cells, varying in function, localization, and substrates. They are subdivided into four main classes based on homology to yeast proteins. Three of the four classes (Classes I, II, and IV) are zinc ("Zn2+") dependent enzymes and are inhibited by the pan-HDAC inhibitors.

Epigenetic modulation of gene expression is an essential biological process, with chromatin structure and gene transcription tightly regulated by the acetylation state of histones in the nucleosome. Histone acetylation is a balance of the actions of histone acetyltransferases ("HATs") and HDACs, with acetylation of histones generally associated with induction of gene transcription and deacetylation with decreases in transcription. Though a seemingly simple concept, it belies the complexity of the effects of HDAC inhibition on chromatin structure. Exposure to HDAC inhibitors rapidly leads to compensating changes in histone methylation and changes in expression of histone modulators. In tumor cells, the most commonly reported effects of HDAC inhibitors relate to

induction of apoptosis, though they have also been shown to interfere with cell growth and differentiation and inhibit angiogenesis. In addition, HDAC inhibitors have been shown to modulate immune responses which, in turn, affect many diverse cellular functions.

To date, more than 15 HDAC inhibitors have been tested in nonclinical and clinical studies. HDAC inhibitors are broadly classified into four main groups based on their structure: hydroxamic acids, cyclic peptides/depsipeptides, benzamides, and short-chain fatty acids. A common mechanism of action of these drugs is to bind a critical Zn2+ ion required for catalytic function of the HDAC enzyme.

Several HDAC inhibitors have demonstrated clinical antitumor activity when dosed at or near the maximum tolerated dose, with four currently approved by the FDA for oncology indications. These are vorinostat for the treatment of cutaneous T cell lymphoma, romidepsin for the treatment of cutaneous T-cell lymphoma, belinostat for the treatment of peripheral T-cell lymphoma, and panobinostat for the treatment of multiple myeloma.

Common side effects seen with these HDAC inhibitors include thrombocytopenia, neutropenia, anemia, fatigue and diarrhea. While HDAC inhibitors have displayed some antitumor activity as single agents, data suggest that the HDAC inhibitors may have a greater role as part of combination regimens.

Rationale for the Combination of HDAC Inhibitors and Antivirals for the Treatment of EBV-Associated Lymphomas

Induction of virus-encoded kinases within EBV^+ lymphomas results in the sensitization of tumor cells to the antiviral agent ganciclovir, a prodrug that is modified and activated by the EBV kinases. The modified ganciclovir serves as a nucleotide analog that blocks the process of DNA synthesis leading to tumor cell death. We believe this approach is likely to have high tumor specificity as only EBV containing tumor cells would be targeted by the activated ganciclovir. The potential for this approach was initially demonstrated in a transplant patient who had developed an EBV^+ immunoblastic lymphoma four months after transplantation. In a cell line derived from the patient's tumor, treatment with arginine butyrate, a pan-HDAC inhibitor, induced expression of EBV lytic phase proteins, which include the viral enzymes that modify ganciclovir, and resulted in halting cell proliferation and reduction in cell viability. Arginine butyrate was added to the patient's existing treatment with ganciclovir with no apparent additional toxicity. Though the patient succumbed to a systemic Aspergillus infection that had preceded arginine butyrate therapy, subsequent pathologic examination of the tumor showed substantial necrosis compared to pre-therapy histology. However, a definitive causal relationship between arginine butyrate/ganciclovir therapy and antitumor effect was confounded by prior treatment with chemotherapy.

Additional clinical support was demonstrated in a Phase 1/2 investigator sponsored trial that combined the HDAC inhibitor arginine butyrate with intravenous ganciclovir in 15 patients with recurrent EBV^+ lymphomas. Arginine butyrate was administered as a continuous intravenous infusion daily on an escalating dose schedule within each patient for 21 days of a 28-day treatment course, combined with a fixed daily dose of ganciclovir that was not interrupted. Eleven patients received at least one full cycle of therapy, and all 15 patients were evaluable for response. Antitumor activity was reported in 10 patients, with 4 complete responses and 6 partial responses.

Development Programs

Viracta's Combination Approach

The use of Nana-val is a novel therapeutic approach to target EBV^+ malignancies, using a low-dose of Viracta's oral proprietary epigenetic drug, nanatinostat, to target the EBV genome and induce the expression of certain viral kinase genes. These viral genes then activate the antiviral prodrug, valganciclovir, which is converted to ganciclovir in the gut, and disrupts the DNA replication cycle. This disruption then leads to chain termination and killing of the tumor cells by inducing apoptosis. This type of killing can be considered a form of synthetic lethality, where neither drug alone would be as effective in killing the tumor cells, but together the two drugs are lethal to the tumor cells.

Nanatinostat is a hydroxamic acid-based Class 1 HDAC inhibitor and is a more than 2,000 times more potent inducer of the latent EBV genes targeted by this approach than arginine butyrate, the first generation HDAC inhibitor previously investigated in an academic setting. Additionally, the class specificity of nanatinostat is critical for both the targeted efficacy and safety of the approach. As a class, HDACs control the acetylation status of a range of histone and non-histone proteins, giving these enzymes a key role in a number of vital cellular processes. HDAC inhibition alters gene expression at many levels, including gene transcription, protein expression, and signal transduction pathways. Cellular effects include control of the cell cycle, cell differentiation and senescence, inflammation, angiogenesis and apoptosis. Nanatinostat has demonstrated pleiotropic activity both in vitro and in vivo across a range of human cancers in nonclinical studies.

Nanatinostat was initially evaluated as a single agent in a Phase 1 clinical trial at oral doses ranging from 5 to 160 mg daily in 39 patients with advanced solid tumors. The maximum tolerated dose ("MTD") of nanatinostat was 80 mg daily, and the recommended Phase 2 dose was determined to be 40 mg daily. This program was beneficial in establishing the early safety and tolerability profiles of nanatinostat before it was acquired by Viracta from Chroma Therapeutics in 2016 for the development of Nana-val.

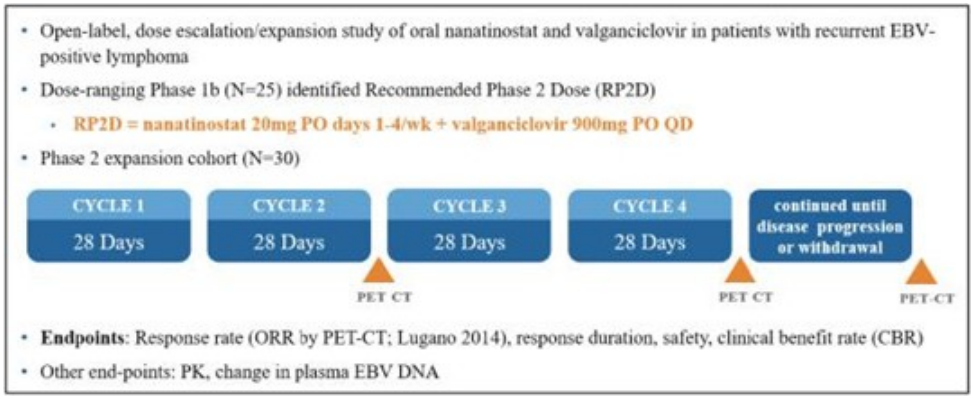
Nanatinostat induces the expression of EBV kinase genes to activate ganciclovir, rather than acting directly as a cytotoxic agent. In clinical trials, nanatinostat at doses below 40 mg daily in combination with valganciclovir has demonstrated clinical activity in patients with recurrent EBV$^+$ lymphomas. In the ongoing Phase 1b/2 trial, 35 patients with R/R EBV$^+$ lymphomas have received the recommended Phase 2 dose regimen of nanatinostat (20 mg p.o. (orally) daily ("QD") for four days/week, i.e., 4 days on, 3 days off), with valganciclovir 900 mg p.o. daily. The combination has been generally well-tolerated in the trial with the most common grade 3/4 adverse events being reversible cytopenias.

Nana-val in Relapsed/Refractory EBV$^+$ Lymphoma

Phase 1b/2 Clinical Trial in Relapsed/Refractory EBV$^+$ Lymphomas

In 2018, Viracta initiated a Phase 1b/2 dose escalation and expansion trial to evaluate the safety and preliminary efficacy and define a recommended Phase 2 dose ("RP2D") of Nana-val in patients with relapsed/refractory EBV$^+$ lymphomas who had received one or more prior therapies and had exhausted standard therapies. Patients were enrolled from approximately 20 centers in the US and 6 centers in Brazil.

Figure 5: Design of Phase 1b/2 Trial in R/R EBV$^+$ Lymphomas



Twenty-five patients were enrolled in the Phase 1b portion of the trial, and the RP2D was determined to be nanatinostat 20 mg p.o. daily for four days/week, i.e., 4 days on, 3 days off, with valganciclovir 900 mg p.o. daily. Thirty patients were enrolled in a Phase 2 expansion arm. In December 2021, the final results of the Phase 1b/2 study were presented at the ASH congress. Nana-val was generally well-tolerated and demonstrated promising activity in multiple lymphoma subtypes, with complete responses in DLBCL, T/NK-NHL, and IA-LPD, and a median duration of response of 10.4 months.

In 55 patients evaluable for safety, the most common grade 3/4 adverse events were reversible cytopenias (Figure 7). Serious adverse events ("SAEs") occurred in 16 patients (29%); SAEs occurring in ≥2 patients were febrile neutropenia and pneumonia (both n=2). No study drug related deaths occurred in the treatment period.

Figure 6: Grade 3/4 Treatment-emergent AEs in ≥3 Patients (5%) from the Phase 1b/2 Trial in R/R EBV⁺ Lymphomas (n=55) (Data Presented at ASH 2021)

	Phase 1b (n=25)			Phase 2 (n=30)		
	All	**G3**	**G4**	**All**	**G3**	**G4**
Thrombocytopenia	13 (52%)	5 (20%)	3 (12%)	7 (23%)	1 (3%)	2 (7%)
Neutropenia	10 (40%)	4 (16%)	5 (20%)	9 (30%)	3 (10%)	4 (13%)
Anemia	9 (36%)	4 (16%)	-	8 (27%)	6 (20%)	1 (3%)
Lymphopenia	6 (24%)	2 (8%)	3 (12%)	4 (13%)	2 (7%)	1 (3%)
Leukopenia	5 (20%)	1 (4%)	2 (8%)	5 (17%)	1 (3%)	1 (3%)
Acute kidney injury	4 (16%)	2 (8%)	1 (4%)	2 (7%)	-	1 (3%)
GI hemorrhage	2 (8%)	2 (8%)	-	2 (7%)	2 (7%)	-
Febrile neutropenia	1 (4%)	1 (4%)	-	3 (10%)	2 (7%)	1 (3%)

Figure 7: Summary of Efficacy per Lymphoma Subtype in evaluable patients (n=43) (Phase 1b/2 Trial in R/R EBV⁺ Lymphoma, Presented at ASH 2021)

	All patients (n=43)	**DLBCL (n=6)**	**Other B-NHL (n=2)**	**ENKTL (n=8)**	**PTCL-NOS/AITL (n=6)**	**CTCL (n=1)**	**HIV-L (n=4)**	**IA-LPD (n=6)**	**Hodgkin (cHL) (n=10)**
Response									
ORR	**17 (40%)**	**4 (67%)**	-	**5 (63%)**	**4 (67%)**	-	-	**3 (50%)**	**1 (10%)**
CR	**8 (19%)**	**2 (33%)**	-	**1 (13%)**	**3 (50%)**	-	-	**2 (33%)**	-
PR	9 (21%)	2	-	4	1	-	-	1	1
SD	7 (16%)	1	-	-	1	-		-	5
PD	19 (44%)	1	2	3	1	1	4	3	4
Clinical benefit rate	24 (56%)	5 (83%)		5 (63%)	5 (83%)			3 (50%)	6 (60%)

** CR: complete response; PR: partial response; PD: progressive disease; ORR: objective response rate: B-NHL: B-cell non-Hodgkin lymphoma; DLBCL: diffuse large B-cell lymphoma; ENKTL: extranodal NK/T cell lymphoma; PTCL-NOS: peripheral T-cell lymphoma not otherwise specified; AITL: angioimmunoblastic T-cell lymphoma; CTCL: cutaneous T-cell lymphoma; IA-LPD: immunodeficiency-associated lymphoproliferative disorder; HIV-L: HIV-associated lymphoma; cHL: classic Hodgkin lymphoma.*

NAVAL-1

An Open-Label, Phase 2 Trial of Nanatinostat in Combination With Valganciclovir in Patients With Epstein-Barr Virus-Positive ("EBV⁺") Relapsed/Refractory Lymphomas

In June 2021, Viracta initiated NAVAL-1, a global, multicenter, open-label Phase 2 basket trial utilizing a Simon 2-stage design that will evaluate the combination of nanatinostat with valganciclovir in patients with R/R EBV⁺ lymphoma. Lymphoma subtypes demonstrating promising activity may be further expanded to assess potential support of future new drug application filings. NAVAL-1 is anticipated to enroll approximately 140 patients at centers in North America, Europe, and the Asia-Pacific region. The primary endpoint of the trial is objective response rate, with key secondary endpoints including duration of response, survival outcomes, and the safety profile of the combined treatment. Patients with EBV⁺ R/R disease following two or more prior therapies (one or more for extranodal NK/T cell lymphoma) without curative treatment options will be eligible for enrollment.

Nana-val in EBV⁺ Solid Tumors

An Open-Label, Multicenter Phase 1b/2 Study of Nanatinostat and Valganciclovir in Patients with Advanced Epstein-Barr Virus-Positive ("EBV⁺") Solid Tumors and in Combination with Pembrolizumab in Patients with Recurrent/Metastatic Nasopharyngeal Carcinoma

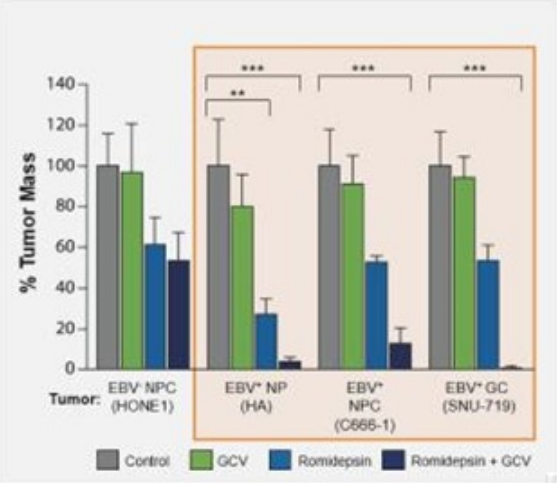
Viracta is also evaluating Nana-val in solid tumors, having received FDA clearance of an IND in July of 2021 for a Phase 1b/2 clinical trial in patients with EBV⁺ solid tumors. In October 2021, Viracta initiated a multinational Phase 1b/2 trial in patients with EBV⁺ recurrent or metastatic nasopharyngeal carcinoma ("R/M NPC") and other EBV⁺ solid tumors. The trial is designed to evaluate the safety and preliminary efficacy of Nana-val alone and in combination with the PD-1 inhibitor pembrolizumab (Keytruda). The Phase 1b dose escalation portion is designed to determine the recommended RP2D of Nana-val in patients with EBV⁺ R/M NPC. In Phase 2,

up to sixty patients with EBV+ R/M NPC will be randomized to receive Nana-val at the RP2D with or without pembrolizumab, to evaluate safety, overall response rate, and potential pharmacodynamic markers. Additionally, patients with other EBV+ solid tumors will be enrolled to receive Nana-val at the RP2D in a Phase 1b dose expansion cohort.

The global annual incidence of NPC and GC is estimated to be approximately 100,000 cases for each of the two malignancy types. Although some treatment options are available, there remains a high unmet need, particularly in patients with relapsed/refractory disease.

As shown in the figure below, the combination of the class I HDAC inhibitor romidepsin with ganciclovir in human tumor murine xenograft mouse models of EBV+ NPC and GC has demonstrated a greater effect upon tumor growth than the administration of either agent alone, providing the nonclinical proof of concept for combining an HDAC inhibitor with an antiviral agent in solid tumors. High tumor uptake of nanatinostat has been demonstrated in murine xenograft mouse models of colorectal cancer.

Figure 8: Murine Model of EBV+ NPC and GC



Source: Hui KW, et al. Int J Cancer:138.125-136 (2016)

About Vecabrutinib

Vecabrutinib is a well-tolerated, selective, reversible, non-covalent inhibitor of Bruton's tyrosine kinase (“BTK”) and interleukin-2-inducible kinase (“ITK”). In December 2021, new preclinical data on vecabrutinib was presented in oral and poster presentations at the 2021 American Society of Hematology (“ASH”) Annual Meeting. The oral presentation featured preclinical data indicating that vecabrutinib may enhance the efficacy and safety of CD19-targeted chimeric antigen receptor T (“CART19”) cell therapy. Though CART19 cell therapy has been shown to effectively treat certain hematological malignancies, rates of long-term durable response after therapy are low and the majority of patients develop resistance. Additionally, CAR T-cell therapies are associated with significant safety concerns such as cytokine release syndrome and neurotoxicity. Viracta is evaluating future development and collaboration opportunities for vecabrutinib in combination with CAR T-cell therapies.

About VRx-510 (formerly SNS-510)

VRx-510 is a preclinical-stage PDK-1 inhibitor. Viracta is evaluating future development and collaboration opportunities for VRx-510 in multiple oncology indications.

Other Preclinical Programs

In addition to current studies aimed at assessing the efficacy of the nanatinostat/valganciclovir modality in treatment of EBV-linked malignancies, Viracta is also investigating in pre-clinical studies the use of its proprietary epigenetic drug candidate, nanatinostat, and its potential therapeutic application in other virus-associated malignancies (e.g., HPV).

License Agreements

Boston University License Agreement

In October 2007, Viracta entered into a license agreement with Trustees of Boston University ("Boston University"), pursuant to which Boston University granted Viracta an exclusive, worldwide license to develop and commercialize certain product candidates for blood disorders (the "Original BU License Agreement"). In connection with the Original BU License agreement, Viracta sold to Boston University 100 shares of special preferred stock and 12,448 shares of Viracta Common Stock (all pre-merger share values).

Between 2009 and 2012, Viracta and Boston University entered into a series of amendments to the Original BU License Agreement, and in August 2018, the parties entered into an amended and restated license agreement, which amended and restated all prior agreements between the parties and superseded all prior agreements and amendments (the "Restated BU License Agreement"). Under the Restated BU License Agreement, Boston University granted Viracta an exclusive, sublicensable, worldwide license to Boston University's patent and other related technology rights to develop and commercialize certain product candidates for the treatment of viral or virally induced conditions, including but not limited to nanatinostat in combination with valganciclovir for the treatment of EBV-associated malignancies. Viracta's obligations under the Restated BU License Agreement include, among other things, using commercially reasonable efforts to bring at least one licensed product to market in the United States and using commercially reasonable efforts to continue development and marketing.

Pursuant to the Restated BU License Agreement, Viracta is required to pay royalties to Boston University ranging from the low single digits as a percentage of net sales for products covered by the licensed patent rights and royalties of less than one percent on net sales for product covered by or developed using the licensed technology. For each year during the term of the Restated BU License Agreement, Viracta is required to pay Boston University an annual minimum royalty of $30,000. In addition, Viracta is required to pay a percentage of certain payments received from sublicensees of the license granted by Boston University, ranging from mid-teens to low single digits as a percentage of the respective payments.

Unless earlier terminated as provided for in the Restated BU License Agreement, the agreement will remain in effect on a product-by-product and country-by-country basis until Viracta's royalty obligations expire. Boston University has certain termination rights in the circumstances of uncured material breach by Viracta, Viracta's insolvency or a challenge of Boston University's patent rights by Viracta.

In August 2018, in connection with the execution of the Restated BU License Agreement, Viracta and Boston University agreed to exchange all 100 shares of special preferred stock for 1,679,186 shares of Series A-1 Preferred Stock (all pre-merger share values). In connection with the Merger, all of the outstanding shares of Private Viracta's convertible preferred stock were converted into shares of the Company's common stock.

ImmunityBio License Agreement

In May 2017, Viracta entered into a license agreement with ImmunityBio, Inc., formerly NantKwest, Inc. ("ImmunityBio"), which was amended by the parties in November 2018 (as amended, the "NK License Agreement"). Pursuant to the NK License Agreement, Viracta granted an exclusive worldwide license to ImmunityBio and its affiliates to develop and commercialize nanatinostat for use in combination with natural killer cell immunotherapies ("NK Covered Products").

Under the NK License Agreement, Viracta is eligible to receive up to a total of $100.0 million in regulatory and commercial milestone payments upon the occurrence of certain milestone events. Viracta is also eligible to earn tiered royalties as a percentage of net sales of licensed NK Covered Products, ranging from the low to mid-single digits.

ImmunityBio is responsible for conducting all necessary studies, including safety studies and clinical trials necessary in connection with seeking regulatory approvals to market NK Covered Products under the NK License Agreement in any territory.

Unless earlier terminated, the NK License Agreement will continue until the expiration of all applicable royalty terms on a product-by-product and country-by-country basis. Both parties have certain termination rights in the circumstances of an uncured material breach by or insolvency of the other party. ImmunityBio has the right to terminate the NK License Agreement in whole or on a product-by-product and/or country-by-country basis without cause upon 90 days prior written notice to Viracta.

Shenzhen Salubris Pharmaceuticals Co. Ltd. License Agreement

In November 2018, Viracta entered into a License Agreement with Shenzhen Salubris Pharmaceutical Co. Ltd., ("Salubris"), pursuant to which the Company granted an exclusive, royalty-bearing license, with the right to grant sublicenses to Salubris to research, develop, use, make, have made, sell, offer for sale, have sold, import, and otherwise commercialize nanatinostat in combination an antiviral drug such as valganciclovir in the Republic of China, excluding Hong Kong, Macau, and Taiwan.

In August 2021, Viracta, through its wholly-owned subsidiary, Viracta Subsidiary, Inc., entered into a Mutual Termination Agreement with Salubris (the "Termination Agreement"), pursuant to which the parties agreed to terminate the exclusive collaboration and license agreement entered into by the parties in November 2018. Under the terms of the Termination Agreement, the Company paid Salubris a payment in the amount of $4.0 million on the effective date of the Termination Agreement, and all licenses granted by the Company to Salubris automatically terminated.

Manufacturing

Viracta uses third party contract labs and facilities for the manufacture and testing of drug substance, drug product, and clinical trial material while providing internal oversight on technical development, quality and regulatory compliance. This outsourcing model allows Viracta to maintain a flexible infrastructure and capital efficiency while focusing its expertise on developing its products.

Viracta expects to continue to rely on third parties for the production of clinical and commercial quantities of any product candidates. There are no complicated biochemistries or unusual equipment required in the manufacturing process for either nanatinostat or valganciclovir.

Viracta has established a quality control and quality assurance program, which includes a set of standard operating procedures and specifications designed to ensure that Viracta's products are manufactured in accordance with cGMPs, and other applicable domestic and foreign regulations.

Competition

The pharmaceutical and biotechnology industries are characterized by rapid technological advancement technologies, significant competition and an emphasis on intellectual property. Although Viracta believes that its technology, the expertise of its executive and scientific team, research, clinical capabilities, development experience and scientific knowledge provide it with competitive advantages, Viracta faces increasing competition from many different sources, including pharmaceutical and biotechnology companies, academic research institutions, governmental agencies and public and private research institutions. Product candidates that Viracta successfully develops and commercializes may be required to compete with existing therapies and new therapies that may become available in the future to be successful.

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

Viracta's commercial potential could be reduced or eliminated if its competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products that Viracta may develop. Viracta's competitors also may obtain FDA or other regulatory approval for their products more rapidly than Viracta may obtain approval for its products, which could result in Viracta's competitors establishing a strong market position before Viracta is able to enter the market or make Viracta's product development more complicated. The key competitive factors affecting the success of all of Viracta's programs are likely to be efficacy, safety, convenience, cost, level or promotional activity devoted to them and intellectual property protection.

For Nana-val, Viracta's proprietary HDAC inhibitor, nanatinostat, in combination with valganciclovir, Viracta is aware of several other approved and clinical-stage HDAC inhibitors being developed by competitors. To Viracta's knowledge, there are no HDAC inhibitors approved for the treatment of EBV^+ lymphoma. However, there are several marketed products and product candidates in development for the treatment of various lymphoma types that do not consider the EBV status of the patients. Some marketed products and therapies are used in the treatment of lymphomas, including EBV^+ lymphomas. In addition, a number of companies and

academic institutions are developing drug candidates for EBV-associated PTLD and other EBV-associated diseases including: Atara Biotherapeutics, Inc., which is conducting a Phase 3 clinical trial and recently filed an MAA in the EU for Tab-cel® (tabelecleucel), a product for virus-associated EBV^+ PTLD. The EMA's Committee for Medicinal Products for Human Use ("CHMP") granted Tab-cel® accelerated assessment and an EU approval decision is anticipated for the second half of 2022. AlloVir, which is conducting clinical trials for Viralym-M ("ALVR105"), its allogeneic, multi-virus T-cell product that targets six viruses including EBV, is planning to initiate several Phase 2 and Phase 3 trials for the treatment of various viruses, including EBV. Tessa Therapeutics, which has an allogeneic CD30-Chimeric Antigen Receptor ("CAR") EBV-specific T cells ("EBVSTs") for CD30 positive lymphomas in Phase 1, and multiple companies are investigating the use of anti-PD1/PD-L1 antibodies for the treatment of EBV-associated malignancies.

Intellectual property

Viracta endeavors to protect and enhance the proprietary technology, inventions and improvements that are commercially important to its business, including seeking, maintaining and defending its patent rights. Viracta owns and licenses issued patents and patent applications relating to its lead product candidate Nana-val, as well as its other product candidates. Viracta's policy is to seek to protect its proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States directed to its proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of its business. Viracta also relies on trade secrets and know-how relating to its proprietary technology and product candidates and continuing innovation to develop, strengthen and maintain its proprietary position in the field of oncology. Viracta also plans to rely on data exclusivity, market exclusivity and patent term extensions when available. Viracta's commercial success will depend in part on its ability to obtain and maintain patent and other proprietary protection for its technology, inventions and improvements; to preserve the confidentiality of its trade secrets; to defend and enforce its proprietary rights, including any patents that it may own or license in the future; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

As of December 31, 2021 Viracta's patent portfolio consisted of issued patents and pending patent applications that Viracta owns or licenses related to its Nana-val product candidate and various other compounds and programs. Specifically, Viracta owns or licenses four issued U.S. patents, and seven pending U.S. non-provisional patent applications and approximately 55 pending foreign patent applications and issued foreign patents, three of which are international patent applications filed under the Patent Cooperation Treaty ("PCT application") and five of which are European regional patent applications.

More specifically with respect to Nana-val, Viracta owns one issued U.S. patent in its owned portfolio described above that has claims directed to nanatinostat as a composition of matter, as well as claims directed to pharmaceutical compositions comprising nanatinostat. This U.S. patent is expected to expire in January 2027, absent any patent term extensions for regulatory delay. In addition, and specifically with respect to Nana-val, Viracta licenses one issued U.S. patent in its portfolio described above that has claims directed to methods of treatment with Nana-val for the treatment of viral or virally-induced conditions caused by a DNA virus, including EBV. This U.S. patent is expected to expire in March 2031, absent any patent term extensions for regulatory delay. Viracta owns an additional patent related to the dosing schedule for Nana-val that will expire in May 2040, again absent any patent term extensions for regulatory delay.

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

With respect to its product candidates and processes it intends to develop and commercialize in the normal course of business, Viracta intends to pursue patent protection covering, when possible, compositions, methods of use, dosing and formulations. Viracta may also pursue patent protection with respect to manufacturing and drug development processes and technologies.

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

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

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. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. drug development

In the United States, the FDA regulates drugs under the Food, Drug, and Cosmetic Act ("FD&C Act") and its implementing regulations. FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. Drugs also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources, and the expenditure of such resources does not assure that regulatory approval will ultimately be obtained. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-marketing 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, voluntary or mandatory 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 fines or penalties. Any agency or judicial enforcement action could have a material adverse effect on Viracta, market acceptance of Viracta's products, and Viracta's reputation.

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

- completion of nonclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice ("GLP") requirements and International Council for Harmonization ("ICH");
- submission to the FDA of an investigational new drug application ("IND"), which must become effective before human clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent institutional review board ("IRB"), or independent 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 substantial evidence of the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA;
- a determination by the FDA within 60 days of its receipt of an NDA to accept the filing for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug will be produced to assess compliance with current good manufacturing practice ("cGMP") requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the Sponsor company, contract research organizations, and/or clinical trial sites that generated the data in support of the NDA filing;
- payment of user fees for FDA review of the NDA;
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy ("REMS"), a Risk Management Plan and the potential requirement to conduct post-approval studies.

The data required to support an NDA are generated in two distinct developmental stages: preclinical and clinical, both of which may include non-clinical (animal) studies. The preclinical and clinical testing and approval processes require substantial time, effort and financial resources, and Viracta cannot be certain that any approvals for any current and future product candidates will be granted on a timely basis, or at all.

Preclinical studies and IND submission

Before testing any drug product candidate in humans, the product candidate must undergo rigorous preclinical testing. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP and ICH regulations for safety/toxicology studies. The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, 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 IND 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, among other things, 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 transport investigational drug across state lines and must become effective before human clinical trials may begin. 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, which are generally required for FDA approval of an NDA, to commence. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development along with any subsequent changes to the investigational plan. Some long-term nonclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—patent or non-patent—for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

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, physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which are designed to protect the rights, integrity, and confidentiality of research subjects and 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, including the website maintained by the U.S. National Institutes of Health, ClinicalTrials.gov.

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

Clinical trials in the United States generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, that may overlap or be combined in certain circumstances.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, tolerability and safety of the drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.
- Phase 2 clinical trials generally involve studies in disease-affected patients to determine the dose and dosing schedule required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the safety and effectiveness of the product for its intended use and to establish the overall benefit/risk relationship of the product to provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

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 confirmatory clinical trials as a condition of approval of an NDA.

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

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or steering 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 safety studies and also must develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in

commercial quantities in accordance with cGMP requirements. The manufacturing process, as performed by the manufacturing facility, must be capable of consistently producing quality batches of Viracta's product candidates. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that Viracta's product candidates do not undergo unacceptable deterioration over their labeled shelf life.

NDA review process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of nonclinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labeling, chemistry and manufacturing information in a request for approval to market the drug for one or more specified indications.

The application must include both negative and ambiguous results of nonclinical 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 must be obtained before a drug may be legally marketed in the United States.

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

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

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may also 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 also closely analyzes the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, nonclinical studies and/or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than Viracta interprets the same data.

Orphan drugs

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

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

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

Expedited development and review programs

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

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A 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 or effectiveness compared to available therapies.

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

Additionally, a drug may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate a substantial improvement over currently available 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. However, all promotional materials for products receiving such accelerated approval must be precleared by FDA's Office of Prescription Drug Promotion ("OPDP").

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, requirements relating to facility registration and drug listing, monitoring and record-keeping requirements, adverse event and other periodic reporting, product sampling and distribution, and product 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. The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion

of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional manufacturing data or nonclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for REMS, to assure the safe use of the product. If the FDA concludes that a REMS is needed, the NDA sponsor must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. 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.
FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. Manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation, and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, its manufacturer or the NDA holder, including recalls.

The FDA may withdraw approval of a product if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Corrective action could delay drug distribution and require significant time and financial expenditures. 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-marketing 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, suspension of the approval, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications;
- suspension or revocation of product approvals;
- product seizure or detention;
- refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

FDA regulation of companion diagnostics

Safe and effective use of a drug may rely upon an *in vitro* companion diagnostic for use in selecting the patients that will be more likely to respond to that therapy. FDA officials have issued guidance that addresses issues critical to developing in vitro companion diagnostics, such as when the FDA will require that the diagnostic and the drug be approved simultaneously. The guidance issued in August 2014 states that if safe and effective use of a therapeutic product depends on an in vitro diagnostic, then the FDA generally will require approval or clearance of the diagnostic at the same time that the FDA approves the therapeutic product.

The FDA requires that devices, or in vitro companion diagnostics, intended to select the patients who will respond to the treatment to obtain premarket approval, 510(k) clearance, or authorization of a De Novo application, depending on the level of risk presented by the companion diagnostic together with available controls to mitigate the risk. Based on the guidance, and the FDA's past treatment of companion diagnostics, the FDA may require premarket approval, 510(k) clearance, or authorization of a De Novo application of one or more in vitro companion diagnostics to identify patient populations suitable for Viracta's therapeutic drug candidates. The review of these in vitro companion diagnostics in conjunction with the review of Viracta's therapeutic drug candidates involves coordination

of review by the FDA's Center for Drug Evaluation and Research, or CDER, and by the FDA's Center for Devices and Radiological Health, or CDRH, Office of In Vitro Diagnostics Device Evaluation and Safety.

The premarket approval, or PMA, process, including the gathering of clinical and manufacturing data and the submission to and review by the FDA involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are also subject to an application fee.

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

If a new medical device does not qualify for the 510(k) clearance process because no predicate device to which it is substantially equivalent can be identified, the device must submit a PMA application unless the device is eligible for De Novo authorization. The De Novo process allows a manufacturer whose novel device would otherwise require premarket approval to request a risk-based assessment of its medical device to determine whether regulatory controls mitigate the risks of the device to provide a reasonable assurance of the device's safety and effectiveness. The FDA may reject the De Novo application if the FDA identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk and requires PMA or that adequate controls cannot be developed to mitigate the device's risks.

Obtaining FDA premarket approval, 510(k) clearance, or De Novo authorization for medical devices is expensive and uncertain, and may take several years, and generally requires significant scientific and clinical data.

After a device is placed on the market, it remains subject to significant regulatory requirements. Among other requirements, medical devices may be marketed only for the uses and indications for which they are cleared or approved, device manufacturers must establish registration and device listings with the FDA and a medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the Quality System Regulation, or QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA and the FDA also may inspect foreign facilities that export products to the U.S.

Other U.S. regulatory matters

Viracta's current and future arrangements with healthcare providers, third-party payors, customers, and others may expose Viracta to broadly applicable fraud and abuse and other healthcare laws and regulations, which may affect the business or financial arrangements and relationships through which Viracta researches, sells, markets, and distributes any products for which Viracta obtains marketing approval. The applicable federal, state and foreign healthcare laws and regulations that may affect Viracta ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug or medical device manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the government may assert that a claim for health care items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal criminal False Claims Act and Civil Monetary Penalties Laws, and the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, and/or impose exclusions from federal health care programs and/or penalties for parties who engage in such prohibited conduct;
- the Federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, also imposes obligations including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the FD&C Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to Centers for Medicare & Medicaid Services ("CMS") information regarding payments and other transfers of value to physicians, teaching hospitals, and other healthcare professionals as well as information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and require the registration of their sales representatives, state laws that require biotechnology companies to report information on the pricing of certain drug products, and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"). If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws. In addition, the distribution of pharmaceutical and/or medical device 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 and/or medical device products. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act as well as other applicable consumer safety requirements.

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

U.S. patent-term restoration and marketing exclusivity

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

Market exclusivity provisions under the FD&C Act also can delay the submission or the approval of certain applications. The FD&C Act provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA"), or a 505(b)(2) NDA submitted by another company for a generic version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FD&C Act 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 nonclinical studies, chemistry, manufacturing and controls data and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness or generate such data themselves.

European Union drug development

Similar to the United States, the various phases of preclinical and clinical research (including any non-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 Ethics Committees ("ECs"). Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the EU will be identical. In the meantime, Clinical Trials Directive 2001/20/EC continues to govern all clinical trials performed in the EU.

European Union drug review and approval

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

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use ("CHMP"), of the EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the European Union, 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, EMA or the competent authorities of the Member States of the European Union make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. Similar to the U.S. patent term-restoration, Supplementary Protection Certificates ("SPCs") serve as an extension to a patent right in Europe for up to five years. SPCs apply to specific pharmaceutical products to offset the loss of patent protection due to the lengthy testing and clinical trials these products require prior to obtaining regulatory marketing approval.

Coverage and reimbursement

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

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

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 Viracta 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 Viracta's products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Healthcare reform

The United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, in March 2010, the ACA, was passed which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the HHS Secretary as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price ("AMP"), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Additionally, for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government

agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial, Congressional and executive branch challenges to certain aspects of the ACA. The Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare Part D drug plans. In December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Although Viracta is aware of no pending constitutional challenges to the ACA, there is no certainty that further legal challenges will not be brought nor can there be any certainty of their outcome.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2029 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for Viracta's products, if approved, and accordingly, Viracta's financial operations.

Additionally, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. For example, at the federal level, the Trump administration released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. Additionally, on November 20, 2020, HHS Office of Inspector General ("OIG") issued a final rule eliminating the federal Anti-Kickback Statute safe harbors for rebates paid by manufactures to Medicare Part D plan sponsors, Medicaid managed care organizations, and those entities' pharmacy benefit managers, the purpose of which is to further reduce the cost of drug products to consumers. The OIG created two new safe harbors for certain point-of-sale reductions in price on prescription pharmaceutical products and certain pharmacy benefit manager service fees. On December 2, 2020, OIG and CMS each issued a final rule that set forth modifications to the federal Anti-Kickback Statute, Civil Monetary Penalties Law and Physician Self-Referral Law (or the Stark Law) (respectively) regulations to remove regulatory barriers to value-based care arrangements. CMS's final rule also clarifies and updates certain long-standing terms that appear throughout the Stark Law regulations. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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 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 Viracta receives marketing approval. However, any negotiated prices for Viracta's products covered by a Part D prescription drug plan likely will be lower than the prices Viracta might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private third-party payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. In addition, in September 2020, President Trump signed an executive order entitled "Lowering Drug Prices by Putting America First" (the "MFN Executive Order"). The MFN Executive Order provides that it is "the policy of the United States that the Medicare program should not pay more for costly Part B or Part D prescription drugs or biological products than the most-favored-nation price" within the member countries of the Organization for Economic Co-operation and Development (the "MFN Price"); and directs the Secretary of the HHS to implement rulemaking to test a payment model pursuant to which Medicare would pay no more than the MFN Price for certain drugs covered by Medicare Parts B and D. While the scope, details, and implementation of these contemplated executive actions (including whether and how their mechanism may differ from that of the proposed IPI drug pricing program discussed above) are not clear, this continues to signal that the U.S. administration intends to pursue new measures to constrain drug

costs and Medicare payments for drugs. Similarly, various members of the current U.S. Congress have indicated that lowering drug prices continues to be a legislative and political priority, and some have introduced proposals aimed at drug pricing.

Human Capital

As of December 31, 2021, we employed 24 full-time employees. Our employees comprised 16 in research and development and 8 in general and administrative capacities. As of such date, all our employees were based in the United States. We also engage temporary consultants and contractors. All of our employees are at-will employees, which means that each employee can terminate his or her relationship with us and we can terminate our relationship with him or her at any time and none of our employees are represented by a labor union with respect to his or her employment with us.

We believe our employees are the driving force to achieving our business goals and growth strategy and we continuously monitor our demand for capable and talented people to support our mission. We invest in our employees through high-quality benefits, competitive compensation packages and practicing fair compensation practices. For our talent pipeline development, we work closely with individual business functions to provide training and hands-on support for managers and leaders, to assess talent and identify development opportunities. Our human capital strategy is overseen at the highest levels of our organization, from the Board of Directors and across our senior management.

Our Code of Business Conduct and Ethics ensures that our core values of respect, integrity, collaboration, innovation, trust, and excellence are applied throughout our operations. Our Code of Business Conduct and Ethics serves as a critical tool to help all of us recognize and report unethical conduct, while preserving and nurturing our culture of honesty and accountability.

Corporate Information

Viracta Therapeutics, Inc. (“Viracta,” the “Company,” or the “combined company”), formerly known as Sunesis Pharmaceuticals, Inc., was incorporated in the state of Delaware in February 1998 and is based in San Diego, California. Our principal executive offices are located at 2533 S. Coast Hwy. 101, Suite 210, Cardiff, California 92007. Our telephone number is (858) 400-8470. Our website address is https://www.viracta.com. Information contained on the website is not incorporated by reference into this Annual Report on Form 10-K or any other filings we make with the SEC.

We may announce material information to the public through filings with the SEC, our website, press releases, public conference calls, and public webcasts. We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the SEC in accordance with the Securities Exchange Act of 1934, as amended (“Exchange Act”). These include our Annual Reports on Form 10-K, our quarterly reports on Form 10-Q, and our current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC.

Item 1A. Risk Factors.

We operate in a rapidly changing environment that involves numerous uncertainties and risks. In addition to the other information included in this Annual Report on Form 10-K, the following risks and uncertainties may have a material and adverse effect on our business, financial condition, results of operations, or stock price. You should consider these risks and uncertainties carefully, together with all of the other information included or incorporated by reference in this Annual Report on Form 10-K. The risks and uncertainties described below may not be the only ones we face. If any of the risks or uncertainties we face were to occur, the trading price of our securities could decline, and you may lose all or part of your investment. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report.

Risk factors include, but are not limited to, statements concerning the following:

Risks related to our financial position:

- our limited operating history and no products approved for commercial sale;
- we have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future;
- our ability to generate revenue and achieve profitability; and
- we will require additional capital to fund our operations and if we fail to obtain necessary financing, we will not be able to complete the development and commercialization of our product candidates.

Risks related to the discovery, development and commercialization of our product candidates:

- our future success is highly dependent on future revenues from our lead product candidate, nanatinostat in combination with valganciclovir ("Nana-val"), and we may be unable to complete development of, obtain approval for and commercialize Nana-val;
- there may be delays in completing the clinical trials for Nana-val in Epstein-Barr virus-positive ("EBV^+") lymphomas and solid tumors, which may lead to a delay in commercializing Nana-val and our development costs increasing;
- clinical development is a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidate;
- our product candidates may not demonstrate safety and efficacy to the satisfaction of the U.S. Food and Drug Administration (the "FDA"), European Medicines Agency (the "EMA") or other comparable foreign regulatory authorities or otherwise produce positive results;
- our future clinical trials may reveal significant adverse events not seen in its preclinical studies or other clinical trials and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of its product candidate;
- any positive results from early preclinical studies and clinical trials are not necessarily predictive of the results of any future clinical trials;
- interim top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data;
- if we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected;
- risks associated with public health threats and epidemics, including the COVID-19 pandemic and related public health emergency;
- we are developing Nana-val, which is a combination containing a product developed and commercialized by parties other than us and approved outside of oncology, which exposes us to additional risks;
- we may develop Nana-val or other product candidates in combination with other therapies, which exposes us to additional risks;

- if we are required by the FDA to obtain approval of a companion diagnostic test in connection with approval of Nana-val or any of our other product candidates, and we do not obtain or face delays in obtaining FDA approval of a diagnostic device, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired;
- we have limited resources and are currently focusing our efforts on developing Nana-val for particular indications and advancing our preclinical programs which may cause us to fail to capitalize on other product candidates that may be more profitable;
- our competitors could develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the products we develop, our commercial opportunities will be negatively impacted;
- changes in methods of product candidate manufacturing or formulation may result in additional costs or delay;
- our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success;
- the market opportunities for our products;
- our ability to grow our product pipeline; and
- our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.

Risks related to the regulatory environment:

- extensive federal and state regulation related to our business by numerous government agencies, including the FDA;
- we may not be able to obtain or maintain orphan drug designation or obtain or maintain orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA, EMA or other comparable foreign regulatory authorities, from approving competing products;
- the potential difficulties from changes to current regulations and future legislation;
- the potential need to seek additional clearances or approvals for our products; and
- potential FDA or state regulatory enforcement action.

Risks related to employee matters, managing our growth, and other risks related to our business:

- our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees;
- the possibility that we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates;
- the potential difficulties growing the size of our organization; and
- federal income tax reform could materially adversely affect our financial condition.

Risks related to our intellectual property:

- our ability to secure and maintain patent or other intellectual property protection for the intellectual property used in our proprietary technologies;
- the possibility that any of our patents may be challenged, invalidated, circumvented or rendered unenforceable; and
- patent and other intellectual property litigation if our products infringe or appear to infringe the intellectual property rights of others.

Risks related to our common stock:

- the volatility of the trading price of our common stock;
- the publication of research reports by securities or industry analysts;
- potential sales of a large number of shares of our common stock;

- anti-takeover provisions in our charter documents and under Delaware law; and
- our intention not to pay dividends for the foreseeable future.

Risks Related to our Financial Position and Need for Additional Capital

We have a limited operating history, have not initiated or completed any large-scale or pivotal clinical trials, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We have no products approved for commercial sale and have not generated any revenue. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We are currently conducting three clinical trials for our lead product candidate, Nana-val, in EBV^+ lymphomas and EBV^+ solid tumors. To date, we have devoted substantially all of our resources to research and development activities, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these operations.

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

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical-stage biopharmaceutical companies in rapidly evolving fields. We may also need to transition from a company with a research and development focus to a company capable of supporting commercial activities. 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.

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

We have incurred significant net losses since our inception, have not generated any revenue from product sales to date and have financed our operations principally through private placements of our convertible preferred and common stock. Our net loss was $114.8 million for the year ended December 31, 2021. As of December 31, 2021, we have an accumulated deficit of $165.7 million. Our lead product candidate, Nana-val, is in multiple ongoing clinical trials. Our other programs are in preclinical discovery and research stages. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products.

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 prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to fund the development of our product candidates, and our ability to achieve and maintain profitability and the performance of our stock.

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

Our business depends entirely on the successful discovery, development and commercialization of product candidates. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales for the next several years, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability, or any current or future collaborator's ability, to achieve several objectives, including:

- successful and timely completion of preclinical and clinical development of our lead product candidate, Nana-val, and our other future product candidates;
- establishing and maintaining relationships with contract research organizations ("CROs") and clinical sites for the clinical development of Nana-val and our other future product candidates;

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

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

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

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for, Nana-val. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA, the EMA or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. In addition, if we obtain marketing approval for any of our product candidates, including Nana-val, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. We are not permitted to market or promote Nana-val, or any other product candidate, in the U.S. before it receives marketing approval from the FDA. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of December 31, 2021, we had $103.6 million in cash and cash equivalents. Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to fund our planned operating expenses and capital expenditures into

mid-2024. Our estimate as to how long we expect our existing cash and cash equivalents to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We plan to use the existing cash and cash equivalents to fund our ongoing and planned clinical trials of Nana-val and to fund our other research and development activities, as well as for working capital and other general corporate purposes. Advancing the development of Nana-val and any other product candidate will require a significant amount of capital. The existing cash and cash equivalents will not be sufficient to fund all of the activities that are necessary to complete the development of Nana-val.

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. Pursuant to the terms of the loan and security agreement between us and Silicon Valley Bank ("SVB") and Oxford Finance LLC ("Oxford"), dated November 4, 2021, (the "SVB-Oxford Loan Facility"), we have borrowed $5.0 million and may be eligible to borrow up to an additional $45.0 million. The additional financing available under the SVB-Oxford Loan Facility is not expected to be sufficient to fund our future operations.

In addition, on May 28, 2021, we entered into an Open Market Sale Agreement℠ (the "Sale Agreement") with Jefferies LLC (the "Sales Agent"), under which we may offer and sell up to $50.0 million of shares (the "Shares") of our common stock from time to time through the Sales Agent. The sales and issuances, if any, of the Shares by us under the Sale Agreement will be pursuant to our "shelf" registration statement on Form S-3, filed with the Securities and Exchange Commission ("SEC") on May 28, 2021 and declared effective by the SEC on June 4, 2021, pursuant to which we registered the offering, sale and issuance of up to $200.0 million in aggregate of our common stock, preferred stock, warrants, subscription rights, debt securities and/or units from time to time in one or more offerings, none of which has been sold as of the date of filing this Annual Report on Form 10-K. The Sales Agent is not required to sell any specific amount of securities, but will act as our sales agent using commercially reasonable efforts to sell the Shares from time to time, consistent with its normal trading and sales practices, applicable state and federal laws, rules and regulations and the rules of The Nasdaq Stock Market, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We have agreed to pay the Sales Agent a commission equal to 3.0% of the aggregate gross proceeds from each sale of Shares pursuant to the Sale Agreement and to provide the Sales Agent with customary indemnification and contribution rights, including for liabilities under the Securities Act. The Sales Agent's obligations to sell the Shares under the Sale Agreement are subject to satisfaction of certain conditions, including customary closing conditions. We are not obligated to sell any of the Shares under the Sale Agreement and may at any time suspend solicitation and offers under the Sale Agreement. The Sale Agreement may be terminated by us at any time by giving 10 days' written notice to the Sales Agent for any reason or by the Sales Agent at any time by giving 10 days' written notice to us for any reason or immediately under certain circumstances, and shall automatically terminate upon the issuance and sale of all of the Shares. As of the date of filing this Annual Report on Form 10-K, no Shares have been issued pursuant to the Sales Agreement, and there is no guarantee that we will seek to or be successful in raising meaningful funding under the Sales Agreement. Even if we sell all of the Shares under the Sales Agreement, the proceeds from such sales are not expected to be sufficient to fund our future operations.

Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, including but not limited to any sales under the Sales Agreement, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we seek to raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, such as our license agreement with ImmunityBio, Inc., we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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

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

We are substantially dependent on the success of our lead product candidate, Nana-val. If we are unable to complete development of, obtain approval for and commercialize Nana-val for one or more indications in a timely manner, our business will be harmed.

Our future success is dependent on our ability to timely and successfully initiate and complete clinical trials, obtain marketing approval for and successfully commercialize Nana-val, our lead product candidate, for which, in June 2021, we announced the

initiation of a Phase 2 clinical trial in EBV$^+$ lymphoma and in October 2021, we announced the initiation of a Phase 1b/2 clinical trial in EBV$^+$ solid tumors. We are investing the majority of our efforts and financial resources in the research and development of Nana-val for multiple indications. Our lead product candidate is a combination product candidate consisting of nanatinostat, a potent and selective small molecule inhibitor of class I histone deacetylases ("HDAC"), and valganciclovir, an FDA-approved anti-viral drug used to treat and prevent disease caused by a virus called cytomegalovirus ("CMV") in people who have received organ transplants. In 2021, we reported final data from a Phase 1b/2 clinical trial evaluating Nana-val in patients with relapsed/refractory EBV$^+$ lymphomas. Prior to these clinical trials, nanatinostat has been evaluated in one previous clinical trial as a monotherapy. Nana-val will require additional clinical development, expansion of manufacturing capabilities, marketing approval from government regulators, substantial investment and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote Nana-val, or any other product candidate, before it receives marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of the Nana-val product candidate will depend on several factors, including the following:

- the successful and timely initiation and completion of our ongoing and planned clinical trials of Nana-val;
- addressing any delays in our clinical trials and additional costs incurred, including as a result of the coronavirus-19 ("COVID-19") pandemic, those resulting from preclinical study delays and adjustment to our clinical trials;
- the initiation and successful patient enrollment and completion of additional clinical trials of Nana-val on a timely basis, including the trial of Nana-val in patients with relapsed/refractory EBV$^+$ lymphomas, and addressing any delays in enrollment and site initiation;
- maintaining and establishing relationships with CROs and clinical sites for the clinical development of Nana-val both in the United States and internationally;
- the type, frequency and severity of adverse events in clinical trials;
- demonstrating efficacy, safety and tolerability profiles that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval;
- the timely receipt of marketing approvals for Nana-val from applicable regulatory authorities;
- the timely identification, development and approval of companion diagnostic tests, if required;
- maintaining compliance with applicable regulatory and quality requirements;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers for clinical development and, if approved, commercialization of Nana-val;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- the protection of our rights in our intellectual property portfolio;
- the successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

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

If there are delays in completing our clinical trials for Nana-val, including NAVAL-1, we will be delayed in commercializing Nana-val, our development costs may increase, and our business may be harmed.

In June 2021, we announced the initiation of NAVAL-1, a global, multicenter, open-label Phase 2 basket trial, in relapsed/refractory EBV$^+$ lymphomas. Following the initiation of NAVAL-1, we have faced challenges in site engagement and timely site initiations, in

large part due to staffing shortages and the overall impact of the COVID-19 pandemic. Our product development costs could increase if we continue to experience delays in this or other trials. Significant trial delays also could shorten any periods during which we may have the exclusive right to commercialize Nana-val or allow our competitors to bring products to market before we do, which would impair our ability to successfully capitalize on Nana-val and may harm our business, results of operations and prospects. Additional events that may result in a delay or unsuccessful completion of clinical development of Nana-val include, among other things:

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

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

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

In addition to Nana-val, our future operating results are dependent in part on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates other than Nana-val. Our product candidate pipeline also includes vecabrutinib, a clinical-stage product candidate, and VRx-510, a preclinical product candidate. We may explore future treatment therapies with vecabrutinib and continue to evaluate development opportunities with VRx-510. A product candidate can unexpectedly fail at any stage of preclinical and/or clinical development. For example, in the case of vecabrutinib, Sunesis decided not to move the program into Phase 2 after assessing the totality of the data including the 500 mg cohort, the highest dose studied in the trial, as Sunesis found insufficient evidence of activity in BTK inhibitor resistant-disease. 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 other 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;
- addressing any delays in our research programs resulting from factors related to the COVID-19 pandemic;
- obtaining regulatory and ethical committee permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of a product candidate for use in clinical trials; and
- adverse events in clinical trials.

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

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

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

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 2013, 2018 and 2019, or diversion of resources to currently handle the COVID-19 public health emergency and pandemic may result in significant reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. In addition, the impact of COVID-19 may cause the FDA to allocate additional resources to product candidates focused on treating related illnesses, which could lead to longer approval processes for our product candidates. Finally, our competitors may file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical trials that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any of our NDAs.

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

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

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

The clinical trials of our product candidates may not demonstrate safety and efficacy to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities or otherwise produce positive results.

Before obtaining marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate with substantial evidence the safety and efficacy of such 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.

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 it to conduct additional clinical trials or abandon certain drug development programs;
- the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated or participants dropping out of these clinical trials at a higher rate than anticipated;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements or a finding that our product candidates have undesirable side effects or other unexpected characteristics or risks;
- the cost of clinical trials of our product candidates being greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate;
- we may experience further delays due to the recent COVID-19 pandemic, including with respect to submission of NDAs, filing of investigational new drug (“IND”) applications and starting any clinical trials for other indications or programs; and
- regulators revising the requirements for approving our product candidates.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing in a timely manner, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may incur unplanned costs, be delayed in seeking and obtaining marketing approval if we receive such approval at all, receive more limited or restrictive marketing approval, be subject to additional post-marketing testing requirements or have the drug removed from the market after obtaining marketing approval.

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

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs, we may need to conduct additional studies to further evaluate the product candidates’ safety, interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may

prevent us from obtaining regulatory approval, achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly. For example, in our ongoing Phase 1b/2 of Nana-val, while most treatment-related adverse events were mild or moderate, most commonly thrombocytopenia, nausea, neutropenia and fatigue, there were instances of Grade 3/4 treatment related adverse events: neutropenia, anemia, and nausea.

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

If further significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, EMA, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects. Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates previously not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

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

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

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain approval to market any of our product candidates.

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

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials, such as the preliminary data from our ongoing Phase 1b/2 clinical trial of Nana-val in patients with EBV^+ solid tumors. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, we may report tumor responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

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

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

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. For instance, patients for our trials are screened using EBV-positivity, which can be determined by the presence of EBV-encoded RNA ("EBER"), as detected by in situ hybridization, and utilizing such biomarker-driven identification and/or certain highly specific criteria related to the cancer sub-types may limit patient populations eligible for our clinical trials. If our strategies for patient identification prove unsuccessful, it may have difficulty enrolling or maintaining patients appropriate for Nana-val.

Enrollment of patients in our clinical trials and maintaining patients in our ongoing clinical trials may be delayed or limited as our clinical trial sites limit their onsite staff or temporarily close as a result of the COVID-19 pandemic. For instance, we have experienced an impact on the timing of clinical site initiations as a result of the COVID-19 pandemic, and we are aware of certain Nana-val clinical trial sites that temporarily stopped or delayed enrolling new patients in response to the COVID-19 pandemic. In addition, patients may not be able to visit clinical trial sites for dosing or data collection purposes due to limitations on travel and physical distancing imposed or recommended by federal or state governments or patients' reluctance to visit the clinical trial sites during the pandemic. These factors resulting from the COVID-19 pandemic could delay the anticipated readouts from our Nana-val clinical trials and our regulatory submissions.

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

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;

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

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

Our operations and financial results could be adversely impacted by the ongoing COVID-19 pandemic in the United States and the rest of the world.

In December 2019, COVID-19 was reported to have surfaced in Wuhan, China, resulting in significant disruptions to Chinese manufacturing and travel. COVID-19 has become a global pandemic, and as a result of measures imposed by the governments in affected regions, many commercial activities, businesses and schools were suspended as part of quarantines and other measures intended to contain this pandemic, and some continue to be limited. As the COVID-19 pandemic continues to persist, we may experience further disruptions that could severely impact our business and clinical trials, including:

- interruption of key research and discovery or other activities related to any impact of COVID-19 contraction by or transmission among our employees, including those that are essential workers and work within our laboratory;
- delays or difficulties in enrolling patients in our clinical trials, or those conducted by third parties, and further incurrence of additional costs as a result of preclinical study and clinical trial delays and adjustments;
- challenges related to ongoing and increased operational expenses related to the COVID-19 pandemic;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and availability of clinical site staff;
- 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 that would otherwise be focused on the conduct of our business or our clinical trials, including because of sickness or the desire to avoid contact with large groups of people or as a result of government-imposed "shelter in place" or similar working restrictions;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- 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, or to discontinue the clinical trials altogether, or which may result in unexpected costs; and
- 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.

We will continue to assess the impact that COVID-19 may have on our ability to effectively conduct our business operations as planned and there can be no assurance that we will be able to 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. For example, on March 19, 2020, the Executive Department of the State of California issued Executive Order N-33-20, ordering all individuals in the State of California to stay home or at their place of residence except as needed to maintain continuity of operations of the federal critical infrastructure sectors. These orders were in place until August 28, 2020. Should COVID-19 cases in California continue to increase, the country or state may re-institute a "shelter in place" order at any time. On June 19, 2020, the FDA also issued new guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in biopharmaceutical products manufacturing. Our primary operations are located in San Diego County. As a result of such county and California state orders and FDA guidance, many of our employees are currently telecommuting, and modified schedules and work protocols to enable adequate physical distancing may impact certain of our operations over the near term and long term. Disruptions caused by the COVID-19 pandemic have also resulted in the incurrence of increased operational expenses. Should these developments continue or worsen, our operations and our program timelines may be negatively impacted and could result in the incurrence of additional costs.

Additionally, certain third parties with whom we engage, including our collaborators, contract organizations, third party manufacturers, suppliers, clinical trial sites, regulators and other third parties with whom we conduct business are similarly adjusting their operations and assessing their capacity in light of the COVID-19 pandemic. If these third parties experience shutdowns or 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, we have experienced an impact on the timing of clinical site initiations as a result of the COVID-19 pandemic. While we have taken certain measures and continue to evaluate other potential measures to mitigate the impact of the COVID-19 pandemic on our trials, there is no guarantee we will be successful in these mitigation efforts. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. In addition, as a result of the COVID-19 pandemic, there could be delays in the manufacturing supply chain for Nana-val, which could delay or otherwise impact our Nana-val clinical trials. We and our 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 on March 18, 2020 and generally, and may need to make further adjustments in the future, including adjustments based on recently issued FDA guidance on manufacturing, supply chain, and pharmaceutical product inspections; resuming normal pharmaceutical manufacturing operations; and updates on conducting clinical trials during the COVID-19 public health emergency. Many of these adjustments are new and untested, may not be effective, 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, we may not be successful in adding trial sites, may experience delays in patient enrollment or in the progression of our clinical trials, may need to suspend our clinical trials, and may encounter other negative impacts to our trials, due to the effects of the COVID-19 pandemic.

The global pandemic of COVID-19 continues to rapidly evolve. While the extent of the impact of the current 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, financial condition and operating results, it may also have the effect of heightening many of the risks described in this "Risk factors" section.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by affected countries and others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

We are developing Nana-val, which is a combination containing a product developed and commercialized by parties other than us and approved outside of oncology, which exposes us to additional risks.

We are developing Nana-val, which is a combination product candidate containing valganciclovir. Valganciclovir is an anti-viral that is approved by the FDA for the treatment and prevention of CMV retinitis in the setting of acquired immunodeficiency syndrome ("AIDS") and post-solid organ transplantation, but valganciclovir is currently not approved for the treatment of cancers. The first generic version of valganciclovir was first approved in 2014. We currently have multiple ongoing clinical studies evaluating nanatinostat and valganciclovir in combination to evaluate its efficacy in patients with relapsed/refractory EBV^+ malignancies. Patients may not be able to tolerate nanatinostat or valganciclovir in combination with each other or may have unexpected consequences. Even if the nanatinostat and valganciclovir combination were to receive marketing approval or be commercialized for the treatment of cancers, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of valganciclovir, or safety, efficacy, manufacturing or supply issues could arise with valganciclovir. This could result in the need to identify other antiviral drug candidates or Nana-val being removed from the market or being less successful commercially. If the FDA, EMA or other comparable foreign regulatory authorities do not revoke their approval of valganciclovir, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with valganciclovir, we may be unable to obtain approval of or successfully market Nana-val.

Additionally, if the third-party providers of valganciclovir are unable to produce sufficient quantities for clinical trials or for commercialization of Nana-val, if the cost become prohibitive, or if our third-party providers are unable to meet applicable regulatory requirements, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. For example, for our ongoing clinical trials of Nana-val, we have entered into supply agreements with third-party manufacturers who currently market a generic version of valganciclovir. If these agreements terminate and we are unable to obtain valganciclovir on the current terms we have negotiated with third parties, the cost to us to conduct this trial may significantly increase or we may be unable to complete future clinical trials.

We may develop Nana-val or other product candidates in combination with other therapies, which exposes us to additional risks.

We may develop Nana-val or other product candidates, in combination with one or more currently approved cancer therapies or therapies in development. Patients may not be able to tolerate Nana-val or any of our other product candidates in combination with other therapies or dosing of Nana-val in combination with other therapies may have unexpected consequences. Even if any of our product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates, or our own products being removed from the market or being less successful commercially.

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

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

If we are required by the FDA to obtain approval of a companion diagnostic test in connection with approval of Nana-val or any of our other product candidates, and we do not obtain or face delays in obtaining FDA approval of a diagnostic device, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication.

One common method used by investigators in our clinical trials to determine EBV positivity of lymphomas is EBV in situ hybridization for EBV encoded RNA ("EBER-ISH"). If the FDA requires a companion diagnostic for the approval of Nana-val and a satisfactory companion diagnostic is not approved and commercially available, we may be required to create or obtain one that would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostic is time consuming and costly.
Companion diagnostics are developed in conjunction with clinical programs for the associated therapeutic product candidate and are subject to regulation as medical devices by the FDA and comparable regulatory authorities, and, to date, the FDA has required premarket approval or clearance of all companion diagnostics for cancer therapies. The approval or clearance of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express the specific genetic alteration that the companion diagnostic was developed to detect.

If the FDA or a comparable foreign regulatory authority requires approval or clearance of a companion diagnostic for any of our product candidates, whether before or after it obtains marketing approval, we, and/or future collaborators, may encounter difficulties in developing and obtaining approval for such product candidate. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval or clearance of a companion diagnostic could delay or prevent approval or continued marketing of such product candidate.

We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidate, if approved, on a timely or profitable basis, if at all.

We have limited resources and are currently focusing our efforts on developing Nana-val for particular indications and advancing our preclinical programs. As a result, we may fail to capitalize on other indications or product candidates that may ultimately have proven to be more profitable.

We are currently focusing the majority of our resources and efforts on developing Nana-val for particular indications and advancing our preclinical programs. As a result, because we have limited resources, we may forgo or delay pursuit of opportunities for other indications or with other product candidates that may have greater commercial potential or may utilize our limited resources on research and development activities that do not yield a viable product candidate. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development activities for Nana-val and other programs may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target markets for Nana-val or any of our other programs, we may relinquish valuable rights to that product candidate or program through collaboration, licensing or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or program.

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

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

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

We are not aware of any FDA- or EMA-approved products for the treatment of EBV^+ lymphomas. Patients with EBV^+ lymphomas receive standard of care therapies for their particular lymphoma subtype. Several HDAC inhibitors have demonstrated clinical antitumor activity, with four currently approved by the FDA for oncology indications. These are vorinostat for the treatment of cutaneous T cell lymphoma, romidepsin for the treatment of cutaneous T-cell lymphoma, belinostat for the treatment of peripheral

T-cell lymphoma, and panobinostat for the treatment of multiple myeloma. In addition, a number of companies and academic institutions are developing drug candidates for EBV-associated PTLD and other EBV-associated diseases including: Atara Biotherapeutics, Inc., which is conducting a Phase 3 clinical trial and recently filed a MAA in the EU for Tab-cel®, a product for virus-associated EBV. The EMA's Committee for Medicinal Products for Human Use (CHMP) granted Tab-cel® accelerated assessment and an EU approval decision is anticipated for the second half of 2022. AlloVir, which is conducting clinical trials for Viralym-M (ALVR105), its allogeneic, multi-virus T-cell product that targets six viruses including EBV, is planning to initiate several Phase 2 and Phase 3 trials for the treatment of various viruses, including EBV. Tessa Therapeutics, which has an allogeneic CD30-Chimeric Antigen Receptor (CAR) EBV-specific T cells (EBVSTs) for CD30 positive lymphomas in Phase 1, and multiple companies are investigating the use of anti-PD1/PD-L1 antibodies for the treatment of EBV-associated malignancies. Many of these current and potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources, and commercial expertise than us. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA, EMA or other comparable foreign regulatory authorities or in discovering, developing and commercializing products in our field before we do.

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

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

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

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

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

delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

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

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

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

The market opportunities for Nana-val and other product candidates we develop, if approved, may be limited to certain smaller patient subsets.

Cancer therapies are sometimes characterized as first-line, second-line or third line, and the FDA often approves new therapies initially only for a particular line of use. When cancer is detected early enough, first-line therapy, such as chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. Our ongoing and planned clinical trials for Nana-val are with patients who have received one or more prior treatments. There is no guarantee that product candidates that we develop, even if approved, would be approved for first-line or second-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials that may be costly, time-consuming and subject to risk.

The number of patients who have the cancers we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for Nana-val and other product candidates may be limited or may not be amenable to treatment with our product candidates. Regulatory approval may limit the market of a product candidate to target patient populations when such biomarker-driven identification and/or highly specific criteria related to the stage of disease progression are utilized. Even if we obtain significant market share for any approved product, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications.

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

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

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

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

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("HHS") decides whether and to what extent a new product will be covered and reimbursed under Medicare. Private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

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

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

Outside the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the 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 product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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

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

Risks Related to Regulatory Approval and Other Legal Compliance Matters

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

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

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

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

certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

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

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

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

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

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

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

On June 23, 2016, the United Kingdom (“U.K.”) held a referendum in which voters approved an exit from the European Union, commonly referred to as “Brexit.” This decision created an uncertain political and economic environment in the U.K. and other European Union countries, and the formal process for leaving the European Union has taken years to complete. The U.K. formally left the European Union on January 31, 2020 and began a transition period which expired on December 31, 2020.

In December 2020, the U.K. and the European Union agreed on a trade and cooperation agreement, under which the U.K. and the European Union will now form two separate markets governed by two distinct regulatory and legal regimes. The trade and cooperation agreement covers the general objectives and framework of the relationship between the U.K. and the European Union, including as it relates to trade, transport and visas. Notably, under the trade and cooperation agreement, U.K. service suppliers no longer benefit from automatic access to the entire European Union single market, U.K. goods no longer benefit from the free movement of goods and there is no longer the free movement of people between the U.K. and the European Union. Depending on the application of the terms of the trade and cooperation agreement, we could face new regulatory costs and challenges.

Adverse consequences concerning Brexit or the future of the European Union could include deterioration in global economic conditions, instability in global financial markets, political uncertainty, volatility in currency exchange rates or adverse changes in the cross-border agreements currently in place, any of which could have an adverse impact on our financial results in the future.

Since the regulatory framework for pharmaceutical products in the United Kingdom relating to quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit will materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom. In the first instance, a separate United Kingdom authorization from any centralized authorization for the EU would need to be applied for in advance of a hard Brexit or before the end of any agreed transition period. In the immediately foreseeable future, the process is likely to remain very similar to that applicable in the EU, albeit that the processes for applications will be separate. Longer term, the United Kingdom is likely to develop its own legislation that diverges from that in the EU.

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

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

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

Moreover, the FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates, if approved, and generate revenue.

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

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

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

In November 2019, we announced that the FDA granted Fast Track designation for Nana-val for the treatment of relapsed/refractory EBV^+ lymphoid malignancies. This Fast Track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures or that we will ultimately obtain regulatory approval of Nana-val. Even though we received this Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw the Fast Track designation if it believes that the Fast Track designation is no longer supported by data from our clinical development program. We may also seek Fast Track designation for additional cancer indications, and we may not be successful in securing such additional designation or in expediting development if such designations were received.

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

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

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

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

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

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

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

We received orphan drug designation from the FDA for Nana-val for the treatment of EBV^+ DLBCL, NOS, PTLD, plasmablastic lymphoma, and T-cell lymphomas. We may be unable to obtain regulatory approval for Nana-val for these orphan populations or any other orphan population, or we may be unable to successfully commercialize Nana-val for such orphan populations due to risks that include:

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

If we are unable to obtain regulatory approval for Nana-val for any orphan population or are unable to successfully commercialize Nana-val for such orphan population, it could harm our business prospects, financial condition and results of operations.

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

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for our one or more of our product candidates. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

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

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

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

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), was passed, which substantially changed the way healthcare is financed by both the government and private insurers and continues to significantly impact the U.S. pharmaceutical industry. Since its enactment, there have been legislative and judicial efforts to repeal, replace, or change some or all of the ACA. For example, various portions of the ACA have been subject to legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court. The Supreme Court held oral arguments on the Fifth Circuit Court case in November 2020 and, on June 17, 2021, the Supreme Court dismissed this case after finding that plaintiffs do not have standing to challenge the constitutionality of the ACA. It is unclear how future litigation and healthcare measures promulgated by the Biden administration will impact the implementation of the ACA, our business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which will stay in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2022. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012,

which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our product candidates, if approved, and accordingly, our financial operations.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, HHS and CMS issued final rules in November and December of 2020 that were expected to impact, among others, price reductions from pharmaceutical manufacturers to plan sponsors under Part D, fee arrangements between pharmacy benefit managers and manufacturers, manufacturer price reporting requirements under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Multiple lawsuits have been brought against the HHS challenging various aspects of the rules. The impact of these lawsuits as well as legislative, executive, and administrative actions of the current administration on us and the pharmaceutical industry as a whole is currently unknown. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

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

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates. It is also possible that additional governmental action is taken to address the COVID-19 pandemic.

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

Additionally, the collection and use of health data in the European Union is governed by the General Data Protection Regulation (“GDPR”), which extends the geographical scope of European Union data protection law to non-European Union entities under certain conditions and imposes substantial obligations upon companies and new rights for individuals. Failure to comply with the GDPR and the applicable national data protection laws of the EU Member States may result in fines up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. The GDPR may increase our responsibility and liability in relation to personal data that we may process, and we may be required to put in place additional mechanisms in an effort to comply with the GDPR. This may be onerous and if our efforts to comply with GDPR or other applicable European Union laws and regulations are not successful, it could adversely affect our business in the European Union. Further, the European Court of Justice (“ECJ”) recently invalidated the EU-U.S. Privacy Shield, which had enabled the transfer of personal data from the EU to the U.S. for companies that had self-certified to the Privacy Shield. To the extent that we were to rely on Privacy Shield, we will not be able to do so in the future, and the ECJ’s decision otherwise may impose additional obligations with respect to the transfer of personal data from the EU to the U.S., each of which could increase our costs and obligations and impose limitations upon our ability to efficiently transfer personal data from the EU to the U.S.

Further, the decision of the United Kingdom ("U.K.") to leave the EU, often referred to as Brexit, has created uncertainty regarding data protection regulation in the U.K. In particular, while the U.K. has implemented legislation that implements and complements the GDPR, with penalties for noncompliance of up to the greater of £17.5 million or four percent of worldwide revenues, aspects of data protection regulation in the U.K., including with respect to cross-border data transfers, remain unclear in the medium to longer term following Brexit. The U.K.'s relationship with the EU may, for example, require us to implement additional safeguards relating to transfers of personal data from the EU to the U.K., which may require us to incur significant costs and expenses in an effort to do so. More generally, we may incur liabilities, expenses, costs, and other operational losses under GDPR and the privacy and data protection laws of applicable EU member states and the United Kingdom in connection with any measures we take to comply with them.

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

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the Securities and Exchange Commission ("SEC") and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or

in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal false claims laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their implementing regulations, also imposes obligations, including mandatory contractual terms, on covered entities, which are health plans, healthcare clearinghouses, and health care providers, as those terms are defined by HIPAA, and their respective business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians, as defined by such law, and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, such reporting obligations for payments and transfers of value made in 2021 to covered recipients were expanded to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance regulations promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing; state and local laws that require the registration of pharmaceutical sales and medical representatives; state laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, research, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be

effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

If we fail to comply with other U.S. healthcare laws and compliance requirements, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

In the United States, our current and future activities with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers are subject to regulation by various federal, state and local authorities in addition to the FDA, which may include but are not limited to, CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice ("DOJ") and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, our business practices, including our clinical research, sales, marketing and scientific/educational grant programs may be required to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the patient data privacy and security provisions of HIPAA transparency requirements, and similar state laws, each as amended, as applicable.

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

Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the ACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Rather, if "one purpose" of the remuneration is to induce referrals, the federal Anti-Kickback Statute is implicated. In addition, the ACA codified case law that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (discussed below).

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for a medical or other item or service that was not provided as claimed or is false or fraudulent.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies are being investigated or, in the past, have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

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

Statute, the ACA amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Analogous U.S. state laws and regulations, including state anti-kickback and false claims laws, may apply to claims involving healthcare items or services reimbursed by any third-party payor, including private insurers our business practices.

HIPAA, as amended by HITECH, and their implementing regulations, imposes requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates that are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

Additionally, the federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, and to report annually certain ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, such reporting obligations for payments and transfers of value made in 2021 to covered recipients were expanded to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants and certified nurse-midwives.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain.

State and local laws also require pharmaceutical and biotechnology companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, establish marketing compliance programs, restrict payments that may be made to healthcare providers professionals and entities and other potential referral sources, file periodic reports with the state relating to pricing and marketing, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register field representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, exclusion, debarment or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or

injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

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

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

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

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

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

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

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

If experienced employees leave, we could experience inefficiencies or a lack of business continuity due to loss of historical knowledge and a lack of familiarity of the new employees with business processes, operating requirements, policies and procedures. It is important to our success that these key employees quickly adapt to and excel in their new roles. If they are unable to do so, our business and financial results could be materially adversely affected. In addition, much of our corporate expertise is concentrated in relatively few employees, the loss of which for any reason could negatively affect our business. Competition for our highly skilled employees is intense and we cannot prevent the resignation of any employee. We have experienced increased turnover at all levels since the start of the COVID-19 pandemic and general labor shortages in various areas of our business, all of which could have a material adverse impact on our business. We may need to increase employee wages and benefits in order to attract and retain the personnel necessary to achieve our goals, and our business, operations, and financial results may suffer if we are unable to do so. We do not maintain “key man” life insurance on any of our senior executives. None of our senior executive team is bound by written employment contracts to remain with us for a specified period. In addition, we have not entered into non-compete agreements with members of our executive management team. The loss of any member of our executive management team could harm our ability to implement our business strategy and respond to the market conditions in which we operate.

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

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

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

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

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

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, 2021, we had 24 full-time employees, including 16 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

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

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

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

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

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems, and those of our third-party CROs, other contractors (including sites performing our clinical trials) and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. To the extent that any disruption or security breach were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability, financial harm and reputational damage and the development and commercialization of our product candidates could be delayed. We cannot assure you that our data protection efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties, will prevent significant breakdowns or breaches in systems or other cyber incidents that cause loss, destruction, unavailability, alteration or dissemination of, or damage or unauthorized access to, our data and other data processed or maintained on our behalf or other assets that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure or dissemination of, or the prevention of access to, data (including trade secrets or other

confidential information, intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to loss, damage, or unauthorized access to, or use, alteration, or disclosure or dissemination of, personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Notifications and follow-up actions related to a security incident could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security incident were to result in any loss, destruction, or alteration of, or damage or unauthorized access to, our data or other information that is processed or maintained on or behalf, or inappropriate disclosure or dissemination of any such information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

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

Our current operations are located in California, and we or the third parties upon whom we depend, may be adversely affected by natural disasters or the COVID-19 pandemic, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

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

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

Our NOL carryforwards may be unavailable to offset future taxable income because of restrictions under U.S. tax law. Our NOLs generated in tax years beginning prior to January 1, 2018 are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law, and therefore could expire unused. Under the Tax Act, as modified by the CARES Act, our federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal NOLs in tax years beginning after December 31, 2020 is limited to 80% of our current year taxable income. Additionally, California recently enacted legislation limiting our ability to use our state NOLs for taxable years 2020 and 2021. As of December 31, 2021, we had federal NOL carryforwards of approximately $147.5 million, which will begin to expire in 2027. In addition, we generated federal

NOL carryforwards of $107.2 million which do not expire. We also have available California NOL carryforwards of approximately $105.3 million as of December 31, 2021, which begin to expire in 2030.

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

U.S. federal income tax reform could materially adversely affect our financial condition.

On December 22, 2017, President Trump signed into law the Tax Act, which significantly revises the Code. The Tax Act, as amended by the CARES Act, among other things, reduces the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, repeals the alternative minimum tax for corporations, limits the tax deduction for interest expense to 30% (50% for taxable years beginning in 2019 or 2020) of adjusted taxable income (except for certain small businesses), limits the deduction in taxable years beginning after December 31, 2020, for NOLs carried forward from taxable years beginning after December 31, 2017, eliminates net operating loss carrybacks for NOLs generated in taxable years beginning after December 31, 2020, and modifies or repeals many business deductions and credits. Our financial statements included elsewhere in this periodic report reflect the effects of the Tax Act based on current guidance.

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

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

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

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

Risks Related to our Intellectual Property

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

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

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

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

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

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

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- if clinical trials encounter delays, the period of time during which we could market our current or future product candidates under patent protection would be reduced;
- patents may be challenged, invalidated, modified, narrowed, revoked, circumvented, found to be unenforceable, found to be not infringed or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates or design around any Viracta owned, co-owned, or licensed patents;
- since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product; or (ii) invent any of the inventions claimed in our patents or patent applications;
- even when laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us, and some of our competitors have substantially greater intellectual property portfolios than us;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

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

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

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

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

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

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

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

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

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

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license;

- we or our licensors or collaborators might not have been the first to make the inventions covered by the issued patents or patent application that we own or license;
- we or our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we own or license will not lead to issued patents;
- issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

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

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

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

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

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

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

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

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

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

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

Competitors may infringe our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent or the patent of our licensors is invalid and/or unenforceable in whole or in part. In patent

litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of sufficient written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

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

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

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

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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

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

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

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

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

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

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

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

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

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

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

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in

foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patent and the patents we might obtain or license in the future.

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

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

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

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

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

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or our licensors’ patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our licensors at

risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop, license or obtain.

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

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

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

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

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

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

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

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. If any of these events

occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

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

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

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

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

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

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

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

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

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

may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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

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

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors, us and our partners; and
- the priority of invention of patented technology.

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

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

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

While we normally seek to obtain the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of the patent applications and patents relating to our product candidates, there may be times when the preparation, filing, prosecution, maintenance, enforcement and defense activities for patents and patent applications relating to our product candidates are controlled by our licensors or collaboration partners. If any of our licensors or collaboration partners fail to prepare, file, prosecute, maintain, enforce, and defend such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. We collaborate with other companies and institutions with respect to research and development matters. Also, we rely on numerous third parties to provide us

with materials that we use to develop our technology. If we cannot successfully negotiate sufficient ownership, licensing, and/or commercial rights to any invention that result from our use of any third-party collaborator's materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator's materials, or data developed in a collaborator's study, our ability to capitalize on the market potential of these inventions or developments may be limited or precluded altogether. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

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

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

Risks Related to our Reliance 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, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our current and planned clinical trials of Nana-val, and we expect to continue to rely upon third parties to conduct additional clinical trials of Nana-val and other 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 with such third parties, we have limited ability to control the amount or timing of resources that any such third party will devote to our clinical trials. The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors. Some of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements with a third party, it would delay our drug development activities.

Our reliance on these third parties for such drug development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our 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 reliable 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 substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process. We are also required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If 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 be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

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

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. In the case of nanatinostat, we rely on a single third-party manufacturer and we currently have no alternative manufacturer in place. We do not have long-term supply agreements, and we purchase our required drug product on a purchase order basis, which means that aside from any binding purchase orders we have from time to time, our supplier could cease supplying to us or change the terms on which it is willing to continue supplying to us at any time. If we were to experience an unexpected loss of supply of nanatinostat or any other product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

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

- the failure of the third party to manufacture our product candidates according to our schedule and specifications, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates, are constrained by the recent COVID-19 pandemic or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements, including manufacturing drug supply pursuant to strictly enforced cGMPs;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of our contract manufacturing partners and are dependent on these contract manufacturing partners for compliance with cGMP regulations for manufacturing both active pharmaceutical ingredients (“API”) and finished drug products. To date, we have obtained API and drug product for nanatinostat from single-source third party CMOs. We are in the process of developing our supply chain for nanatinostat and valganciclovir and intend to put in place framework agreements under which third-party CMOs will generally provide us with necessary quantities of API and drug product on a project-by-project basis based on our development needs. As we advance our product candidates through

development, we will consider redundant supply for the API and drug product for each of our product candidates to protect against any potential supply disruptions. However, we may be unsuccessful in putting in place such framework agreements or protecting against potential supply disruptions.

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

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

We entered into a collaboration agreement with ImmunityBio, and we may form or seek additional strategic alliances or collaborations in the future. Such alliances and collaborations may inhibit future opportunities, or we may not realize the benefits of such collaborations or alliances.

We have entered into a license agreement with ImmunityBio, Inc., formerly NantKwest, Inc. (“ImmunityBio”) for the development and commercialization of nanatinostat, and we may form or seek strategic alliances, joint ventures or collaborations or enter into licensing arrangements with other third parties that we believe will complement or augment our development and commercialization efforts with respect to future product candidates that we may develop.

In May 2017, we entered into a license agreement with ImmunityBio, which was amended by the parties in November 2018 (as amended, the “NK License Agreement”). Pursuant to the NK License Agreement, we granted an exclusive worldwide license to ImmunityBio and its affiliates to develop and commercialize nanatinostat for use in combination with natural killer cell immunotherapies (“NK Covered Products”). Under the NK License Agreement, we are eligible to receive up to a total of $100.0 million in regulatory and commercial milestone payments upon the occurrence of certain milestone events. We are also eligible to earn tiered royalties as a percentage of net sales of licensed NK Covered Products, ranging from the low to mid-single digits. ImmunityBio is responsible for conducting all necessary studies, including safety studies and clinical trials necessary in connection with seeking regulatory approvals to market NK Covered Products under the NK License Agreement in any territory.

Future efforts for additional alliances or collaborations may also require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex.

Furthermore, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, it will achieve the revenues or specific net income that justifies such transaction. For example, in November 2018, we entered into a collaboration and license agreement (the “Salubris License Agreement”) with Shenzhen Salubris Pharmaceutical Co. Ltd. (“Salubris”), pursuant to which we granted Salubris an exclusive license, with the right to grant sublicenses, to our patent and know-how rights to develop and commercialize nanatinostat in combination with an antiviral drug, such as valganciclovir, for treatment, prevention, or diagnosis of virus-associated malignancies in humans and non-humans in the People's Republic of China (excluding Hong Kong, Macau, and Taiwan). However, the expected benefit of such transaction was not realized as, in August 2021, prior to receiving any milestones or royalties under the Salubris License Agreement, we entered into a Mutual Termination Agreement with Salubris (the “Termination Agreement”), pursuant to which the parties agreed to terminate the Salubris License Agreement. Under the terms of the Termination Agreement, we paid Salubris a payment in the amount of $4.0 million on the effective date of the Termination Agreement, and all licenses granted by the Company to Salubris automatically terminated.

We depend on ImmunityBio to develop and commercialize our product candidate within its licensed field and territory, and we have limited control over how ImmunityBio will conduct development and commercialization activities for such product candidate.

Under the existing license agreement with ImmunityBio, we rely on ImmunityBio for a substantial portion of the financial resources and for the development, regulatory, and commercialization activities for the NK Covered Products, and we have limited control over the amount and timing of resources that ImmunityBio devotes to the NK Covered Products. In addition, payments associated with development, regulatory and commercial milestones that we may be eligible to receive, as well as royalties, will be dependent upon further advancement of the NK Covered Products by ImmunityBio. If these milestones are not met and if the NK Covered Products are not commercialized, we will not receive future revenues from the collaboration. ImmunityBio may fail to develop or effectively commercialize the NK Covered Products for a variety of reasons, including because: ImmunityBio does not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as limited cash or human resources or a change in strategic focus; ImmunityBio decides to pursue a competitive product developed outside of our collaboration; or ImmunityBio cannot obtain the necessary regulatory approvals.

The collaboration agreement with ImmunityBio subjects us to a number of risks, including:

- ImmunityBio may not commit sufficient resources to the development, regulatory approval, marketing or distribution of the NK Covered Products;
- ImmunityBio may be unable to successfully complete the clinical development of the NK Covered Products or obtain all necessary approvals from the FDA and similar foreign regulatory agencies required to market the NK Covered Products;
- ImmunityBio may fail to manufacture the NK Covered Products in compliance with requirements of the FDA and similar foreign regulatory agencies and in commercial quantities sufficient to meet market demand;
- there may be disputes between us and ImmunityBio, including disagreements regarding their license agreement with us, that may result in (1) the delay of (or prevent entirely) the achievement of development, regulatory and commercial objectives that would result in milestone payments, (2) the delay or termination of the development or commercialization of the NK Covered Products, (3) costly litigation or arbitration that diverts our management's attention and resources; and/or (4) termination of the underlying license agreement.
- ImmunityBio may not comply with applicable regulatory guidelines with respect to developing or commercializing the NK Covered Products, which could adversely impact the development of or sales of the NK Covered Products and could result in administrative or judicially imposed sanctions, including warning letters, civil and criminal penalties, injunctions, product seizures or detention, product recalls, total or partial suspension of production and refusal to approve any new drug applications;
- ImmunityBio may experience financial difficulties;
- business combinations or significant changes in the business strategy of ImmunityBio may also adversely affect such partners ability to perform its obligations under their license agreement with us;
- ImmunityBio may not properly maintain our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- ImmunityBio may develop or commercialize nanatinostat in a manner that may adversely impact our development or commercialization of Nana-val and/or future product candidates outside of such collaborations; and
- ImmunityBio could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

If ImmunityBio does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the development, regulatory approval, and commercialization efforts related to the NK Covered Products could be delayed. It may be necessary for us to assume the responsibility at our own expense for the development of the NK Covered Products. In that event, we would likely need to seek additional funding and our potential to generate future revenues from the NK Covered Products could be significantly reduced and our business could be materially and adversely harmed.

We have entered into collaborations with third parties in connection with the development of nanatinostat. Even if we believe that the development of such product candidates is promising, our partners may choose not to proceed with such development.

Our existing agreements with ImmunityBio, and any future collaboration agreements we may enter into, are generally subject to termination by the counterparty on short notice upon the occurrence of certain circumstances. Accordingly, even if we believe that the

development of product candidates is worth pursuing, our partners may choose not to continue with such development. If any of our collaborations are terminated, we may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner on short notice, and the terms of any additional collaboration or other arrangements that we establish may not be favorable to us.

We are also at risk that our current and any potential collaborations or other arrangements may not be successful. Factors that may affect the success of our collaborations include the following:

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

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

We may not realize the potential benefits of our licensing arrangements for product candidates such as vosaroxin and DAY101 (formerly TAK-580) and the royalty purchase agreement with XOMA relating to such product candidates and may not receive any future milestones or royalty payments.

There can be no assurance that product candidate that been out-licensed, such as vosaroxin to Denovo and DAY101 (formerly TAK-580) to DOT Therapeutics-1, Inc., will be successfully developed and commercialized. The product candidate(s) may fail in development, or our partner(s) may elect to discontinue development and/or terminate their agreement(s) with us. Completing development of one of these product candidates could require significant resources. If we cannot find another partner and do not undertake development on our own, there will be no possibility of any future upside from such product candidate, including payments that we may be eligible for under our royalty purchase agreement with XOMA (US) LLC.

We may fail to make timely milestone or royalty payments under our agreements, triggering remedies that would be adverse to us.

Under certain existing agreements, we have certain milestone and royalty obligations, such as the remaining development milestones payable for our development of VRx-510 and on future sales of VRx-510, when and if approved and commercialized, to Takeda Oncology. In addition, we are required to pay RPI Finance Trust (“RPI”), an entity related to Royalty Pharma, a specified percentage of any consideration we receive for vosaroxin. If we do not make timely payments, our partners may seek remedies.

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

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

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products 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 or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

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

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

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

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

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

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

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a business combination or sale or disposition of a business unit or

development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;

- collaborators may rely on third parties to conduct development, manufacturing, and/or commercialization activities, and except for remedies available to us under our collaboration agreements, we have limited ability to control the conduct of such activities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product, if approved, relative to other products;
- we may grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all;
- collaborators may not provide us with timely and accurate information regarding development progress and activities under the collaboration or may limit our ability to share such information, which could adversely impact our ability to report progress to our investors and otherwise plan our own development of our product candidates;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator’s sales and marketing activities or other operations may not be in compliance with applicable laws, resulting in civil or criminal proceedings.

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

We do not know whether an active, liquid and orderly trading market will continue for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.

We can provide no assurance that we will be able to sustain an active trading market for our shares. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of common stock as consideration.

The price of our stock is volatile.

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

Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition to the factors discussed in this "Risk factors" section and elsewhere in this periodic report, these factors include:

- the timing and results of preclinical studies and clinical trials of our product candidates, those conducted by third parties or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements;
- the impact of any natural disasters or public health emergencies, such as the COVID-19 pandemic; and
- general economic, political, industry and market conditions.

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

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

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

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

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

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

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

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

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

Certain holders of shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradeable in the public market, subject to the restrictions of Rule 144 in the case of our affiliates. Any sales of securities by these stockholders could have a material adverse effect on the market price for our common stock.

If we fail to maintain proper and effective internal controls, our ability to produce accurate consolidated financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. As a private company, the operating entity that survived the Merger has never been required to test its internal controls within a specified period. This will require that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner.

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

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate consolidated financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

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

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

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

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

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

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

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of their stock.

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

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

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

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

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

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

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

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

Our amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings.

It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceuticals industry depends on our ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. We will be highly dependent on our management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could impact negatively our ability to implement successfully our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses.

We are expected to take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could result in our common stock being less attractive to investors.

We qualify as a smaller reporting company under the rules of the SEC. As a smaller reporting company, we are able to take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in our SEC filings. Decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of the reporting exemptions applicable to a smaller reporting company until we are no longer a smaller reporting company, which status ends once we have a public float greater than $250.0 million. In that event, we could still be a smaller reporting company if our annual revenues are below $100.0 million, and we have a public float of less than $700.0 million.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Viracta corporate headquarters are located in Cardiff, California, where Viracta leases approximately 5,337 square feet of office space, under a lease that expires in August 2023 with an option to renew for an additional one-year term. Viracta believes that these existing facilities will be adequate for its near-term needs. If required, Viracta believes that suitable additional or alternative space would be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock is traded on the Nasdaq Capital Market under the symbol "VIRX."

Holders of Record

As of March 4, 2022, there were 62 registered stockholders of record for our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. We expect to retain available cash to finance ongoing operations and the potential growth of our business. Any future determination to pay dividends on our common stock will be at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial conditions, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Unregistered Sales of Equity Securities

None.

Issuer Repurchases of Equity Securities

None.

Securities Authorized for issuance Under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Item 6. Reserved.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the accompanying notes and other financial information included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth under "Risk Factors" under Item 1A of Part I of this Annual Report on Form 10-K and elsewhere in this Annual Report on Form 10-K. Please also see the section entitled "Forward-Looking Statements."

Overview

Viracta is a clinical-stage, precision oncology company focused on advancing new medicines for the treatment of virus-associated malignancies. The association of viruses and cancer has been well characterized, and Viracta's lead program is focused on cancers associated with the Epstein-Barr virus ("EBV"). Viracta's lead product candidate is an all-oral combination therapy of its proprietary investigational drug, nanatinostat and the antiviral agent valganciclovir (collectively referred to as "Nana-val"). Nana-val is currently being investigated in multiple ongoing clinical trials, including NAVAL-1, a pivotal, global, multicenter, open-label Phase 2 basket trial for the treatment of multiple subtypes of relapsed/refractory ("R/R") Epstein-Barr virus-positive ("EBV$^+$") lymphoma, as well as a multinational, open-label Phase 1b/2 trial for the treatment of EBV$^+$ recurrent or metastatic nasopharyngeal carcinoma ("R/M NPC") and other EBV$^+$ solid tumors. Viracta's development pipeline also includes vecabrutinib, a clinical-stage non-covalent ITK/BTK inhibitor and VRx-510 (formerly SNS-510), a preclinical-stage PDK-1 inhibitor. Viracta is evaluating future development and collaboration opportunities for vecabrutinib in combination with chimeric antigen receptor ("CAR") T-cell therapies and VRx-510 in multiple oncology indications.

EBV$^+$ Lymphoma

In June 2021, Viracta announced the initiation of NAVAL-1, a global, multicenter, open-label Phase 2 basket trial to evaluate Nana-val for the treatment of R/R EBV$^+$ lymphoma with centers in North America, Europe, and Asia-Pacific. The primary endpoint of the trial is objective response rate, with key secondary endpoints including duration of response, survival outcomes, and the safety profile of the combined treatment. Patients with relapsed or refractory disease following two or more prior therapies (one or more for extranodal NK/T cell lymphoma) without curative treatment options will be eligible for enrollment. If successful, Viracta believes this trial could potentially support multiple new drug application filings across various EBV$^+$ lymphoma subtypes. The trial employs a Simon two-stage design where a limited number of patients are initially enrolled into cohorts in Stage 1 and, if a pre-specified activity threshold is reached, additional patients will be enrolled in Stage 2. During Stage 2, Viracta anticipates discussing the preliminary results with the U.S. Food and Drug Administration (the "FDA") and may amend the protocol to include additional patients as necessary to enable registration. Viracta anticipates providing an update on the first cohort(s) that have expanded into Stage 2 in the second half of 2022.

Viracta is also conducting a Phase 1b/2 trial of Nana-val for the treatment of EBV$^+$ R/R lymphoma and final results from this trial were presented in an oral presentation at the 63rd American Society of Hematology ("ASH") Annual Meeting in December 2021. The data demonstrated promising activity in multiple subtypes of heavily pre-treated, R/R EBV$^+$ lymphoma patients, and a generally well-tolerated safety profile. Complete responses were observed in diffuse large B-cell lymphoma ("DLBCL"), T/NK-cell lymphoma ("T/NK-NHL"), and immunodeficiency-associated lymphoproliferative disorders ("IA-LPD"). The median duration of response was 10.4 months.

Viracta has received Fast Track Designation by the FDA for the treatment of R/R EBV$^+$ lymphoid malignancies, in addition to orphan drug designations for the treatment of EBV$^+$ diffuse large B-cell lymphoma, not otherwise specified ("EBV$^+$DLBCL,NOS"), post-transplant lymphoproliferative disorders ("PTLD"), plasmablastic lymphoma, and T-cell lymphoma.

EBV$^+$ Solid Tumors

In October 2021, Viracta announced the initiation of a multinational, open-label Phase 1b/2 trial for the treatment of EBV$^+$ R/M NPC and other EBV$^+$ solid tumors. The trial is designed to evaluate the safety and preliminary efficacy of Nana-val alone and in combination with the PD-1 checkpoint inhibitor pembrolizumab (Keytruda). The Phase 1b dose escalation portion is designed to evaluate safety and to determine the recommended Phase 2 dose ("RP2D") of Nana-val in patients with EBV$^+$ R/M NPC. In Phase 2, up to sixty patients with EBV$^+$ R/M NPC will be randomized to receive Nana-val at the RP2D with or without pembrolizumab, to evaluate safety, overall response rate, and potential pharmacodynamic markers. Additionally, patients with other EBV$^+$ solid tumors

will be enrolled to receive Nana-val at the RP2D in a Phase 1b dose expansion cohort. Viracta anticipates providing preliminary clinical data from the trial in 2022.

Impact of COVID-19

In December 2019, a novel strain of coronavirus, otherwise known as COVID-19, was reported in Wuhan, China. On March 11, 2020, the World Health Organization (the "WHO") declared COVID-19 a pandemic, and on March 13, 2020, the United States declared a national emergency with respect to the coronavirus pandemic. This pandemic has severely impacted global economic activity, and many countries and many states in the United States have reacted to the pandemic by instituting quarantines, mandating business and school closures, and restricting travel. The effects of the COVID-19 pandemic continue to rapidly evolve, and the full impact of the COVID-19 pandemic remains highly uncertain and subject to change. For example, we have experienced an impact on the timing of clinical site initiations as a result of the COVID-19 pandemic. We have taken certain measures and continue to evaluate other potential measures to mitigate the impact of the COVID-19 pandemic on our trials. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. These effects could have a material impact on our operations. The continued COVID-19 pandemic may negatively impact our workforce and our research and development activities. See Item 1A - "Risk Factors" for additional information regarding the potential impact of the COVID-19 pandemic on our business, results of operations and financial condition.

Financial Operations Overview

Research and Development Expenses

We expense all research and development expenses as they are incurred. Research and development expenses primarily include:

- clinical and regulatory-related costs;
- expenses incurred under agreements with contract research organizations ("CROs");
- manufacturing and stability testing costs and related supplies and materials; and
- employee-related expenses, including salaries, benefits, travel, and share-based compensation expense.

The majority of our research and development expenses to date have been incurred in connection with the development of Nana-val. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. The successful development and commercialization of Nana-val is still highly uncertain. We are unable to estimate with any certainty the costs we will incur in the continued development and regulatory review of Nana-val, though such costs may be significant. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We may never succeed in achieving marketing approval for our product candidate.

The costs of clinical trials may vary significantly over the life of a project owing to, but not limited to, the following:

- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible subjects;
- the number of subjects that participate in the trials;
- the number of doses that subjects receive;
- the cost of comparative agents used in trials;
- the drop-out or discontinuation rates of subjects;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidate.

We do not yet know when Nana-val may be commercially available, if at all.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including share-based compensation. Other general and administrative expenses include professional fees for accounting, tax, patent costs, legal services, insurance, facility costs and costs associated with being a publicly traded company, including fees associated with investor relations and directors and officers liability insurance premiums. We expect that general and administrative expenses will increase in the future as we expand our operating activities, prepare for the growth needs associated with potential commercialization of Nana-val and continue to incur additional costs associated with being a publicly traded company and maintaining compliance with exchange listing and SEC requirements. These increases will likely include higher consulting costs, legal fees, accounting fees, directors' and officers' liability insurance premiums and fees associated with investor relations.

Other income (expense)

Other income (expense) consists of interest income and expense as well as various income or expense items of a non-recurring nature. We earn interest income from interest-bearing accounts and money market accounts for cash and cash equivalents. Interest expense is primarily attributable to interest charges associated with borrowings under our loan and security agreements.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are 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. Our actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 in the Notes to Consolidated Financial Statements of this Annual Report on Form 10-K, we believe the following accounting policies are critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expenses

We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. This process involves reviewing contract and purchase orders, reviewing the terms of vendor agreements, communicating with applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the services when it has not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice monthly in arrears for services performed.

Clinical Trial Costs and Accruals

We accrue clinical trial costs based on work performed. In determining the amount to accrue, we rely on estimates of total costs incurred based on enrollment, the completion of clinical trials and other events. We follow this method because we believe reasonably dependable estimates of the costs applicable to various stages of a clinical trial can be made. However, the actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending on a number of factors. Differences between the actual clinical trial costs and the estimated clinical trial costs that we have accrued in any prior period are recognized in the subsequent period in which the actual costs become known. Historically, our estimated accrued expenses have approximated actual expenses incurred; however, material differences could occur in the future.

Other Information

Net Operating Loss Carryforwards

As of December 31, 2021, we had federal and California tax net operating loss carryforwards of approximately $147.5 million and $105.3 million, respectively. The federal and California net operating loss carryforwards will begin to expire in 2027 and 2030, respectively, unless previously utilized. The portion of federal net operating losses created after 2017 of approximately $107.2 million do not expire and will carry forward indefinitely. As of December 31, 2021, we also had federal and California research and development tax credit carryforwards of $1.5 million and $1.8 million, respectively. Additionally, the Company has Orphan Drug Credit carryforwards of $7.3 million. The federal research and development tax credit carryforwards will begin to expire in 2027 unless previously utilized. The California research and development tax credit will carry forward indefinitely. Furthermore, under the

U.S. tax legislation enacted in December 2017, although the treatment of tax losses generated before December 31, 2017 has generally not changed, tax losses generated in calendar year 2018 and beyond do not expire but may only offset 80% of our taxable income. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not completed our analysis to determine what, if any, impact any prior ownership change has had on our ability to utilize our net operating loss carryforwards.

Results of Operations

Comparison of Years Ended December 31, 2021 and 2020

The following table summarizes the results of our operations for the fiscal years ended December 31, 2021 and December 31, 2020 (in thousands):

	Year Ended December 31,		
	2021	2020	Change
Research and development expenses	$ 23,861	$ 13,467	$ 10,394
Purchased and acquired in-process research and development	88,478	—	88,478
General and administrative expenses	15,437	5,348	10,089
Gain on Royalty Purchase Agreement	13,500	—	13,500

Research and development expenses. Research and development expenses for the year ended December 31, 2021 compared to the year ended December 31, 2020 increased by approximately $10.4 million. The increase in research and development expenses was primarily due to increases in costs incurred to support the initiation of the NAVAL-1 and solid tumor trials as well as an increase in headcount and non-cash share-based compensation.

Purchased and acquired in-process research and development. Purchased in-process research and development was related to the payment of $4.0 million to terminate the exclusive collaboration and license agreement with Shenzhen Salubris Pharmaceutical Co. Ltd. The Company had granted Salubris an exclusive license, with the right to grant sublicenses, to the Company's patent and know-how rights to develop and commercialize nanatinostat in combination with an antiviral drug, such as valganciclovir, for treatment, prevention, or diagnosis of virus-associated malignancies in humans and non-humans in the Republic of China, excluding Hong Kong, Macau, and Taiwan, which was re-acquired upon termination. The acquired in-process research and development included non-cash and non-recurring cost of $84.5 million associated with the estimated fair value of the in-process research and development projects acquired in the asset acquisition with no alternative future use, which was charged to expense on the Sunesis merger date.

General and administrative expenses. General and administrative expenses for the year ended December 31, 2021 compared to the year ended December 31, 2020 increased by approximately $10.1 million. The increase was largely due to significant and non-recurring costs associated with the Merger, in addition to incremental costs associated with being a publicly traded company, including legal fees, audit fees, consulting expenses, filing fees and increased directors and officer's insurance costs, as well as an increase in non-cash share-based compensation.

Gain on royalty purchase agreement. The gain was associated with upfront proceeds of $13.5 million recorded in connection with the multi-license milestone and royalty monetization transaction with XOMA (US) LLC.

Liquidity and Capital Resources

As of December 31, 2021, we have devoted substantially all of our efforts to product development and have not realized product sales revenues from our planned principal operations. We have a limited operating history, and the sales and income potential of our business and market are unproven. We have experienced net losses since our inception and, as of December 31, 2021, had an accumulated deficit of approximately $165.7 million. We expect to continue to incur net losses for at least the next several years. A successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure. If we are unable to generate revenues adequate to support our cost structure, we will need to raise additional equity through the issuance of our common stock, through other equity or debt financings or through collaborations or partnerships with other companies. As of December 31, 2021, we had cash and cash equivalents of approximately $103.6 million and working capital of approximately $96.2 million. In February 2021, as noted below, we completed the sale of common stock in a private placement

resulting in gross proceeds of approximately $65.0 million. Additionally, we received approximately $17.1 million in cash and cash equivalents in the Merger previously discussed. We also received $13.5 million in upfront proceeds related to the Royalty Purchase Agreement with XOMA (US) LLC, as discussed in the financial statement footnotes. In May 2021, we entered into an Open Market Sale Agreement℠ (the "Sale Agreement") with Jefferies LLC (the "Sales Agent"), under which we may offer and sell up to $50.0 million of shares of our common stock from time to time through the Sales Agent. As of the date of the filing of this Annual Report on Form 10-K, no shares have been sold pursuant to the Sales Agreement.

On November 4, 2021, we entered into a loan and security agreement with Silicon Valley Bank ("SVB") and Oxford Finance LLC ("Oxford") for up to $50.0 million. In connection with entering the new $50.0 million credit facility, we and SVB agreed to terminate our prior $15.0 million loan and security agreement with SVB. The existing $5.0 million debt balance outstanding from our previous credit facility with SVB was relieved under this new $50.0 million credit facility. The Loan Agreement was accounted for as a modification based on the effect of the changes in terms from the original SVB Loan Agreement. Under the terms of the $50.0 million credit facility, the remaining $45.0 million is available in two additional tranches of $20.0 million and $25.0 million under certain circumstances, and we are under no obligation to draw funds in the future.

Based on our current financial position and business plan, management believes that our existing cash and cash equivalents, as well as our credit facility, will be sufficient to fund our planned operations for at least twelve months from the issuance date of the consolidated financial statements included in this Annual Report on Form 10-K.

We expect to continue to incur expenses and increase operating losses for at least the next several years. In the near-term, we anticipate incurring costs as we:

- conduct ongoing and planned development activities;
- initiate pre-approval and pre-commercialization activities for our lead product candidate;
- continue the preparation of the commercial manufacturing process;
- maintain, expand, and protect our intellectual property portfolio; and
- continue to fund the additional accounting, legal, insurance and other costs associated with being a public company.

The following table summarizes our cash flows for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,	
	2021	2020
Net cash used in operating activities	$ (18,851)	$ (16,054)
Net cash provided by (used in) investing activities	12,891	(55)
Net cash provided by financing activities	62,425	44,980
Net increase in cash and cash equivalents	$ 56,465	$ 28,871

Operating Activities. Cash used in operating activities was $18.9 million for the year ended December 31, 2021, as compared to cash used in operating activities of $16.1 million for the year ended December 31, 2020. This change was primarily due to operating results, which included the $13.5 million cash inflow associated with the Royalty Purchase Agreement with XOMA (US) LLC, and recorded into income in the period.

Investing Activities. Net cash provided by investing activities was $12.9 million for the year ended December 31, 2021, compared to cash used in investing activities of $0.1 million for the year ended December 31, 2020. This change was a result of the cash and cash equivalents acquired in the Merger offset by purchases of property and equipment and in-process research and development.

Financing Activities. Net cash provided by financing activities was $62.4 million for the year ended December 31, 2021 compared to cash provided by financing activities of $45.0 million for the year ended December 31, 2020. These amounts substantially reflect the net proceeds of the respective financing transactions closed in 2021 and 2020, respectively.

The amount and timing of our future funding requirements will depend on many factors, including but not limited to:

- we may not have sufficient financial and other resources to complete clinical development and commercialization for Nana-val;
- we may not be able to provide acceptable evidence of safety and efficacy for Nana-val;
- we may be required to undertake additional clinical trials and other studies of Nana-val;

- FDA may disagree with the design of our future clinical trials if any are necessary;
- we may experience variability in subjects, adjustments to clinical trial procedures and inclusion of additional clinical trial sites;
- FDA may not agree with the analysis of our clinical trial results;
- the results of our clinical trials may not meet the level of statistical or clinical significance or other bioequivalence parameters required by FDA for marketing approval;
- subjects in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to our products;
- contract manufacturers, suppliers, and/or consultants may not meet appropriate timelines;
- we may not be able to obtain, maintain and enforce our patents and other intellectual property rights;
- we may not be able to establish commercial-scale manufacturing capabilities; and
- we may not be able to establish commercialization capabilities.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation, or asset sale transactions. Any equity or debt financing may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to other parties rights to develop or commercialize our drug candidates that we would prefer to retain.

Contractual Obligations and Commitments

We enter into short-term and cancellable agreements in the normal course of operations with clinical sites and contract research organizations, or CROs, for clinical research studies, professional consultants and various third parties for preclinical research studies, clinical supply manufacturing and other services through purchase orders or other documentation, or that are undocumented except for an invoice. Such short-term agreements are generally outstanding for periods less than one year and are settled by cash payments upon delivery of goods and services. The nature of the work being conducted under these agreements is such that, in most cases, the services may be cancelled upon prior notice of 90 days or less. Payments due upon cancellation generally consist only of payments for services provided and expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation. These payments are not included in the table of contractual obligations above.

On March 22, 2021, we entered into the Royalty Purchase Agreement with XOMA (US) LLC, pursuant to which, XOMA (US) LLC paid us an upfront payment of $13.5 million for the right to receive future milestones and royalties that we are entitled to receive under the terms of a license agreement with DOT Therapeutics-1, Inc. dated December 16, 2019 and a license agreement with Denovo Biopharma LLC dated December 5, 2019, net of certain obligations we have to a third party. Pursuant to the Royalty Purchase Agreement, we (directly or through a wholly owned subsidiary) are also eligible to receive an up to $20.0 million pre-commercialization, event-based milestone.

For descriptions of additional contractual obligations and commitments, see the section titled “Commitments and Contingencies” and "Debt" in the Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosure about Market Risk

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements and the report of our independent registered public accounting firm are included in this report on the pages indicated in Item 15 of Part IV of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As required by SEC Rule 13a-15(b), as of December 31, 2021 we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2021.

Managements Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that: (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the consolidated financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled "Internal Control — Integrated Framework (2013 Framework)" published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2021, the end of our most recent fiscal year.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the quarter ended December 31, 2021 that materially affect, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of the Registered Public Accounting Firm

As a smaller reporting company and non-accelerated filer, we are not required to provide an attestation report on our internal control over financial reporting issued by the Company's independent registered public accounting firm.

Item 9B. Other Information.

Annual Meeting of Stockholders

Our annual meeting of stockholders will be held at 10:00 a.m. Pacific Time on Wednesday, June 8, 2022, as a virtual meeting. Holders of record at the close of business on Tuesday, April 19, 2022, will be entitled to vote at the meeting.

Pursuant to the provisions of the Company's Bylaws, for any stockholder to propose business (other than pursuant to and in compliance with Exchange Act Rule 14a-8) or make a nomination before the annual meeting, the stockholder must have given timely notice in writing to the secretary and any such nomination or proposed business must constitute a proper matter for stockholder action. Under the Company's Bylaws, to be timely, a stockholder's notice must be delivered to or mailed and received at the principal executive offices of the corporation not less than one hundred twenty (120) calendar days before the one year anniversary of the date on which the corporation first mailed its proxy statement to stockholders in connection with the previous year's annual meeting of stockholders; provided, however, that in the event that no annual meeting was held in the previous year or the date of the annual meeting has been changed by more than thirty (30) days from the date of the prior year's meeting, notice by the stockholder to be timely must be so received not later than the close of business on the later of one hundred twenty (120) calendar days in advance of such annual meeting and ten (10) calendar days following the date on which public announcement of the date of the meeting is first made. Because the Company did not hold an annual meeting last year, the Company has determined that the date by which stockholders must deliver such notice for the purposes of the Annual Meeting is March 26, 2022, which is 10 days after the filing of this Annual Report on Form 10-K. Pursuant to Rule 14a-8, for a stockholder to submit a proposal for inclusion in the Company's proxy materials for the Annual Meeting, the stockholder must comply with the requirements set forth in Rule 14a-8 including with respect to the subject matter of such proposal and must deliver the proposal and all required documentation to the Company a reasonable time before the Company begins to print and send its proxy materials for the meeting. For the purposes of the 2022 Annual Meeting of Stockholders, the Company has determined that March 26, 2022 is a reasonable time before the Company plans to begin printing and mailing its proxy materials. The public announcement of an adjournment or postponement of the Annual Meeting date will not commence a new time period (or extend any time period) for giving such notice under the Company's Bylaws or submitting a proposal pursuant to Rule 14a-8.

Executive Incentive Compensation Plan

Effective March 14, 2021, we adopted an Executive Incentive Compensation Plan (the "Incentive Compensation Plan"). The Incentive Compensation Plan became effective on the business day immediately prior to the effective date of the registration statement of which this prospectus forms a part. Our Incentive Compensation Plan will allow our compensation committee (or other committee designated by our board of directors) to grant incentive awards, generally payable in cash, to employees selected by our compensation committee, including our executive officers, based upon performance goals established by our compensation committee.

Under our Incentive Compensation Plan, our compensation committee will determine the performance goals applicable to any award, which goals may include, without limitation, goals related to research and development, regulatory milestones or regulatory-related goals, financial milestones, new product or business development, other product release milestones, publications, cash flow, internal structure, leadership development, project, function or portfolio-specific milestones, license or research collaboration agreements, capital raising, patentability and individual objectives such as peer reviews or other subjective or objective criteria. The performance goals may differ from participant to participant and from award to award.

The compensation committee will administer our Incentive Compensation Plan and will, in its sole discretion and at any time, increase, reduce or eliminate a participant's actual award, and/or increase, reduce or eliminate the amount allocated to the bonus pool for a particular performance period. The actual award may be below, at or above a participant's target award, in the discretion of the administrator. The administrator may determine the amount of any increase, reduction or elimination on the basis of such factors as it deems relevant, and it will not be required to establish any allocation or weighting with respect to the factors it considers.

Actual awards generally will be paid in cash (or its equivalent) only after they are earned, and, unless otherwise determined by the administrator, to earn an actual award a participant must be employed by us through the date the actual award is paid. The administrator of the Incentive Compensation Plan may reserve the right to settle an actual award with a grant of an equity award under our then-current equity compensation plan, which equity award may have such terms and conditions, including vesting, as the administrator determines. Payment of awards will occur as soon as practicable after they are earned, but no later than the dates set forth in our Incentive Compensation Plan.

Awards under our Incentive Compensation Plan are subject to any clawback policy of ours, which we may be required to adopt from time to time to comply with applicable laws. The administrator also may impose such other clawback, recovery or recoupment provisions with respect an award under our Incentive Compensation Plan as the administrator determines necessary or appropriate, including for example, reduction, cancellation, forfeiture or recoupment upon a termination of a participant's employment for cause. Certain participants may be required to reimburse us for certain amounts paid under an award under our Incentive Compensation Plan in connection with certain accounting restatements we may be required to prepare due to our material noncompliance with any financial reporting requirements under applicable securities laws, as a result of misconduct.

Our board of directors and our compensation committee will have the authority to amend, suspend or terminate our Incentive Compensation Plan, provided such action does not impair the existing rights of any participant with respect to any earned awards.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information called for by this item will be set forth in our Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021 (the "Proxy Statement") and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees which is available on our internet website at https://www.viracta.com. The Code of Business Conduct and Ethics contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics, and is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Item 11. Executive Compensation.

Information required by this item will be contained in our Proxy Statement and is incorporated herein by reference.

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

Information required by this item will be contained in our Proxy Statement and is incorporated herein by reference.

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

Information required by this item will be contained in our Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

Information required by this item will be contained in our Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) List the following documents filed as a part of the report:

(1) Financial Statements. The following consolidated financial statements of Viracta Therapeutics, Inc., together with the report thereon of Ernst & Young LLP (PCAOB ID No. 42), an independent registered public accounting firm, are included in this Annual Report on Form 10-K.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

(2) Those financial statement schedules.

None.

(3) Exhibits

A list of exhibits to this Annual Report on Form 10-K is set forth on the Exhibit Index immediately preceding the signature page and is incorporated herein by reference

(b) See Exhibit Index

(c) See item (15(a)(2) above.

Item 16. Form 10-K Summary

None.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Viracta Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Viracta Therapeutics, Inc. (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

Critical Audit Matters

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

Reverse merger asset acquisition accounting

Description of the Matter

As described in Note 7 to the consolidated financial statements, on February 24, 2021, the Company completed a reverse merger transaction with Sunesis Pharmaceuticals, Inc. (“Sunesis”). The Company was determined to be the accounting acquirer of Sunesis and the merger was accounted for as an asset acquisition. The fair value of the asset acquisition total consideration was $103 million, which included net assets of $19 million and acquired in-process research and development (“IPR&D”) of $84 million.

Auditing the Company’s accounting for the reverse merger was challenging because of the judgment involved in evaluating whether the transaction met the criteria of a business combination or an asset acquisition. The subjective considerations included whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets and if the acquired entity consisted of inputs and processes applied to those inputs that had the ability to contribute to the creation of outputs.

How We Addressed the Matter in Our Audit

To test the Company’s accounting for its reverse merger with Sunesis, we performed audit procedures that included, among others, assessing management’s conclusion that the transaction be treated as an asset acquisition with the Company as the acquiring entity. We inspected minutes of board of directors’ meetings, executed transaction agreements, and other information to assess the nature and structure of the transaction to determine if there were processes and/or activities with inputs that would be sufficient to constitute a business.

Clinical trial and contracts accruals

Description of the Matter

During the year ended December 31, 2021, the Company incurred $23.9 million for research and development expense and as of December 31, 2021, the Company accrued $3.4 million for clinical trial and contract expenses. As described in Note 2 of the consolidated financial statements, the Company records accruals for estimated costs of research and development activities that include contract services for clinical trials. Clinical trial activities performed by third parties are accrued and expensed based upon estimates of the proportion of work completed over the life of the individual clinical trial and patient enrollment rates in accordance with agreements established with contract research organizations ("CROs") and clinical trial sites. Estimates are determined by reviewing contracts, vendor agreements and purchase orders, and through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services.

Auditing management’s accounting for clinical trial and contract accruals is especially challenging as evaluating the progress or stage of completion of the activities under the Company’s research and development agreements is dependent upon a high volume of data from third-party service providers and internal clinical personnel.

How We Addressed the Matter in Our Audit

To test the completeness of the Company’s clinical trial and contracts accruals, among other procedures, we obtained supporting evidence of the research and development activities performed for clinical trial and research and development contracts. We corroborated the progress of significant research and development activities through discussion with the Company’s personnel that oversee the research and development projects, and inspection of the Company’s contracts and related amendments with third parties. To verify the appropriate measurement of clinical trial and contracts accruals, we compared the costs for a sample of transactions against the related invoices and contracts, evaluated the Company’s documentation of timelines and future projections of contract progress, and confirmed certain amounts incurred to-date with third-party service providers. We also examined a sample of subsequent payments to evaluate the completeness of the clinical trial and contracts accruals.

/s/ Ernst & Young LLP

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

San Diego, California
March 16, 2022

Viracta Therapeutics, Inc.
Consolidated Balance Sheets
(In thousands, except par value and share data)

	December 31,	
	2021	2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 103,554	$ 47,089
Prepaid expenses and other current assets	1,719	110
Total current assets	105,273	47,199
Property and equipment, net	242	44
Operating lease right-of-use asset	640	986
Other assets	2,397	76
Total assets	$ 108,552	$ 48,305
Liabilities and stockholders' equity (deficit)		
Current Liabilities:		
Accounts payable	$ 2,901	$ 1,557
Accrued expenses	5,802	3,362
Operating lease liabilities	381	334
Current portion of long-term debt	—	1,031
Total current liabilities	9,084	6,284
Long-term debt, net	4,819	4,155
Operating lease liabilities, less current portion	278	658
Preferred stock warrant liability	—	106
Commitments and contingencies		
Series A-1 Convertible Preferred Stock, $0.0001 par value; 4,819,012 shares authorized, 4,819,012 shares issued and outstanding as of December 31, 2020; liquidation preference of $13,720,612 at December 31, 2020	—	2,968
Series B Convertible Preferred Stock, $0.0001 par value; 2,788,249 shares authorized, 2,788,249 shares issued and outstanding as of December 31, 2020; liquidation preference of $16,811,782 at December 31, 2020	—	15,484
Series C Convertible Preferred Stock, $0.0001 par value; 1,587,722 shares authorized, 1,587,722 shares issued and outstanding as of December 31, 2020; liquidation preference of $10,695,494 at December 31, 2020	—	9,392
Series D Convertible Preferred Stock, $0.0001 par value; 2,240,916 shares authorized, 2,224,329 shares issued and outstanding as of December 31, 2020; liquidation preference of $16,774,988 at December 31, 2020	—	16,589
Series E Convertible Preferred Stock, $0.0001 par value; 7,472,730 shares authorized, 7,392,240 shares issued and outstanding as of December 31, 2020; liquidation preference of $39,999,997 at December 31, 2020	—	38,869
Stockholders' equity (deficit):		
Convertible preferred stock, $0.0001 par value; 10,000,000 shares authorized as of December 31, 2021; 10,248 shares issued and outstanding as of December 31, 2021	5,452	—
Common stock, $0.0001 par value; 400,000,000 shares authorized; 37,424,863 and 905,987 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	4	1
Additional paid-in capital	254,592	4,714
Accumulated deficit	(165,677)	(50,915)
Total stockholders' equity (deficit)	94,371	(46,200)
Total liabilities and stockholders' equity (deficit)	$ 108,552	$ 48,305

See accompanying notes to consolidated financial statements.

Viracta Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Years Ended December 31,	
	2021	2020
Operating expenses:		
Research and development	$ 23,861	$ 13,467
Purchased and acquired in-process research and development	88,478	—
General and administrative	15,437	5,348
Total operating expenses	127,776	18,815
Gain on Royalty Purchase Agreement	13,500	—
Loss from operations	(114,276)	(18,815)
Other income (expense):		
Gain on forgiveness of PPP Loan	257	—
Interest income	38	48
Interest expense	(491)	(216)
Other expense	(290)	(34)
Total other expense	(486)	(202)
Net loss and comprehensive loss	$ (114,762)	$ (19,017)
Net loss per share of common stock, basic and diluted	$ (3.60)	$ (58.56)
Weighted-average shares used to compute basic and diluted net loss per share	31,870,067	324,728

See accompanying notes to consolidated financial statements.

Viracta Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands)

	Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Series E Convertible Preferred Stock		Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance December 31, 2019	4,819	$ 2,968	2,788	$ 15,484	1,588	$ 9,392	2,224	$ 16,589	—	$ —	—	$ —	72	$ —	$ 3,515	$ (31,898)	$ (28,383)
Exercise of warrants and stock options to purchase common stock	—	—	—	—	—	—	—	—	—	—	—	—	830	1	847	—	848
Vesting of early exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	—	4	—	4	—	4
Issuance of convertible preferred stock net issuance cost	—	—	—	—	—	—	—	—	7,392	38,869	—	—	—	—	—	—	—
Share-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	348	—	348
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(19,017)	(19,017)
Balance December 31, 2020	4,819	$ 2,968	2,788	$ 15,484	1,588	$ 9,392	2,224	$ 16,589	7,392	$ 38,869	—	$ —	906	$ 1	$ 4,714	$ (50,915)	$ (46,200)
Exercise of warrants and stock options to purchase common stock	—	—	—	—	—	—	—	—	—	—	—	—	411	—	339	—	339
Vesting of early exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	—	4	—	3	—	3
Issuance of common stock net of issuance costs	—	—	—	—	—	—	—	—	—	—	—	—	12,012	1	62,316	—	62,317
Issuance of common stock to former stockholders of Sunesis upon Merger	—	—	—	—	—	—	—	—	—	—	—	—	5,173	—	97,982	—	97,982
Conversion of convertible preferred stock into common stock upon Merger	(4,819)	(2,968)	(2,788)	(15,484)	(1,588)	(9,392)	(2,224)	(16,589)	(7,392)	(38,869)	—	—	18,812	2	83,300	—	83,302
Reclassification of preferred stock warrant liability to equity	—	—	—	—	—	—	—	—	—	—	—	—	—	—	396	—	396
Issuance of convertible preferred stock to former stockholders of Sunesis upon Merger	—	—	—	—	—	—	—	—	—	—	10	5,452	—	—	—	—	5,452
Vesting of restricted stock units	—	—	—	—	—	—	—	—	—	—	—	—	107	—	—	—	—
Share-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	5,542	—	5,542
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(114,762)	(114,762)
Balance December 31, 2021	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	10	$ 5,452	37,425	$ 4	$254,592	$ (165,677)	$ 94,371

See accompanying notes to consolidated financial statements.

Viracta Therapeutics, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Years Ended December 31,	
	2021	2020
Operating activities		
Net loss	$ (114,762)	$ (19,017)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on forgiveness of PPP Loan	(257)	—
Acquired in-process research and development	84,478	—
Purchased in-process research and development	4,000	—
Share-based compensation expense	5,542	348
Depreciation and amortization	178	32
Change in fair value of preferred stock warrant liability	290	12
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,045)	(28)
Other assets	884	(49)
Accounts payable	922	969
Accrued liabilities	907	1,674
Lease liabilities, net	12	5
Net cash used in operating activities	(18,851)	(16,054)
Investing activities		
Purchase of property and equipment	(252)	(55)
Purchase of in-process research and development	(4,000)	—
Cash acquired in connection with the Merger	17,143	—
Net cash provided by (used in) investing activities	12,891	(55)
Financing activities		
Proceeds from debt, net of issuance costs	(234)	5,260
Issuance of common stock, net of issuance costs	62,320	851
Issuance of preferred stock for cash, net of offering costs	—	38,869
Exercise of warrants and stock options to purchase common stock	339	—
Net cash provided by financing activities	62,425	44,980
Net increase in cash and cash equivalents	56,465	28,871
Cash and cash equivalents at beginning of period	47,089	18,218
Cash and cash equivalents at end of period	$ 103,554	$ 47,089
Supplemental disclosure of cash flow information		
Interest paid	$ 343	$ 115
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ 1,106
Noncash financing activities		
Warrants issued in connection with debt	$ —	$ 94
Warrant liability reclassification to equity	$ 396	$ —
Issuance of convertible preferred stock upon Merger	$ 5,452	$ —
Conversion of convertible preferred stock into common stock upon Merger	$ 83,302	$ —
Issuance of common stock upon Merger	$ 97,982	$ —

See accompanying notes to consolidated financial statements.

1. Organization and Basis of Presentation

Viracta Therapeutics, Inc. ("Viracta," the "Company," or the "combined company"), formerly known as Sunesis Pharmaceuticals, Inc., was incorporated in the state of Delaware in February 1998 and is based in San Diego, California. Viracta is a precision oncology company, focused on the development of new medicines targeting virus-associated malignancies. The Company is currently conducting three clinical trials for its combination product candidate as a potential therapy for the treatment of relapsed/refractory Epstein-Barr virus-positive lymphoma.

Merger Transaction between Private Viracta Therapeutics, Inc. and Sunesis Pharmaceuticals, Inc. and Name Change

On November 29, 2020, the Company, then operating as Sunesis Pharmaceuticals, Inc., entered into an agreement and plan of merger and reorganization (the "Merger Agreement") with privately-held Viracta Therapeutics, Inc. ("Private Viracta") and Sol Merger Sub, Inc., a wholly-owned subsidiary of the Company ("Merger Sub"). On February 24, 2021, transactions contemplated by the Merger Agreement were completed, and Merger Sub merged into Private Viracta, with Private Viracta as surviving the merger as a wholly owned subsidiary of the Company (the "Merger"). Sunesis changed its name to Viracta Therapeutics, Inc. On February 25, 2021, the combined company's common stock began trading on The Nasdaq Global Select Market under the ticker symbol "VIRX".

Except as otherwise indicated, references herein to "Viracta," the "Company," or the "combined company", refer to Viracta Therapeutics, Inc. on a post-Merger basis, and the term "Private Viracta" refers to the business of privately-held Viracta Therapeutics, Inc., prior to the completion of the Merger. References to "Sunesis" refer to Sunesis Pharmaceuticals, Inc. prior to completion of the Merger.

Pursuant to the terms of the Merger Agreement, each outstanding share of Private Viracta common stock outstanding immediately prior to the closing of the Merger was converted into approximately 0.1119 shares of Company common stock (the "Exchange Ratio"), after taking into account the Reverse Stock Split, as defined below. Immediately prior to the closing of the Merger, all shares of Private Viracta preferred stock then outstanding were exchanged into shares of common stock of Private Viracta. In addition, all outstanding options exercisable for common stock of Private Viracta and warrants exercisable for capital stock of Private Viracta became options and warrants exercisable for the same number of shares of common stock of the Company multiplied by the Exchange Ratio at an exercise price equal to the pre-Merger price divided by the Exchange Ratio. Immediately following the Merger, stockholders of Private Viracta owned approximately 86% of the outstanding common stock of the combined company.

This transaction was accounted for as a reverse asset acquisition in accordance with generally accepted accounting principles in the United States of America ("GAAP"), as Viracta was considered to be acquiring Sunesis and the Merger was accounted for as an asset acquisition, even though Sunesis was the legal acquirer and the issuer of the common stock in the Merger. This determination was primarily based on the facts that, immediately following the Merger: (i) Private Viracta's stockholders owned a substantial majority of the voting rights in the combined company, (ii) Private Viracta designated a majority of the members of the initial board of directors of the combined company, and (iii) Private Viracta's senior management holds all key positions in the senior management of the combined company. As a result, as of the closing date of the Merger, the net assets of Sunesis were recorded at their acquisition-date relative fair values in the accompanying consolidated financial statements of the Company and the reported operating results prior to the Merger are those of Private Viracta.

To determine the accounting for this transaction under GAAP, a company must assess whether an integrated set of assets and activities should be accounted for as an acquisition of a business or an asset acquisition. The guidance required an initial screen test to determine if substantially all of the fair value of the gross assets acquired was concentrated in a single asset or group of similar assets. The initial screen test was not met as there was no single asset or group of similar assets for Sunesis that represented a significant majority in this acquisition. However, at the time of the closing of the Merger, Sunesis did not have processes or an organized workforce that significantly contributed to its ability to create outputs, and substantially all of its fair value was concentrated in cash, working capital, and in-process research and development ("IPR&D"). As such, the acquisition was treated as an asset acquisition.

Concurrent with the execution of the Merger Agreement, Private Viracta entered into an agreement for the sale of common stock in a private placement, which was completed immediately prior to the close of the Merger and resulted in gross proceeds of approximately $65.0 million. In connection with the closing of the Merger and the concurrent private placement of common stock, the holders of the Company's preferred stock waived their right to exchange their shares into any class of the Company's stock other than common stock.

On February 24, 2021, in connection with, and prior to the completion of, the Merger, the Company effected a 3.5-for-one reverse stock split of its then outstanding common stock (the "Reverse Stock Split"). The par value and the authorized shares of the common stock were not adjusted as a result of the Reverse Stock Split. Unless otherwise noted herein, references to share and per-share amounts give retroactive effect to the Reverse Stock Split and the Exchange Ratio which was effectuated upon the Merger.

Liquidity and Risks

As of December 31, 2021, the Company has devoted substantially all of its efforts to product development and has not realized product sales revenues from its planned principal operations. The Company has a limited operating history, and the sales and income potential of the Company's business and market are unproven. The Company has experienced net losses since its inception and, as of December 31, 2021, had an accumulated deficit of $165.7 million. The Company expects to continue to incur net losses for at least the next several years. A successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure. If the Company is unable to generate revenues adequate to support its cost structure, the Company will need to raise additional equity through the issuance of its common stock, through other equity or debt financings or through collaborations or partnerships with other companies. As of December 31, 2021, the Company had cash and cash equivalents of approximately $103.6 million and working capital of $96.2 million. In February 2021, as disclosed above, Private Viracta completed the sale of common stock in a private placement resulting in gross proceeds of approximately $65.0 million. Additionally, the Company received approximately $17.1 million in cash and cash equivalents in the Merger previously discussed. Finally, in March 2021, the Company received $13.5 million in upfront proceeds related to the Royalty Purchase Agreement with XOMA (US) LLC (see Note 5).

On November 4, 2021, the Company entered into a loan and security agreement with Silicon Valley Bank ("SVB") and Oxford Finance LLC ("Oxford") for up to $50.0 million, with $5.0 million refinanced at the time of entering into the agreement and $45.0 million available under certain circumstances.

Based on the Company's current financial position and business plan, management believes that its existing cash and cash equivalents, as well as its credit facility, will be sufficient to fund the Company's planned operations for at least twelve months from the issuance date of these consolidated financial statements.

The COVID-19 pandemic has caused significant business disruption around the globe. The extent of the impact of COVID-19 on the Company's operational and financial performance will depend on certain developments, including the duration and spread of the pandemic and the impact on the Company's clinical trials, employees, and vendors. At this point, the degree to which COVID-19 may impact the Company's financial condition or results of operations is uncertain. A continued and prolonged pandemic could have a material and adverse impact on financial results and business operations of the Company, including the timing and ability of the Company to complete certain clinical trials and other efforts required to advance the development of its product candidates and raise additional capital.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries and have been prepared in accordance with GAAP. All intercompany balances and transactions have been eliminated upon consolidation.

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 of expenses during the reporting period. Actual results could differ materially from those estimates.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash and cash equivalents.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity from the date of purchase of three months or less to be cash equivalents.

Property and Equipment

Property and equipment, which consisted of office equipment, were stated at cost and depreciated over the estimated useful lives of the assets (three to five years) using the straight-line method. Leasehold improvements were amortized over the shorter of their estimated useful lives or the lease term.

Leases

The Company classifies leases as either operating or finance leases at inception and as necessary at modification. Leased assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. The Company does not obtain and control its right to use the identified asset until the lease commencement date.

Operating leases are included in operating lease right-of-use ("ROU") assets, and operating lease liabilities on the Company's balance sheets. Operating lease ROU assets and liabilities are recognized at lease commencement date based on the present value of lease payments over the lease term. When readily determinable, the Company uses the rate implicit in the lease to discount lease payments; however, when the rate is not readily determinable, the Company uses the incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The incremental borrowing rate is the rate of interest that the Company would have to pay to borrow an amount equal to the lease payments on a collateralized basis over a similar term and in a similar economic environment. The operating lease ROU asset also includes any initial direct costs, lease payments made prior to lease commencement, and lease incentives received. Variable lease payments are expensed as incurred and are not included within the ROU asset and lease liability calculation. The Company's lease terms are the noncancelable period and may include options to extend the lease when it is reasonably certain that it will exercise that option. Lease cost for lease payments is recognized on a straight-line basis over the lease term. The Company does not separate lease and non-lease components.

The Company does not recognize ROU assets and lease liabilities for short-term leases, which have a lease term of twelve months or less and do not include an option to purchase the underlying asset that the Company is reasonably certain to exercise. Lease cost for short-term leases is recognized on a straight-line basis over the lease term.

Revenue Recognition

Revenue is recognized when control of the promised goods or services is transferred to the Company's customers in an amount that reflects the consideration the Company expects to receive from its customers in exchange for those goods and services. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the transaction price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when or as the Company satisfies the performance obligation(s).

At contract inception, the Company assesses the goods and services promised within each contract and assesses whether each promised good or service is distinct and determines that those are performance obligations. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. The Company considers factors such as the research, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. The Company considers a performance obligation satisfied once the Company has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. The Company recognizes revenue for satisfied performance obligations only when the Company determines there are no uncertainties regarding payment terms or transfer of control.

Collaborative Arrangements

The Company evaluates collaboration arrangements to determine whether units of account within the collaboration arrangement exhibit the characteristics of a vendor and customer relationship. For arrangements and units of account where a customer relationship exists, the Company applies the revenue recognition guidance. The Company enters into collaborative arrangements with partners that may include payment to the Company of one or more of the following: (i) license fees; (ii) payments related to the achievement of developmental, regulatory, or commercial milestones; and (iii) royalties on net sales of licensed products.

If a contract has multiple performance obligations, the Company allocates the transaction price to each distinct performance obligation in an amount that reflects the consideration the Company is entitled to receive in exchange for satisfying each distinct performance obligation. For each distinct performance obligation, revenue is recognized when (or as) the Company transfers control of the product or the service applicable to such performance obligation. The Company evaluates each performance obligation to determine if it can be satisfied at a point in time or over time. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

License Fees

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license.

Milestone Payments

At the inception of each arrangement that includes milestone payments (variable consideration), the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. If it is probable that a milestone event would occur at the inception of the arrangement, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each reporting period, the Company evaluates the probability of achievement of such milestones and any related constraint(s), and if necessary, may adjust the Company's estimate of the overall transaction price. To date, the Company has not recognized any milestone revenue resulting from its collaborative arrangements.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, the Company recognizes revenue when the related sales occur. To date, the Company has not recognized any royalty revenue resulting from its collaborative arrangements.

Clinical Trial and Contracts Accruals

The Company accrues clinical trial costs based on work performed. In determining the amount to accrue, the Company relies on estimates of total costs incurred based on enrollment, the completion of clinical trials and other events. The Company follows this method because it is believed to be reasonably dependable estimates of the costs applicable to various stages of a clinical trial can be made. However, the actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending on a number of factors. Differences between the actual clinical trial costs and the estimated clinical trial costs that have been accrued in any prior period are recognized in the subsequent period in which the actual costs become known. Historically, estimated accrued expenses have approximated actual expenses incurred; however, material differences could occur in the future.

Research and Development Expenses

Research and development costs are expensed as incurred. These costs consist primarily of salaries and other personnel-related expenses, including share-based compensation; facility-related expenses; and services performed by clinical research organizations, research institutions, and other outside service providers.

The Company makes estimates of its accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. This process involves reviewing contract and purchase orders, reviewing the terms of vendor agreements, communicating with applicable personnel to identify services that have been performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for the services when it has not yet been invoiced or otherwise notified of actual cost. The majority of the Company's service providers invoice monthly in arrears for services performed.

Income Taxes

Income taxes are accounted for under the asset and liability method. This approach requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of the differences between the tax basis of assets or liabilities and their carrying amounts in the consolidated financial statements using the enacted tax rates and laws that are anticipated to be in effect when the differences are expected to reverse. The Company provides a valuation allowance against net deferred tax assets if it is more likely than not that these items will either expire before the Company is able to realize their benefit or if future deductibility is uncertain.

In accordance with the accounting standards for uncertain tax positions, the Company evaluates the recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities.

Share-Based Compensation

The Company accounts for share-based compensation expense related to stock options granted to employees, members of the board of directors, and outside consultants by estimating the fair value of each stock option on the date of grant using the Black-Scholes option pricing model. The Company accounts for restricted stock units ("RSUs") by determining the fair value of each restricted stock unit based on the closing market price of the common stock on the date of grant. The Company recognizes share-based compensation on a straight-line basis over the requisite service period of the stock-based award, and forfeitures are recognized as they occur. The estimate of fair value for share-based compensation for stock options requires management to make estimates and judgments about, among other things, employee exercise behavior and volatility of the Company's common stock. The judgments directly affect the amount of compensation expense that will be recognized.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is used in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and managed its business as one segment operating in the United States. All long-lived assets were located in the United States at December 31, 2021 and December 31, 2020.

Fair Value Measurements

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

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

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

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

The carrying amounts of the Company's cash and cash equivalents, prepaid expenses, accounts payable and accrued liabilities approximate fair values for these financial instruments due to their short maturities. The money market funds, classified as cash equivalents, are Level 1 and had an amortized cost and estimated fair value of $14.9 million as of December 31, 2021. The Company had no money market funds prior to 2021.

The preferred stock warrant liability, a level 3 fair value measurement, was $0 as of December 31, 2021, due to the reclassification to equity, and $106,000 as of December 31, 2020. The Company had no liabilities measured at fair value on a recurring basis as of December 31, 2021. The Company had no assets or liabilities measured at fair value on a recurring basis as of December 31, 2020, other than the preferred stock warrant liability.

Preferred Stock Warrant Liability

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the preferred stock warrant liability were as follows:

	February 24, 2021 (date of Merger close)
Expected volatility	90.2%
Risk-free interest rate	1.38%
Expected dividend yield	0%
Expected term	9.3 years
Fair value per share of preferred stock	$ 17.15

The following table provides a reconciliation of the preferred stock warrant liability measured at fair value using Level 3 significant unobservable inputs (in thousands):

	Preferred Stock Warrant Liability
Balance at December 31, 2020	$ 106
Change in fair value of preferred stock warrant liability	290
Reclassification to equity	(396)
Balance at December 31, 2021	$ —

Net Loss Per Share

Basic loss per common share is computed by dividing net loss by the weighted average number of common shares and warrants to purchase common stock for nominal consideration outstanding during the period. Diluted loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding, plus the impact of common shares, if dilutive, resulting from the exercise of outstanding common stock equivalents. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding due to the Company's net loss position.

The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	December 31,	
	2021	2020
Shares issuable upon conversion of preferred stock	292,799	18,811,552
Common stock options and RSUs outstanding	4,797,240	1,127,842
Warrants to purchase preferred stock	—	23,100
Warrants to purchase common stock	23,100	—
Total excluded securities	5,113,139	19,962,494

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, *Debt – Debt with Conversion and Other options (Subtopic 470-20) and Derivative and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40)*. The amendments in this ASU reduce the number of accounting models for convertible debt instruments and convertible preferred stock, as well as amend the guidance for the derivatives scope exception for contracts in an entity's own equity to reduce form-over-substance-based accounting conclusions. In addition, this ASU improves and amends the related earnings per share guidance. The amendments in this ASU are effective for the Company on January 1, 2024, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. Adoption is either a modified retrospective method or a fully retrospective method of transition. The Company early adopted ASU 2020-06 on January 1, 2021, electing the modified retrospective transition method that allows for a cumulative-effect adjustment in the period of adoption. The adoption of ASU 2020-06 did not have a material impact on the Company's consolidated financial statements.

In October 2021, the FASB issued ASU No. 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers.* The amendment requires acquiring entities to apply Topic 606 to recognize and measure contract assets and contract liabilities in a business combination. The ASU will be effective for the Company for the annual

periods beginning after December 15, 2022, with early adoption permitted. The Company early adopted ASU 2021-08 in the fourth quarter of 2021 with no material impact on its consolidated financial statements.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies that the Company will adopt as of the specified effective date. The Company has evaluated recently issued accounting pronouncements and as a result, based on the Company's preliminary assessment, do not believe any will have a material impact on the consolidated financial statements or related footnote disclosures.

3. Collaboration and License Agreements

Shenzhen Salubris Pharmaceuticals Co. Ltd. License Agreement

On November 30, 2018, the Company entered into a License Agreement (the "Salubris Agreement") with Shenzhen Salubris Pharmaceutical Co. Ltd., ("Salubris"), pursuant to which the Company granted an exclusive, royalty-bearing license, with the right to grant sublicenses to Salubris to research, develop, use, make, have made, sell, offer for sale, have sold, import, and otherwise commercialize nanatinostat in combination with an antiviral drug such as valganciclovir in the Republic of China, excluding Hong Kong, Macau, and Taiwan.

On August 19, 2021, the Company, through its wholly-owned subsidiary, Viracta Subsidiary, Inc., entered into a Mutual Termination Agreement with Salubris, effective August 20, 2021 (the "Termination Agreement"), pursuant to which the parties agreed to terminate the Salubris Agreement. Under the terms of the Termination Agreement, the Company paid Salubris a payment in the amount of $4.0 million on the effective date of the Termination Agreement, and all licenses granted by the Company to Salubris automatically terminated. The Company recorded the $4.0 million payment as purchased and acquired in-process research and development in the statement of operations and comprehensive loss for the year ended December 31, 2021.

ImmunityBio License Agreement

On May 1, 2017, the Company entered into a License Agreement (the "NK Agreement") with ImmunityBio, Inc., formerly NantKwest, Inc. ("ImmunityBio") whereby the Company granted an exclusive worldwide license to ImmunityBio and its affiliates to develop and commercialize nanatinostat for use in combination with NK cell immunotherapies. ImmunityBio will be responsible for conducting all necessary studies, including safety studies and clinical trials necessary in connection with seeking regulatory approvals to market the product in any territory. If ImmunityBio requires nanatinostat, the Company has the right to manufacture nanatinostat to be sold as part of a therapeutic product utilizing nanatinostat at a transfer price related to Viracta's cost to ImmunityBio.

In accordance with the NK Agreement, the Company is also eligible to receive up to a total of $100.0 million in milestone payments, with respect to the licensed products. The Company is eligible to earn tiered royalties on net sales of licensed products by ImmunityBio, its affiliates or sublicensees, ranging from the low to mid-single digits. The Company has recognized no revenue from milestones (variable consideration), which are fully constrained, or royalties to date.

Unless earlier terminated, the NK Agreement will continue until the expiration of all applicable royalty terms on a product-by-product and country-by-country basis. There are no performance, cancellation, termination, or refund provisions in the arrangement that contain material financial consequences to the Company.

4. Financial Statement Details

Accrued expenses consist of the following (in thousands):

	December 31,	
	2021	2020
Accrued payroll and benefits	$ 1,695	$ 1,501
Accrued clinical trial and contract expenses	3,380	1,095
Accrued professional services and expenses	180	716
Other accrued expenses	547	50
Total accrued expenses	$ 5,802	$ 3,362

5. XOMA Transaction

On March 22, 2021, the Company entered into a Royalty Purchase Agreement with XOMA (US) LLC ("XOMA"), in which XOMA purchased the potential future milestones and royalties associated with existing licenses relating to two clinical-stage product candidates, DAY101 and vosaroxin, which were obtained in the Merger (the "XOMA Transaction"). The Company received an upfront payment of $13.5 million and may receive up to $20.0 million in a pre-commercialization, event-based milestone. The upfront payment is nonrefundable, there are no clawback provisions, and the Company has no significant involvement or obligations going forward related to potential future milestones and royalties. The Company has recognized no income from the pre-commercialization, event-based milestone to date.

In December 2019, Sunesis entered into a license agreement with DOT Therapeutics-1, LLC ("DOT-1") to grant DOT-1 a worldwide, exclusive license of DAY101. The DOT-1 license agreement includes up to $57.0 million in potential pre-commercialization, event-based milestone payments and royalty payments on future sales of DAY101, when and if approved and commercialized, $3.0 million of which was received by Sunesis prior to the XOMA Transaction. Also in December 2019, Sunesis entered into an agreement to license vosaroxin to Denovo Biopharma LLC, which includes up to $57.0 million in potential regulatory and commercial milestones, and double-digit royalties on future sales of vosaroxin, when and if approved and commercialized. The potential milestone and royalty payments related to DAY101 and vosaroxin were sold in the XOMA Transaction.

6. Debt

Loan Agreement

On July 30, 2020, Private Viracta and Silicon Valley Bank (the "Lender") entered into a loan and security agreement (the "SVB Loan Agreement"), providing for up to $15.0 million in four tranches. Upon entering into the SVB Loan Agreement, Private Viracta borrowed $5.0 million.

The loan was due on the scheduled maturity date of July 1, 2024 and had an interest only period through January 31, 2022, followed by 30 equal monthly payments of principal plus accrued interest commencing on February 1, 2022. The per annum interest rate for any outstanding loan was the lesser of (i) 10%, or (ii) the greater of (A) 3.5% above the prime rate or (B) 6.75%. The interest rate as of December 31, 2020 was 6.75% per annum. In addition, a final payment of 7.0% of the amount of the loan drawn was due on the earlier of the Maturity Date, acceleration of the loan, or prepayment of the loan. The final payment was accrued through interest expense using the effective interest method. The debt issuance costs and warrants issued (Note 8) were accounted for as a debt discount. The debt discount was being amortized as interest expense over the term of the loan using the effective interest method. If the Company elected to prepay the loan, a prepayment fee equal to 1% or 2% of the then outstanding principal balance was also due, depending upon when the prepayment occurs. No prepayment fee is charged if the credit is replaced with a new facility from the same bank.

On November 4, 2021, the Company entered into a new loan and security agreement with SVB and Oxford (the "Loan Agreement") for up to $50.0 million. In connection with entering the new $50.0 million credit facility, the Company and SVB agreed to terminate the Company's prior $15.0 million loan and security agreement with SVB. The existing $5.0 million debt balance from the Company's previous credit facility with SVB was relieved under this new $50.0 million credit facility. The Loan Agreement was accounted for as a modification based on the effect of changes in terms from the original SVB Loan Agreement. Under the terms of the $50.0 million credit facility, the remaining $45.0 million is available in two additional tranches of $20.0 million and $25.0 million under certain circumstances, and the Company is under no obligation to draw funds in the future.

The loan will be due on the scheduled maturity date of November 1, 2026 (the "Maturity Date"). In accordance with the original terms of the Loan Agreement, repayment of the loan is interest only through December 31, 2023, and, upon completion of the certain milestones, the interest only period would be extended through December 31, 2024. This period of interest only will be followed by 35 equal monthly payments of principal plus accrued interest commencing on January 1, 2024, or if the milestone is achieved, the period of interest only will be followed by 23 equal monthly payments of principal plus accrued interest commencing on January 1, 2025. The per annum interest rate for any outstanding loan is equal to the greater of (i) 8.15% and (ii) the sum of (a) the Prime Rate, as reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 4.90%. In addition, a final payment of 5.0% of the amount of the loan drawn will be due on the earlier of the Maturity Date, acceleration of the loan, or prepayment of the loan. The final payment is being accrued through interest expense using the effective interest method. If the Company elects to prepay the loan, a prepayment fee equal to 1% or 2% of the then outstanding principal balance will also be due, depending upon when the prepayment occurs. If the Company elects to not draw certain portions of the loan, the Company will incur a 3% fee of the undrawn portion.

The Company is subject to customary affirmative and restrictive covenants under the Loan Agreement. The Company's obligations under the Loan Agreement are secured by a first priority security interest in substantially all of its current and future assets, other than

the Company's intellectual property. The Company has also agreed not to encumber its intellectual property assets, except as permitted by the Loan Agreement.

The Loan Agreement also contains customary indemnification obligations and customary events of default, including, among other things, the Company's failure to fulfill certain obligations under the Loan Agreement and the occurrence of a material adverse change in the Company's business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan, or a material impairment in the perfection or priority of Lender's lien in the collateral or in the value of such collateral. In the event of default by the Company under the Loan Agreement, the Lender would be entitled to exercise their remedies thereunder, including the right to accelerate the debt, upon which the Company may be required to repay all amounts then outstanding under the Loan Agreement. As of December 31, 2021, the Company was in compliance with all financial covenants under the Loan Agreement and there had been no material adverse change.

The debt issuance costs are being accounted for as a debt discount. The debt discount is being amortized as interest expense over the term of the loan using the effective interest method. The carrying value of the debt approximates the fair value (Level 2) as of December 31, 2021.

The following table summarizes future principal payments (in thousands) under the terms of the Loan Agreement:

Year Ending December 31,	
2022	$ —
2023	—
2024	1,714
2025	1,714
Thereafter	1,572
Total future principal payments	5,000
Unamortized discount	(181)
Total, net	$ 4,819

Paycheck Protection Program Loan

On April 24, 2020, Viracta received loan proceeds of $0.3 million from First Republic Bank, as lender, pursuant to the Payment Protection Program ("PPP") of the CARES Act (the "PPP Loan"). The maturity date of the PPP Loan was April 23, 2022, with a per annum interest rate of 1.0%. The PPP Loan was evidenced by a promissory note dated April 23, 2020, which contained customary events of default relating to, among other things, payment defaults and breaches of representations and warranties. The PPP Loan could have been prepaid by the Company at any time prior to maturity with no prepayment penalties.

All or a portion of the PPP Loan was potentially eligible for forgiveness by the U.S. Small Business Administration ("SBA") upon the Company's application and upon documentation of expenditures in accordance with the SBA requirements. Under the CARES Act and PPP Flexibility Act, loan forgiveness was available for the sum of documented payroll costs, covered mortgage interest, covered rent payments and covered utilities during the 24-week period beginning on the date of loan disbursement. In the event the PPP Loan, or any portion thereof, was forgiven pursuant to the PPP, the amount forgiven would be applied to outstanding principal and would include accrued interest.

The Company used all proceeds from the PPP Loan to retain employees, maintain payroll and make lease and utility payments, and sought forgiveness in accordance with the program in late 2020.

In June 2021, the Company received notification from the SBA that the Company's Forgiveness Application of the PPP Loan and accrued interest, totaling $0.3 million, was approved in full and the Company had no further obligations related to the PPP Loan. Accordingly, the Company recorded a gain on the forgiveness of the PPP Loan for the year ended December 31, 2021.

7. Merger

The Merger, which closed on February 24, 2021, was accounted for as a reverse asset acquisition pursuant to Topic 805, *Business Combinations*, as substantially all of its fair value was concentrated in cash, working capital, and IPR&D. As the IPR&D assets had no alternative future use, the fair value attributable to these assets was recorded as acquired IPR&D in the Company's consolidated statements of operations for the year ended December 31, 2021.

The estimated fair value of total consideration given was $103.4 million based on 5,173,772 shares of Sunesis common stock and 10,248 shares of Sunesis convertible preferred stock (or 292,799 Sunesis common shares on an as-converted basis) outstanding immediately prior to the merger date. The number of outstanding common stock and preferred stock on an as-converted basis was multiplied by the Sunesis closing common stock price of $18.62 on the date of the merger, plus transaction costs of approximately $1.6 million, to determine the estimated fair value of total consideration.

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

Net assets acquired (1)	$	18,956
Acquired IPR&D (2)		84,478
Purchase price	$	103,434

(1) Net assets acquired (in thousands):

Cash and cash equivalents	$	17,143
Prepaid expenses and other assets		3,768
Accounts payable and accrued liabilities		(1,955)
Net assets acquired	$	18,956

(2) Represents the research and development projects of Sunesis which were in-process, but not yet completed. Current accounting standards require that the fair value of IPR&D projects acquired in an asset acquisition with no alternative future use be allocated a portion of the consideration transferred and charged to expense on the acquisition date. The acquired IPR&D assets did not have outputs or employees.

8. Stockholders' Equity

Common Stock

The total number of shares of common stock of Viracta outstanding as of December 31, 2021 and December 31, 2020 was 37,424,863 and 905,987, respectively.

Concurrent Financing

On February 24, 2021, immediately prior to the closing of the Merger, the Company completed the February 2021 private placement offering of an aggregate of 12,012,369 shares of common stock for gross proceeds of $65.0 million and incurred fees and other offering costs of approximately $2.7 million.

Sales Agreement

On May 28, 2021, the Company entered into an Open Market Sale Agreement℠ (the "Sale Agreement") with Jefferies LLC (the "Sales Agent"), under which the Company may offer and sell up to $50.0 million shares (the "Shares") of its common stock, par value $0.0001 per share ("Common Stock"), from time to time through the Sales Agent. The sales and issuances, if any, of the Shares by the Company under the Sale Agreement will be pursuant to the Company's registration statement on Form S-3 (the "Registration Statement"), filed with the SEC on May 28, 2021 and declared effective by the SEC on June 4, 2021.

Sales, if any, of the Shares pursuant to the Sale Agreement may be made in negotiated transactions or transactions that are deemed to be "at the market offerings" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, including sales made directly on The Nasdaq Stock Market, or sales made into any other existing trading market for the Common Stock. The Sales Agent is not required to sell any specific amount of securities, but will act as the Company's sales agent using commercially reasonable efforts to sell the Shares from time to time, consistent with its normal trading and sales practices, applicable state and federal laws, rules and regulations and the rules of The Nasdaq Stock Market, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). As of December 31, 2021, the Company has incurred legal and accounting costs of $0.1 million related to the Sales Agreement. As of December 31, 2021, no shares had been issued pursuant to the Sales Agreement.

Convertible Preferred Stock

On November 25, 2020, the Company completed a Series E Preferred Stock equity financing, issuing 7,392,240 shares at a price per share of $5.41, which yielded gross proceeds of approximately $40.0 million. The Series E Preferred Stock was convertible into common stock at any time prior to the Merger. The number of shares of common stock that will be issued upon such conversion is determined by dividing its original issuance price by the applicable conversion price.

Liquidation Preference

The outstanding shares would have been entitled to certain liquidation preferences according to their agreements, in the event of any liquidation, dissolution, or winding up of the Company, either voluntary or involuntary. Series E Preferred Stock held liquidation preference priority over Series D Preferred Stock, Series C Preferred Stock, Series B Preferred Stock and Series A-1 Preferred Stock. Series D Preferred Stock held liquidation preference priority over Series C Preferred Stock, Series B Preferred Stock and Series A-1 Preferred Stock. Series C Preferred Stock held liquidation preference priority over both Series B Preferred Stock and Series A-1 Preferred Stock. Series B Preferred Stock held priority over Series A-1 Preferred Stock.

If, upon the occurrence of such event, the proceeds distributed among the holders of the Series E Preferred Stock, the Series D Preferred Stock, the Series C Preferred Stock, the Series B Preferred Stock, and the Series A-1 Preferred Stock would have been insufficient to permit the full payment of the aforementioned preferential amounts to each holder of convertible preferred stock, then the entire proceeds legally available for distribution to the convertible preferred stock would have been distributed ratably among the holders of the Series E Preferred Stock, Series D Preferred Stock, Series C Preferred Stock, the Series B Preferred Stock, and the Series A-1 Preferred Stock in proportion to the full preferential amount that each such holder of convertible preferred stock was otherwise entitled to receive.

Upon completion of the distributions required by the above-mentioned liquidation preferences, any remaining proceeds would have been distributed among the holders of Series E Preferred Stock, Series D Preferred Stock, Series C Preferred Stock, Series B Preferred Stock, Series A-1 Preferred Stock and common stock pro rata based on the number of shares of common stock held by each, assuming full conversion of the Series E Preferred Stock, Series D Preferred Stock, Series C Preferred Stock, the Series B Preferred Stock, and the Series A-1 Preferred Stock, to common stock at the then-effective conversion price for such shares.

Dividends

The holders of shares of Series E Preferred Stock, Series D Preferred Stock, Series C Preferred Stock, Series B Preferred Stock, and Series Preferred Stock would have been entitled to receive dividends, out of any assets legally available, prior and in preference to any declaration or payment of any dividend on the common stock, in an amount at least equal to 8% per annum of the Series E original issue price, Series D original issue price, Series C original issue price, the Series B original issue price and the Series A-1 original issue price, respectively, all subject to adjustment from time to time for recapitalizations, payable when and if declared by the Company's board of directors. The Company did not declared any dividends on its convertible preferred stock.

Voting

The holder of each share of Series E Preferred Stock, Series D Preferred Stock, Series C Preferred Stock, Series B Preferred Stock and Series A-1 Preferred Stock would have been entitled to one vote for each share of common stock into which such preferred stock could then be converted and, with respect to such vote, such holder had full voting rights and powers equal to the voting rights and powers of the holders of common stock and would have been entitled to notice of any stockholders' meeting in accordance with the Company's bylaws.

The Company was a party to a voting agreement with certain holders of its capital stock. The parties to the voting agreement had agreed, subject to certain conditions, to vote the shares of the Company's capital stock held by them so as to elect the following individuals as directors: (1) two individuals designated by the holders of a majority of the outstanding shares of Series A-1 Preferred Stock, Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock, (2) one individual who is an industry expert designated by the holders of a majority of the outstanding shares of Series A-1 Preferred Stock, Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock, voting together as a single class and on an as-converted to Common Stock basis, (3) one individual designated by certain Series E holder, so long as that holder owns any shares of Series E Preferred Stock, (4) one individual designated by the holders of a majority of the outstanding shares of Series E Preferred Stock, (5) one individual who is an industry expert designated by the holders of a majority the outstanding shares of Series E Preferred Stock, and (6) the Company's Chief Executive Officer.

Upon the consummation of the merger with Sunesis Pharmaceuticals, Inc., the obligations of the parties to the voting agreement to vote its shares so as to elect these nominees, as well as the other rights and obligations under this agreement, terminated and none of

the Company's stockholders have any special rights regarding the nomination, election or designation of members of the combined company's board of directors.

Redemption

The Company's convertible preferred stock were not explicitly redeemable or at a specified date in the future. The convertible preferred stock were presented outside of stockholders' equity because in the event of certain deemed liquidation events considered not solely within the Company's control, such as a merger, acquisition and sale of all or substantially all of the Company's assets, the convertible preferred stock were redeemable at the option of the holders. As these deemed liquidation events were not probable of occurring, the Company did not adjust the carrying values of the convertible preferred stock.

Automatic Conversion - Merger

Upon the closing of a sale of shares of common stock in a public offering, all outstanding shares of Series A-1 Preferred Stock, Series B Preferred Stock, Series C Preferred Stock, Series D Preferred Stock and Series E Preferred Stock were automatically converted into shares of common stock at the then effective conversion price, given that (a) the offering results in gross proceeds to the Company of at least $40.0 million before underwriting discount and commissions, and (b) the shares of common stock were listed for trading on the NASDAQ Global Market. In connection with the closing of the merger and the concurrent private placement of common stock, the holders of the Company's preferred stock waived their right to exchange their shares into any class of stock other than common and converted to common stock immediately prior to the closing of the concurrent private placement of common stock.

In connection with the Merger, all of the outstanding shares of Private Viracta's convertible preferred stock were converted into 18,811,552 shares of the Company's common stock. As of December 31, 2020, Private Viracta's convertible preferred stock was classified as temporary equity on the accompanying consolidated balance sheets in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities whose redemption is based upon certain change in control events outside of Private Viracta's control, including liquidations, sale or transfer of control of Private Viracta. Private Viracta did not adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because the occurrence of any such change of control event was not deemed probable.

With the Merger, the Company obtained 10,000,000 shares of authorized preferred stock available for future issuance in one or more series. Upon issuance, the Company can determine the rights, preferences, privileges and restrictions thereof. These rights, preference and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. There were 10,248 shares of this preferred stock outstanding as of December 31, 2021, of which 1,915 shares were Series E Stock and 8,333 shares were Series F Stock.

The Series E Stock and Series F Stock are non-voting Series E and Series F Convertible Preferred Stock at a stated price of $500 and $600 per share, respectively. Each share of non-voting Series E Stock and Series F Stock is convertible at a conversion ratio equal to the stated price divided by the conversion price, which is $17.50 per share and $21.00 per share, respectively, provided that conversion will be prohibited if, as a result, the holder and its affiliates would own more than 9.98% of the total number of shares of common stock then outstanding. In the event of the Company's liquidation, dissolution, or winding up, holders of Series E and Series F Stock will receive a payment before any proceeds are distributed to the holders of Common Stock. Shares of Series E and Series F Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of this outstanding Series E Stock will be required to amend the terms of the Series E and Series F Stock. Shares of the Series E and Series F Stock will not be entitled to receive any dividends, unless and until specifically declared by the Company's board of directors, and will rank:

- senior to all of the Company's Common Stock;
- senior to any class or series of the Company's capital stock hereafter created specifically ranking by its terms junior to the Series E and Series F Stock;
- on parity with any class or series of the Company's capital stock hereafter created specifically ranking by its terms on parity with the Series E and Series F Stock; and
- junior to any class or series of the Company's capital stock hereafter created specifically ranking by its terms senior to the Series E and Series F Stock; in each case, as to distributions of assets upon the Company's liquidation, dissolution or winding up whether voluntarily or involuntarily.

Warrants

Concurrent with the issuance of convertible promissory notes in 2018, the Company issued to the note investors warrants to purchase 250,323 shares of Viracta Common Stock (the "Common Warrants"). The Common Warrants' exercise price was $0.09 per share. Unless previously exercised, the Common Warrants will expire on the seven-year anniversary of the date of issuance. As of December 31, 2021, Common Warrants to purchase 86,209 shares of Viracta Common Stock remain unexercised. These shares have been included in the weighted average shares outstanding for both basic and diluted earnings per share for the years ended December 31, 2021 and 2020 as their exercise price is for nominal consideration.

In July 2020, the Company issued warrants exercisable for 206,440 pre-merger shares of Series E preferred stock, at a pre-merger exercise price of $0.6055 per share, to Silicon Valley Bank in conjunction with the Company's entry into the SVB Loan Agreement (the "Lender Warrants"). Upon completion of the Merger, the Lender Warrants became exercisable for 23,100 shares of common stock at an exercise price of $5.42 per share. The Lender Warrants will expire on July 30, 2030.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance are as follows in common equivalent shares:

	December 31,	
	2021	2020
Conversion of preferred stock	292,799	18,811,552
Common stock warrants	109,309	193,266
Preferred stock warrants	—	23,100
Stock options issued and outstanding for all plans	4,051,572	1,127,842
RSUs outstanding	745,668	—
Authorized for future option grants	1,169,523	1,108,809
Common stock authorized for the ESPP	60,948	—
Total	6,429,819	21,264,569

Equity Incentive Plans

In January 2017, the Company adopted the Viracta Therapeutics, Inc. 2016 Equity Incentive Plan (the "2016 Plan"), which permitted stock option and restricted stock unit grants to employees, members of the board of directors, and outside consultants. The Plan allowed for grants of incentive stock options with exercise prices of at least 100% of the fair market value of Viracta's common stock, nonqualified options with exercise prices of at least 85% of the fair market value of the Company's common stock, restricted stock, and restricted stock units. All stock options granted under the 2016 Plan have a ten-year life and generally vest over zero to four years. In connection with the closing of the Merger, no further awards will be made under the 2016 Plan but the 2016 Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the 2016 Plan.

At the time of the close of the Merger, the Company adopted the Viracta Therapeutics, Inc. 2021 Equity Incentive Plan (the "2021 Plan"), which also permits stock options and restricted stock unit grants to employees, members of the board of directors, and outside consultants. The maximum number of shares of the Company's common stock available for issuance under the 2021 Plan equals the sum of (a) 2,628,571 shares; (b) any shares of common stock of the Company which are subject to awards under the Sunesis 2011 Equity Incentive Plan (the "Sunesis 2011 Plan") or the 2016 Plan as of the effective date of the 2021 Plan which become available for issuance under the 2021 Plan after such date in accordance with its terms; and (c) an annual increase on the first day of each calendar year beginning with January 1 of the calendar year following the effectiveness of the 2021 Plan and ending with the last January 1 during the initial ten year term of the 2021 Plan. This annual increase would be equal to the lesser of (i) 3,771,428 shares, (ii) five percent of the number of shares of the Company's common stock outstanding (on an as-converted basis) on the final day of the immediately preceding calendar year, and (iii) such number of shares of the Company's common stock as determined by the Company's board of directors. The 2021 Plan allows for grants of incentive stock options with exercise prices of at least 100% of the fair market value of Viracta's common stock, nonqualified options with exercise prices of at least 100% of the fair market value of the Company's common stock, restricted stock, and restricted stock units. All stock options granted to date have a ten-year life and generally vest over zero to four years.

Additionally, in connection with the closing of the Merger, no further awards will be made under the Sunesis 2011 Plan. As of December 31, 2021, 88,019 fully vested options remain outstanding under the Sunesis 2011 Plan with a weighted average exercise price of $27.65 per share.

The share-based compensation recorded in the accompanying consolidated statements of operations for the years ending December 31, 2021 and 2020 is presented below (in thousands):

	Year Ended December 31,	
	2021	2020
Research and development	$ 2,122	$ 158
General and administrative	3,420	190
Total	$ 5,542	$ 348

On June 30, 2021, the Company adopted the 2021 Inducement Equity Incentive Plan (the "2021 Inducement Plan") and reserved 1,000,000 shares for future grant under the 2021 Inducement Plan. As of December 31, 2021, there were 715,000 shares available for issuance under the 2021 Inducement Plan.

Stock Options

The Company recorded share-based compensation related to stock options of $4.8 million and $0.3 million for the year ended December 31, 2021 and 2020, respectively. Fair value is determined on the date of grant for options. Compensation expense is recognized over the vesting period based on the fair value of the options.

The fair value of stock options is estimated using the Black-Scholes model with the assumptions disclosed in the following table:

	Year Ended December 31,	
	2021	2020
Risk free interest rate	0.66% - 1.33%	0.46% - 0.87%
Expected option term	5.8 - 6.3 years	5.5 - 6.3 years
Expected volatility of common stock	84.15% - 90.20%	72.13% - 90.20%
Expected dividend yield	0%	0%

The expected term of stock options is based on the simplified method, which is an average of the contractual term of the option and its vesting period. The expected volatility of stock options is based upon the historical volatility of a number of publicly traded companies in similar stages of clinical development. The risk-free interest rate is based on the average yield of U.S. Treasury Bills appropriate for the expected term of the stock option grants. The Company has not historically paid cash dividends and does not anticipate declaring dividends in the future. As of December 31, 2021, unrecognized compensation expense related to unvested options granted totaled $17.3 million. The expense is expected to be recognized over a weighted-average period of 3.0 years.

A summary of the stock option activity under the 2016 Plan and the 2021 Plan during the period ended December 31, 2021 is presented below (in thousands except for per share and weighted average term):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2020	1,128	$ 1.08	8.5	$ 2,827
Granted	3,223	$ 8.82		
Exercised	(301)	$ 0.98		$ 8
Cancelled	(86)	$ 3.23		$ 154
Outstanding at December 31, 2021	3,964	$ 7.33	8.9	$ 1,973
Outstanding at December 31, 2021 (Sunesis 2011 Plan)	88	$ 27.65	3.4	$ —
Vested and exercisable at December 31, 2021	852	$ 7.39	7.8	$ 829

The intrinsic values of the above represent the aggregate value of the total pre-tax intrinsic value based upon a common stock price of $3.65 and $3.58 at December 31, 2021 and 2020, respectively, and the contractual exercise price.

The weighted average grant date fair value per share of employee stock options granted during the years ended December 31, 2021 and 2020 was $6.25 and $1.64, respectively.

Restricted Stock Units

The Company recorded share-based compensation related to RSUs of $0.7 million for the year ended December 31, 2021. There were no RSUs granted prior to 2021. For RSU equity awards, grant date fair value is estimated using the closing stock price on the date of grant. Compensation expense is recognized over the vesting period based on the fair value of the RSUs.

A summary of the restricted stock unit activity under the plans during the period ended December 31, 2021 is presented below (in thousands except for per share and weighted average term):

	RSUs	Weighted Average Grant Date Fair Value per Share	Weighted Average Remaining Contractual Term (Years)
Outstanding at December 31, 2020	—	$ —	—
Granted	852	4.22	
Vested	(107)	4.22	
Cancelled	—	—	
Outstanding at December 31, 2021	745	$ 4.22	3.4

As of December 31, 2021, unrecognized compensation expense related to unvested RSUs totaled $2.7 million. The expense is expected to be recognized over a weighted-average period of 3.4 years.

Employee Stock Purchase Plan

The Company adopted the 2011 Employee Stock Purchase Plan (the “2011 ESPP”) as part of the Merger. The 2011 ESPP permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. Eligible employees can purchase shares of the Company’s common stock at 85% of the lower of the fair market value of the common stock at (i) the beginning of a 12-month offering period, or (ii) at the end of one of the two related 6-month purchase periods. No participant in the 2011 ESPP may be issued or transferred shares of common stock value at more than $25,000 per calendar year.

As of December 31, 2021, there were 60,948 shares available for future issuance under the 2011 ESPP.

9. Commitments and Contingencies

Leases

In 2018, the Company negotiated a one-year lease for its office (“Lease”). The effective date of the Lease was September 1, 2018. Under the terms of the Lease the rental rate was $14,132 per month. In June 2019, the Company amended the term of the Lease to extend the termination date to August 31, 2020. Under the terms of the Lease amendment, the rental rate was $14,980 per month. Upon the Lease amendment, the Company no longer met the short-term lease exemption and recorded an operating lease right-of-use (“ROU”) asset and corresponding lease liability for $225,000.

In June 2020, the Company amended the Lease and another existing office lease to enter into a noncancelable operating lease to extend the lease term through August 2023 with a renewal option for an additional year (“Amended Lease”). The Amended Lease monthly base rent will increase approximately 4% annually from $20,019 to $21,444 over the life of the lease, including utilities and other operating costs. Upon the execution of the Amended Lease, the Company recorded an operating lease ROU asset and corresponding lease liability for $667,000.

In August 2020, the Company entered into an additional noncancelable operating lease agreement for certain office space with a lease term from August 2020 through August 2023 with a renewal option for an additional year (“New Lease”). The New Lease also includes a buyout option to terminate the lease prior to its expiration with at least one month’s prior written notice and a one-time payment equal to four months’ rent. The New Lease monthly base rent will increase approximately 4% to 9% from $12,462 to

$14,033 over the life of the lease, including utilities and other operating costs. In connection with the execution of the New Lease, the Company recorded an operating lease ROU asset and corresponding lease liability for $439,000.

The following table summarizes future minimum payments under the term loan facility as of December 31, 2021 (in thousands):

Year Ending December 31,	
2022	$ 416
2023	284
2024	—
2025	—
Thereafter	—
Total lease payments	700
Less: imputed interest	(41)
Total operating lease liabilities	$ 659

Total lease expense for the years ended December 31, 2021 and 2020 was $608,000 and $297,000, respectively. At December 31, 2021, the Company had remaining lease liabilities of approximately $659,000 of which $278,000 was recorded as noncurrent lease liability as of December 31, 2021, and operating lease ROU assets of $640,000. Total cash paid for amounts included in the measurement of operating lease liabilities was $546,000 and $343,000 for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021 and 2020, the weighted average discount rate for the operating leases was 8.0% for both periods, and the weighted average remaining lease term was 1.6 years as of December 31, 2021. There were no new or amended lease arrangements executed in 2021.

Indemnifications

As permitted under Delaware law, the Company indemnifies its officers, directors, and employees for certain events and occurrences while the officer, or director is, or was, serving at the Company's request in such capacity.

10. Income Taxes

As a result of the Company's significant operating loss carryforwards and the corresponding valuation allowance, no income tax provision/benefit has been recorded as of December 31, 2021 and 2020. Significant components of the Company's deferred tax assets and liabilities as of December 31, 2021 and 2020 are detailed below (in thousands).

	Years Ended December 31,	
	2021	**2020**
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 37,319	$ 18,617
Federal and California research and development credit carryforwards	6,674	3,899
Share-based compensation expense	701	76
Capitalized 59(e) Expenses and Amortization	4,804	2,276
Other, net	107	218
Total deferred tax assets	49,605	25,086
ROU asset	(134)	(207)
Total deferred tax liabilities	(134)	(207)
Net deferred tax asset	49,471	24,879
Valuation allowance	(49,471)	(24,879)
Net deferred tax liability	$ —	$ —

The Company's effective income tax rate differs from the statutory federal rate of 21% for the years ended December 31, 2021 and 2020 due to the following:

	Years Ended December 31,	
	2021 %	2020 %
Federal statutory rate	21	21
State tax benefit, net of federal benefit	7	—
Valuation allowance	(9)	(20)
General business credits	3	11
Acquired IPR&D	(21)	—
State rate true up	—	(5)
Other	(1)	(7)
Effective income tax rate	—	—

At December 31, 2021, the Company had federal and state net operating loss carryforwards of $147.5 million and $105.3 million, respectively. The federal loss carryforwards begin to expire in 2027, unless previously utilized, and the state carryforwards begin to expire in 2030. The Company has federal loss carryforwards of $107.2 million that are not subject to expiration. The Company also has federal and state research credit carryforwards of $1.5 million and $1.8 million, respectively. Additionally the Company has Orphan Drug Credit carryforwards of $7.3 million. The federal research credit carryforwards will begin expiring in 2027, unless previously utilized. The state research credit will carry forward indefinitely. The change in the valuation allowance is an increase of $24.6 million and $3.8 million for the years ended December 31, 2021 and December 31, 2020, respectively.

Pursuant to Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the Company's net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an IRC Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards and these financial statements do not contain any adjustment relating to such potential limitations. Due to the existence of the valuation allowance, future changes in the Company's net operating loss and research and development credit carryforwards will not impact the Company's effective tax rate.

In accordance with authoritative guidance, the impact of an uncertain income tax position is recognized at the largest amount that is "more likely than not" to be sustained upon audit by the relevant taxing authority. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The following table summarizes the activity related to the Company's unrecognized tax benefits (in thousands):

	Years Ended December 31,	
	2021	2020
Gross unrecognized tax benefits at the beginning of the year	$ 3,971	$ 1,952
Additions based on tax positions related to the current year	991	709
Additions for tax positions of prior years	—	1,310
Gross unrecognized tax benefits at the end of the year	$ 4,962	$ 3,971

The amount of the unrecognized tax benefits that would impact the effective tax rate, absent the valuation allowance, would be $4.5 million. Due to the full valuation allowance, the future changes in unrecognized tax benefits will not impact the Company's effective tax rate. At December 31, 2021, the Company has not accrued any interest or penalties related to uncertain tax positions. The Company does not anticipate that there will be a significant change in the amount of unrecognized tax benefits over the next twelve months. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. The Company is subject to taxation in the U.S. and California. Due to the existence of net operating loss carryforwards, all tax periods from inception of the Company are open for examination by taxing authorities for all jurisdictions. The Company is not currently under examination by any tax authority.

11. Subsequent Events

For the purposes of the consolidated financial statements as of December 31, 2021 and for the year ended, the Company has evaluated subsequent events through the date the audited annual consolidated financial statements were issued. The Company has concluded that no subsequent event has occurred that required disclosure in the consolidated financial statements other than what has been disclosed.

Index to Exhibits

Exhibit Number	Description
2.1	Agreement and Plan of Merger and Reorganization, dated November 29, 2020, by and among the Registrant, Sol Merger Sub, Inc. and Viracta Therapeutics, Inc., incorporated by reference to Exhibit 2.1 of the Registrants Current Report on Form 8-K filed on November 30, 2020
2.2	Form of Viracta Therapeutics, Inc.'s Support Agreement, dated November 29, 2020, by and between Viracta Therapeutics, Inc. and each of the parties named in each agreement therein, incorporated by reference to Exhibit 10.2 of the Registrants Current Report on Form 8-K filed on November 30, 2020
2.3	Form of Registrant's Support Agreement, dated November 29, 2020, by and between the Registrant and each of the parties named in each agreement therein, incorporated by reference to Exhibit 10.1 of the Registrants Current Report on Form 8-K filed on November 30, 2020
2.4	Form of Lock-Up Agreement, dated November 29, 2020, by each of the parties named in each agreement therein, incorporated by reference to Exhibit 10.3 of the Registrants Current Report on Form 8-K filed on November 30, 2020
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrants Annual Report on Form 10-K/A filed on May 23, 2007
3.2	Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrants Current Report on Form 8-K filed on December 11, 2007
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.4 of the Registrant's filing on Form S-8 filed on July 10, 2009
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on February 14, 2011
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on September 7, 2016
3.6	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on February 24, 2021
3.7	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed on February 24, 2021
3.8	Certificate of Validation of Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.11 of the Registrant's Quarterly Report of Form 10-Q on August 8, 2018
3.9	Amendment to Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on November 30, 2020
3.10	Certificate of Designation of Series F Convertible Preferred Stock of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on July 12, 2019.
3.11	Certificate of Designation of Series E Convertible Preferred Stock of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on January 22, 2019.
4.1	Description of Capital Stock, incorporated by reference to Exhibit 4.1 of the Registrant's Annual Report on Form 10-K filed on February 24, 2021
4.2	Specimen Preferred Series E Stock Certificate, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on January 22, 2019
4.3	Specimen Preferred Series F Stock Certificate, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on July 12, 2019
4.4	Specimen Common Stock Certificate of the Registrant, incorporated by reference to Exhibit 4.2 of the Registrant's Annual Report on Form 10-K filed on March 29, 2011
10.1#	Executive Employment Agreement between the Company and Ivor Royston, MD, dated May 31, 2017, incorporated by reference to Exhibit 10.18 on the Registrant's filing on Form S-4/A (File No. 333-251567) on January 13, 2021

10.2#	Executive Employment Agreement between the Company and Daniel Chevallard, dated July 29, 2019, incorporated by reference to Exhibit 10.19 on the Registrant's filing on Form S-4/A (File No. 333-251567) on January 13, 2021
10.3#	Executive Employment Agreement between the Company and Lisa Rojkjaer, MD, dated as of February 26, 2020, incorporated by reference to Exhibit 10.20 on the Registrant's filing on Form S-4/A (File No. 333-251567) on January 13, 2021
10.4#	Viracta Therapeutics, Inc. 2016 Equity Incentive Plan, as amended, and forms of agreements thereunder, incorporated by reference to Exhibit 10.21 on the Registrant's filing on Form S-4/A (File No. 333-251567) on January 13, 2021
10.5	Loan and Security Agreement between the Company and Silicon Valley Bank, dated as of July 30, 2020, incorporated by reference to Exhibit 10.22 on the Registrant's filing on Form S-4/A (File No. 333-251567) on January 13, 2021
10.6	Warrant to Purchase Preferred Stock between the Company and Silicon Valley Bank, dated July 30, 2020, incorporated by reference to Exhibit 10.23 on the Registrant's filing on Form S-4/A (File No. 333-251567) on January 13, 2021
10.7+	Amended and Restated License Agreement between the Company and Boston University, dated as of August 22, 2018, incorporated by reference to Exhibit 10.24 on the Registrant's filing on Form S-4/A (File No. 333-251567) on January 13, 2021
10.8+	License Agreement between the Company and NantKwest, Inc., dated as of May 1, 2017 and Amendment No. 1 thereto, incorporated by reference to Exhibit 10.25 on the Registrant's filing on Form S-4/A (File No. 333-251567) on January 13, 2021
10.9+	Exclusive Collaboration and License Agreement between the Company and Salubris Pharmaceutical Co. Ltd., dated as of November 30, 2018, incorporated by reference to Exhibit 10.26 on the Registrant's filing on Form S-4/A (File No. 333-251567) on January 13, 2021
10.10	Lease Agreement between the Company and PLASTINO II, a limited partnership, dated as of June 11, 2020, incorporated by reference to Exhibit 10.27 on the Registrant's filing on Form S-4/A (File No. 333-251567) on January 13, 2021
10.11	Lease Agreement between the Company and PLASTINOII, a limited partnership, dated as of August 1, 2020, incorporated by reference to Exhibit 10.28 on the Registrant's filing on Form S-4/A (File No. 333-251567) on January 13, 2021
10.12#	Amended and Restated Outside Director Compensation Plan, incorporated by reference to Exhibit 10.12 on the Company's Quarterly Report on Form 10-Q filed with the SEC on May 13, 2021
10.13+	Royalty Purchase Agreement by and between the Registrant and XOMA (US) LLC, dated March 22, 2021, incorporated by reference to Exhibit 10.13 on the Registrant's filing on Form 10-Q on May 13, 2021
10.14#	Sunesis Pharmaceuticals, Inc. 2011 Employee Stock Purchase Plan, incorporated by reference to Exhibit 99.2 on the Registrant's filing on Form S-8 (File No. 333-174732) on June 6, 2011
10.15#	Forms of Stock Option Grant Notice and Option Agreement under the 2011 Equity Incentive Plan, incorporated by reference to Exhibit 10.57 on the Company's Annual Report filed on Form 10-K with the SEC on March 14, 2012
10.16#	2011 Equity Incentive Plan, as amended, incorporated by reference to Appendix A on the Registrant's filing on form DEF 14A (File No. 000-51531) on April 20, 2017
10.17#	Form of Executive Severance Benefits Agreement between Sunesis Pharmaceuticals, Inc. and certain officers, incorporated by reference to Exhibit 10.29 on the Registrant's filing on Form S-4 (File No. 333-251567) on December 22, 2020
10.18#	Form of Retention Benefits Letter between Sunesis Pharmaceuticals, Inc. and certain officers, incorporated by reference to Exhibit 10.4 on the Company's Current Report on Form 8-K filed with the SEC on November 30, 2020
10.19#	Sunesis Pharmaceuticals, Inc. 2021 Equity Incentive Plan, incorporated by reference to ANNEX E on the Registrant's filing on Form S-4/A (File No. 333-251567) on January 13, 2021
10.20	Open Market Sale Agreement[SM], dated May 28, 2021, by and between Viracta Therapeutics, Inc. and Jefferies LLC, incorporated by reference to the Registrant's filing on Form S-3 (333-256647) on May 28, 2021
10.21	First Amendment to Loan and Security Agreement between Viracta Subsidiary, Inc. and Silicon Valley Bank, dated as of May 27, 2021, incorporated by reference to Exhibit 10.2 on the Company's Current Report on Form 8-K filed with the SEC on May 28, 2021
10.22#	2021 Inducement Equity Incentive Plan and form of agreement thereunder, incorporated by reference to Exhibit 10.3 on the Company's Quarterly Report on Form 10-Q filed with the SEC on August 12, 2021
10.23#	Amendment to Employment Agreement between Viracta Therapeutics, Inc. and Ivor Royston, M.D., dated August 12, 2021, incorporated by reference to Exhibit 10.4 on the Registrant's filing on the Form 10-Q on August 8, 2021

10.24#	Amendment to Employment Agreement between Viracta Therapeutics, Inc. and Daniel Chevallard, dated August 12, 2021, incorporated by reference to Exhibit 10.5 on the Registrant's filing on the Form 10-Q on August 8, 2021
10.25#	Amendment to Employment Agreement between Viracta Therapeutics, Inc. and Lisa Rojkjaer, M.D., dated August 12, 2021, incorporated by reference to 10.6 on the Registrant's filing on the Form 10-Q on August 8, 2021
10.26	Mutual Termination Agreement, dated August 20, 2021, by and between Viracta Subsidiary, Inc. and Shenzhen Salubris Pharmaceutical Co. Ltd., incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on August 23, 2021
10.27+	Loan and Security Agreement, dated November 4, 2021, by and among Viracta Therapeutics, Inc., Viracta Subsidiary, Inc., Silicon Valley Bank and Oxford Finance LLC, incorporated by reference to 10.2 on the Registrant's filing on the Form 10-Q on November 10, 2021
10.28^	Executive Incentive Compensation Plan
21.1^	List of Subsidiaries
23.1^	Consent of Independent Registered Public Accounting Firm
24.1^	Power of Attorney (included on the signature page hereto)
31.1^	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2^	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32.1^†	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.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)

^ Filed herewith.

# Indicates management contract or compensatory plan.

+ Portions of the exhibit have been omitted pursuant to Item 601(b)(10) of Regulation S-K. The Company agrees to furnish to the Securities and Exchange Commission a copy of any omitted portions of the exhibit upon request.

† The certifications attached as Exhibit 32.1 that accompany this Annual Report on Form 10-K are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Viracta Therapeutics, Inc. 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.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Viracta Therapeutics, Inc.

Date: March 16, 2022 By: /s/ Ivor Royston, M.D.
Ivor Royston, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 16, 2022 By: /s/ Daniel Chevallard
Daniel Chevallard
Chief Operating Officer, Chief Financial Officer and Secretary
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Ivor Royston, M.D. **Ivor Royston, M.D.**	Director, President and Chief Executive Officer (Principal Executive Officer)	March 16, 2022
/s/ Daniel Chevallard **Daniel Chevallard**	Chief Operating Officer and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 16, 2022
/s/ Roger Pomerantz, M.D. **Roger Pomerantz, M.D.**	Chairman of the Board of Directors	March 16, 2022
/s/ Thomas Darcy **Thomas Darcy**	Director	March 16, 2022
/s/ Michael Huang, M.S., MBA **Michael Huang, M.S., MBA.**	Director	March 16, 2022
/s/ Sam Murphy, Ph.D. **Sam Murphy, Ph.D.**	Director	March 16, 2022
/s/ Nicole Onetto, M.D. **Nicole Onetto, M.D.**	Director	March 16, 2022
/s/ Barry Simon, M.D. **Barry Simon, M.D.**	Director	March 16, 2022
/s/ Gur Roshwalb, M.D. **Gur Roshwalb, M.D.**	Director	March 16, 2022
/s/ Stephen Rubino, Ph.D., MBA **Stephen Rubino, Ph.D., MBA**	Director	March 16, 2022
/s/ Jane Barlow, M.D., MPH, MBA **Jane Barlow, M.D., MPH, MBA**	Director	March 16, 2022
/s/ Flavia Borellini, Ph.D **Flavia Borellini, Ph.D**	Director	March 16, 2022

Exhibit 10.28

VIRACTA THERAPEUTICS, INC.

EXECUTIVE INCENTIVE COMPENSATION PLAN

1. Purposes of the Plan. The Plan is intended to increase stockholder value and the success of the Company by motivating Employees to (a) perform to the best of their abilities and (b) achieve the Company's objectives.

2. Definitions.

2.1 "Actual Award" means as to any Performance Period, the actual award (if any) payable to a Participant for the Performance Period, subject to the authority of the Administrator (as defined in Section 3) under Section 4.4.

2.2 "Affiliate" means any corporation or other entity (including, but not limited to, partnerships and joint ventures) that, from time to time and at the time of any determination, directly or indirectly, is in control of or is controlled by the Company.

2.3 "Board" means the Board of Directors of the Company.

2.4 "Bonus Pool" means the pool of funds available for distribution to Participants. Subject to the terms of the Plan, the Administrator establishes the Bonus Pool for each Performance Period.

2.5 "Code" means the U.S. Internal Revenue Code of 1986, as amended. Reference to a specific section of the Code or regulation thereunder will include such section or regulation, any valid regulation or formal guidance of general or direct applicability promulgated under such section or regulation, and any comparable provision of any future legislation or regulation amending, supplementing or superseding such section or regulation.

2.6 "Committee" means a committee appointed by the Board (pursuant to Section 3) to administer the Plan.

2.7 "Company" means Viracta Therapeutics, Inc., a Delaware corporation, or any successor thereto.

2.8 "Company Group" means the Company and any Parents, Subsidiaries, and Affiliates.

2.9 "Disability" means a permanent and total disability determined in accordance with uniform and nondiscriminatory standards adopted by the Administrator from time to time.

2.10 "Employee" means any executive, officer, or other employee of the Company Group, whether such individual is so employed at the time the Plan is adopted or becomes so employed subsequent to the adoption of the Plan.

2.11 "Fiscal Year" means the fiscal year of the Company.

2.12 "Parent" means a "parent corporation," whether now or hereafter existing, as defined in Code Section 424(e).

2.13 "Participant" means as to any Performance Period, an Employee who has been selected by the Administrator for participation in the Plan for that Performance Period.

2.14 "Performance Period" means the period of time for the measurement of the performance criteria that must be met to receive an Actual Award, as determined by the Administrator. A Performance Period may be divided into one or more shorter periods if, for example, but not by way of limitation, the

Administrator desires to measure some performance criteria over twelve (12) months and other criteria over three (3) months.

2.15 "Plan" means this Executive Incentive Compensation Plan (including any appendix attached hereto), as may be amended from time to time.

2.16 "Section 409A" means Section 409A of the Code and any applicable state law equivalent, as each may be promulgated, amended or modified from time to time.

2.17 "Subsidiary" means a "subsidiary corporation," whether now or hereafter existing, as defined in Code Section 424(f), in relation to the Company.

2.18 "Target Award" means the target award, at one hundred percent (100%) of target level performance achievement, payable under the Plan to a Participant for a Performance Period, as determined by the Administrator in accordance with Section 4.2.

2.19 "Tax Withholdings" means tax, social insurance and social security liability or premium obligations in connection with the awards under the Plan, including without limitation: (a) all federal, state, and local income, employment and any other taxes (including the Participant's U.S. Federal Insurance Contributions Act (FICA) obligation) that are required to be withheld by the Company Group, (b) the Participant's and, to the extent required by the Company Group, the fringe benefit tax liability of the Company Group associated with an award under the Plan, and (c) any other taxes or social insurance or social security liabilities or premium the responsibility for which the Participant has, or has agreed to bear, with respect to such award under the Plan.

2.20 "Termination of Employment" means a cessation of the employee-employer relationship between an Employee and the Company Group, including without limitation a termination by resignation, discharge, death, Disability, retirement, or the disaffiliation of a Parent, Subsidiary or Affiliate. For purposes of the Plan, transfer of employment of a Participant between any members of the Company Group (for example, between the Company and a Subsidiary) will not be deemed a Termination of Employment.

3. Administration of the Plan.

3.1 Administrator. The Plan will be administered by the Board or a Committee (the "Administrator"). To the extent necessary or desirable to satisfy applicable laws, the Committee acting as the Administrator will consist of not less than two (2) members of the Board. The members of any Committee will be appointed from time to time by, and serve at the pleasure of, the Board. The Board may retain the authority to administer the Plan concurrently with a Committee and may revoke the delegation of some or all authority previously delegated. Different Administrators may administer the Plan with respect to different groups of Employees. Unless and until the Board otherwise determines, the Board's Compensation Committee will administer the Plan.

3.2 Administrator Authority. It will be the duty of the Administrator to administer the Plan in accordance with the Plan's provisions. The Administrator will have all powers and discretion necessary or appropriate to administer the Plan and to control its operation, including, but not limited to, the power to (a) determine which Employees will be granted awards, (b) prescribe the terms and conditions of awards, (c) interpret the Plan and the awards, (d) adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Employees who are non-U.S. nationals or employed outside of the U.S. or to qualify awards for special tax treatment under the laws of jurisdictions other than the U.S., (e) adopt rules for the administration, interpretation and application of the Plan as are consistent therewith, and (f) interpret, amend or revoke any such rules. Any determinations and decisions made or to be made by the Administrator pursuant to the provisions of the Plan, unless specified otherwise by the Administrator, will be in the Administrator's sole discretion.

3.3 Decisions Binding. All determinations and decisions made by the Administrator and/or any delegate of the Administrator pursuant to the provisions of the Plan will be final, conclusive, and binding on all persons, and will be given the maximum deference permitted by law.

3.4 Delegation by Administrator. The Administrator, on such terms and conditions as it may provide, may delegate all or part of its authority and powers under the Plan to one or more directors and/or officers of the Company. Such delegation may be revoked at any time.

3.5 Indemnification. Each person who is or will have been a member of the Administrator will be indemnified and held harmless by the Company against and from (a) any loss, cost, liability, or expense that may be imposed upon or reasonably incurred by him or her in connection with or resulting from any claim, action, suit, or proceeding to which he or she may be a party or in which he or she may be involved by reason of any action taken or failure to act under the Plan or any award, and (b) from any and all amounts paid by him or her in settlement thereof, with the Company's approval, or paid by him or her in satisfaction of any judgment in any such claim, action, suit, or proceeding against him or her, provided he or she will give the Company an opportunity, at its own expense, to handle and defend the same before he or she undertakes to handle and defend it on his or her own behalf. The foregoing right of indemnification will not be exclusive of any other rights of indemnification to which such persons may be entitled under the Company's Certificate of Incorporation or Bylaws, by contract, as a matter of law, or otherwise, or under any power that the Company may have to indemnify them or hold them harmless.

4. Selection of Participants and Determination of Awards.

4.1 Selection of Participants. The Administrator will select the Employees who will be Participants for any Performance Period. Participation in the Plan will be on a Performance Period by Performance Period basis. Accordingly, an Employee who is a Participant for a given Performance Period in no way is guaranteed or assured of being selected for participation in any subsequent Performance Period or Performance Periods. No Employee will have the right to be selected to receive an award under this Plan or, if so selected, to be selected to receive a future award.

4.2 Determination of Target Awards. The Administrator may establish a Target Award for each Participant (which may be expressed as a percentage of a Participant's average annual base salary for the Performance Period or a fixed dollar amount or such other amount or based on such other formula or factors as the Administrator determines).

4.3 Bonus Pool. Each Performance Period, the Administrator may establish a Bonus Pool, which pool may be established before, during or after the applicable Performance Period. Actual Awards will be paid from the Bonus Pool (if a Bonus Pool has been established).

4.4 Discretion to Modify Awards. Notwithstanding any contrary provision of the Plan, the Administrator, at any time prior to payment of an Actual Award, may: (a) increase, reduce or eliminate a Participant's Actual Award, and/or (b) increase, reduce or eliminate the amount allocated to the Bonus Pool. The Actual Award may be below, at or above the Target Award, as determined by the Administrator. The Administrator may determine the amount of any increase, reduction, or elimination based on such factors as it deems relevant, and will not be required to establish any allocation or weighting with respect to the factors it considers.

4.5 Discretion to Determine Criteria. Notwithstanding any contrary provision of the Plan, the Administrator will determine the performance goals, if any, applicable to any Target Award (or portion thereof) which may include, without limitation, goals related to: research and development milestones; regulatory milestones or regulatory-related goals; gross margin; financial milestones; new product or business development; operating margin; product release timelines or other product release milestones; publications; cash flow; procurement; savings; internal structure; leadership development; project function or portfolio-specific milestones; license or research collaboration agreements; capital raising;

initial public offering preparations; patentability; and individual objectives such as peer reviews or other subjective or objective criteria. As determined by the Administrator, the performance goals may be based on U.S. generally accepted accounting principles ("GAAP") or non-GAAP results and any actual results may be adjusted by the Administrator for one-time items or unbudgeted or unexpected items and/or payments of Actual Awards under the Plan when determining whether the performance goals have been met. The performance goals may be based on any factors the Administrator determines relevant, including without limitation on an individual, divisional, portfolio, project, business unit, segment or Company-wide basis. Any criteria used may be measured on such basis as the Administrator determines, including without limitation: (a) in absolute terms, (b) in combination with another performance goal or goals (for example, but not by way of limitation, as a ratio or matrix), (c) in relative terms (including, but not limited to, results for other periods, passage of time and/or against another company or companies or an index or indices), (d) on a per-share basis, (e) against the performance of the Company as a whole or a segment of the Company and/or (f) on a pre-tax or after-tax basis. The performance goals may differ from Participant to Participant and from award to award. Failure to meet the applicable performance goals will result in a failure to earn the Target Award, except as provided in Section 4.4.

5. Payment of Awards.

5.1 Right to Receive Payment. Each Actual Award will be paid solely from the general assets of the Company Group. Nothing in this Plan will be construed to create a trust or to establish or evidence any Participant's claim of any right other than as an unsecured general creditor with respect to any payment to which the Participant may be entitled.

5.1 Timing of Payment. Payment of each Actual Award will be made as soon as practicable after the end of the Performance Period to which the Actual Award relates and after the Actual Award is approved by the Administrator, but in no event after the later of (a) the fifteenth (15^{th}) day of the third (3^{rd}) month of the Fiscal Year immediately following the Fiscal Year in which the Participant's Actual Award first becomes no longer subject to a substantial risk of forfeiture, and (b) March 15 of the calendar year immediately following the calendar year in which the Participant's Actual Award first becomes no longer subject to a substantial risk of forfeiture. Unless otherwise determined by the Administrator, to earn an Actual Award a Participant must be employed by the Company Group on the date the Actual Award is paid, and in all cases subject to the Administrator's discretion pursuant to Section 4.4.

5.2 Form of Payment. Each Actual Award generally will be paid in cash (or its equivalent) in a single lump sum. The Administrator reserves the right to settle an Actual Award with a grant of an equity award with such terms and conditions, including any vesting requirements, as determined by the Administrator.

5.3 Payment in the Event of Death or Disability. If a Termination of Employment occurs due to a Participant's death or Disability prior to payment of an Actual Award that the Administrator has determined will be paid for a prior Performance Period, then the Actual Award will be paid to the Participant or the Participant's estate, as the case may be, subject to the Administrator's discretion pursuant to Section 4.4.

6. General Provisions.

6.1 Tax Matters.

6.1.1 Section 409A. It is the intent that this Plan be exempt from or comply with the requirements of Section 409A so that none of the payments to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities or ambiguous terms will be interpreted to be so exempt or so comply. Each payment under this Plan is intended to constitute a separate payment for purposes of Treasury Regulations Section 1.409A-2(b)(2). In

no event will the Company Group have any liability, obligation, or responsibility to reimburse, indemnify or hold harmless any Participant or other Employee for any taxes, penalties or interest imposed, or other costs incurred, as a result of Section 409A.

6.1.2 Tax Withholdings. The Company Group will have the right and authority to deduct from any Actual Award all applicable Tax Withholdings. Prior to the payment of an Actual Award or such earlier time as any Tax Withholdings are due, the Company Group is permitted to deduct or withhold, or require a Participant to remit to the Company Group, an amount sufficient to satisfy any Tax Withholdings with respect to such Actual Award.

6.2 No Effect on Employment or Service. Neither the Plan nor any award under the Plan will confer upon a Participant any right regarding continuing the Participant's relationship as an Employee or other service provider to the Company Group, nor will they interfere with or limit in any way the right of the Company Group or the Participant to terminate such relationship at any time, with or without cause, to the extent permitted by applicable laws.

6.3 Forfeiture Events.

6.3.1 Clawback Policy; Applicable Laws. All awards under the Plan will be subject to reduction, cancellation, forfeiture, or recoupment in accordance with any clawback policy that the Company Group is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable laws. In addition, the Administrator may impose such other clawback, recovery or recoupment provisions with respect to an award under the Plan as the Administrator determines necessary or appropriate, including without limitation a reacquisition right in respect of previously acquired cash, stock, or other property provided with respect to an award. Unless this Section 6.3.1 is specifically mentioned and waived in a written agreement between a Participant and a member of the Company Group or other document, no recovery of compensation under a clawback policy will give the Participant the right to resign for "good reason" or "constructive termination" (or similar term) under any agreement with a member of the Company Group.

6.3.2 Additional Forfeiture Terms. The Administrator may specify when providing for an award under the Plan that the Participant's rights, payments, and benefits with respect to the award will be subject to reduction, cancellation, forfeiture, or recoupment upon the occurrence of specified events, in addition to any otherwise applicable vesting or performance conditions of the award. Such events may include, without limitation, termination of the Participant's status as an Employee for "cause" or any act by a Participant, whether before or after the Participant's status as an Employee terminates, that would constitute "cause."

6.3.3 Accounting Restatements. If the Company is required to prepare an accounting restatement due to the material noncompliance of the Company, as a result of misconduct, with any financial reporting requirement under the securities laws, then any Participant who knowingly or through gross negligence engaged in the misconduct, or who knowingly or through gross negligence failed to prevent the misconduct, and any Participant who is one of the individuals subject to automatic forfeiture under Section 304 of the Sarbanes-Oxley Act of 2002, will reimburse the Company Group the amount of any payment with respect to an award earned or accrued during the twelve (12) month period following the first public issuance or filing with the U.S. Securities and Exchange Commission (whichever first occurred) of the financial document embodying such financial reporting requirement.

6.4 Successors. All obligations of the Company under the Plan, with respect to awards under the Plan, will be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business or assets of the Company.

6.5 Nontransferability of Awards. No award under the Plan may be sold, transferred, pledged, assigned, or otherwise alienated or hypothecated, other than by will or by the laws of descent and distribution, and except as provided in Section 5.3. All rights with respect to an award granted to a Participant will be available during his or her lifetime only to the Participant.

7. Amendment, Termination, and Duration.

7.1 Amendment, Suspension, or Termination. The Administrator may amend or terminate the Plan, or any part thereof, at any time and for any reason. The amendment, suspension or termination of the Plan will not, without the consent of the Participant, alter or impair any rights or obligations under any Actual Award earned by such Participant. No award may be granted during any period of suspension or after termination of the Plan.

7.2 Duration of Plan. The Plan will commence on the date first adopted by the Board or the Compensation Committee of the Board, and subject to Section 7.1 (regarding the Administrator's right to amend or terminate the Plan), will remain in effect thereafter until terminated.

8. Legal Construction.

8.1 Gender and Number. Unless otherwise indicated by the context, any feminine term used herein also will include the masculine and any masculine term used herein also will include the feminine; the plural will include the singular and the singular will include the plural.

8.2 Severability. If any provision of the Plan is or becomes or is deemed to be invalid, illegal, or unenforceable for any reason in any jurisdiction or as to any Participant, such invalidity, illegality, or unenforceability will not affect the remaining parts of the Plan, and the Plan will be construed and enforced as if the invalid, illegal, or unenforceable provision had not been included.

8.3 Governing Law. The Plan and all awards will be construed in accordance with and governed by the laws of the State of California, but without regard to its conflict of law provisions.

8.4 Bonus Plan. The Plan is intended to be a "bonus program" as defined under U.S. Department of Labor regulations section 2510.3-2(c) and will be construed and administered in accordance with such intention.

8.5 Headings. Headings are provided herein for convenience only, and will not serve as a basis for interpretation or construction of the Plan.

9. Compliance with Applicable Laws. Awards under the Plan (including without limitation the granting of such awards) will be subject to all applicable laws, rules and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

* * *

Exhibit 21.1

Subsidiaries of Viracta Therapeutics, Inc.*

Name of Subsidiary	Jurisdiction of Incorporation or Organization
Viracta Subsidiary, Inc.	Delaware
Viracta Royalty Fund, LLC	Delaware

* Inclusion on the list above is not an admission that any of the above entities, individually or in the aggregate, constitutes a significant subsidiary within the meaning of Rule 1-02(w) of Regulation S-X and Item 601(b)(21)(ii) of Regulation S-K.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-256647) of Viracta Therapeutics, Inc.,
(2) Registration Statement (Form S-4 No. 333-251567) of Sunesis Pharmaceuticals, Inc.,
(3) Registration Statement (Form S-8 No. 333-255002) pertaining to the Viracta Therapeutics, Inc. 2021 Equity Incentive Plan, Viracta Therapeutics, Inc. 2011 Employee Stock Purchase Plan and Viracta Subsidiary, Inc. 2016 Equity Incentive Plan of Viracta Therapeutics, Inc.,
(4) Registration Statement (Form S-8 Nos. 333-174732, 333-195781, 333-202696, 333-217849, 333-231342 and 333-238141) pertaining to the 2011 Equity Incentive Plan and the 2011 Employee Stock Purchase Plan of Sunesis Pharmaceuticals, Inc., and
(5) Registration Statement (Form S-8 Nos. 333-180101, 333-187234, 333-210183 and 333-223632) pertaining to the 2011 Equity Incentive Plan of Sunesis Pharmaceuticals, Inc.;

of our report dated March 16, 2022, with respect to the consolidated financial statements of Viracta Therapeutics, Inc. included in this Annual Report (Form 10-K) of Viracta Therapeutics, Inc. for the year ended December 31, 2021.

/s/ Ernst & Young LLP

San Diego, California
March 16, 2022

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ivor Royston, certify that:

1. I have reviewed this annual report on Form 10-K of Viracta Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 16, 2022

By: /s/ Ivor Royston
Ivor Royston
Chief Executive Officer
President
Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Daniel Chevallard, certify that:

1. I have reviewed this annual report on Form 10-K of Viracta Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 16, 2022

By: /s/ Daniel Chevallard
Daniel Chevallard
Chief Financial Officer
Chief Operating Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. § 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Ivor Royston, the chief executive officer of Viracta Therapeutics, Inc. (the "Company"), certify for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge,

(i) the Annual Report of the Company on Form 10-K for the year ended December 31, 2021 (the "Report"), fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 16, 2022

By: /s/ Ivor Royston
Ivor Royston
Chief Executive Officer
President
Director

I, Daniel Chevallard, the chief financial officer of Viracta Therapeutics, Inc. (the "Company"), certify for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge,

(i) the Annual Report of the Company on Form 10-K for the year ended December 31, 2021 (the "Report"), fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 16, 2022

By: /s/ Daniel Chevallard
Daniel Chevallard
Chief Financial Officer
Chief Operating Officer